§ 1395. Prohibition against any Federal interference

Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.


§ 1395a. Free choice by patient guaranteed

(a) Basic freedom of choice

Any individual entitled to insurance benefits under this subchapter may obtain health services from any institution, agency, or person qualified to participate under this subchapter if such institution, agency, or person undertakes to provide him such services.

(b) Use of private contracts by medicare beneficiaries

(1) In general

Subject to the provisions of this subsection, nothing in this subchapter shall prohibit a physician or practitioner from entering into a private contract with a medicare beneficiary for any item or service—

(A) for which no claim for payment is to be submitted under this subchapter, and

(B) for which the physician or practitioner receives—

(i) no reimbursement under this subchapter directly or on a capitated basis, and

(ii) receives no amount for such item or service from an organization which receives reimbursement for such item or service under this subchapter directly or on a capitated basis.

(2) Beneficiary protections

(A) In general

Paragraph (1) shall not apply to any contract unless—

(i) the contract is in writing and is signed by the medicare beneficiary before any item or service is provided pursuant to the contract;

(ii) the contract contains the items described in subparagraph (B); and

(iii) the contract is not entered into at a time when the medicare beneficiary is facing an emergency or urgent health care situation.

(B) Items required to be included in contract

Any contract to provide items and services to which paragraph (1) applies shall clearly indicate the medicare beneficiary that by signing such contract the beneficiary—

(i) agrees not to submit a claim (or to request that the physician or practitioner submit a claim) under this subchapter for such items or services even if such items or services are otherwise covered by this subchapter;

(ii) agrees to be responsible, whether through insurance or otherwise, for payment of such items or services and understands that no reimbursement will be provided under this subchapter for such items or services;

(iii) acknowledges that no limits under this subchapter (including the limits under section 1385w–4(g) of this title) apply to amounts that may be charged for such items or services;

(iv) acknowledges that Medigap plans under section 1395ss of this title do not, and other supplemental insurance plans may elect not to, make payments for such items and services because payment is not made under this subchapter; and

(v) acknowledges that the medicare beneficiary has the right to have such items or services provided by other physicians or practitioners for whom payment would be made under this subchapter.

Such contract shall also clearly indicate whether the physician or practitioner is excluded from participation under the medicare program under section 1320a–7 of this title.

(3) Physician or practitioner requirements

(A) In general

Paragraph (1) shall not apply to any contract entered into by a physician or practitioner unless an affidavit described in subparagraph (B) is in effect during the period any item or service is to be provided pursuant to the contract.

(B) Affidavit

An affidavit is described in this subparagraph if—
(i) the affidavit identifies the physician or practitioner and is in writing and is signed by the physician or practitioner;  
(ii) the affidavit provides that the physician or practitioner will not submit any claim under this subchapter for any item or service provided to any medicare beneficiary (and will not receive any reimbursement or amount described in paragraph (1)(B) for any such item or service) during the 2-year period beginning on the date the affidavit is signed; and  
(iii) a copy of the affidavit is filed with the Secretary no later than 10 days after the first contract to which such affidavit applies is entered into.  

(C) Enforcement  
If a physician or practitioner signing an affidavit under subparagraph (B) knowingly and willfully submits a claim under this subchapter for any item or service provided during the 2-year period described in subparagraph (B)(i) (or receives any reimbursement or amount described in paragraph (1)(B) for any such item or service) with respect to such affidavit—  
(i) this subsection shall not apply with respect to any items and services provided by the physician or practitioner pursuant to any contract on and after the date of such submission and before the end of such period; and  
(ii) no payment shall be made under this subchapter for any item or service furnished by the physician or practitioner during the period described in clause (i) (and no reimbursement or payment of any amount described in paragraph (1)(B) shall be made for any such item or service).  

(4) Limitation on actual charge and claim submission requirement not applicable  
Section 1395w–4(g) of this title shall not apply with respect to any item or service provided to a medicare beneficiary under a contract described in paragraph (1).  

(5) Definitions  
In this subsection:  

(A) Medicare beneficiary  
The term “medicare beneficiary” means an individual who is entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter.  

(B) Physician  
The term “physician” has the meaning given such term by paragraphs (1), (2), (3), and (4) of section 1395a(r) of this title.  

(C) Practitioner  
The term “practitioner” has the meaning given such term by section 1395a(b)(18)(C) of this title.  

References in Text  
Parts A and B of this subchapter, referred to in subsec. (b)(5)(A), are classified to sections 1395c et seq. and 1395 et seq., respectively, of this title.  

Amendments  
2003—Subsec. (b)(5)(B). Pub. L. 108–173 substituted “paragraphs (1), (2), (3), and (4) of section 1395a(r)” for “section 1395a(r)(1)”.  

Effective Date of 1997 Amendment  
Section 4507(c) of Pub. L. 105–33 provided that: “The amendment made by subsection (a) [amending this section and section 1395y of this title] shall apply with respect to contracts entered into on and after January 1, 1998.”  

Report to Congress on Effect of Private Contracts  
Section 4507(b) of title IV of Pub. L. 105–33 provided that: “Not later than October 1, 2001, the Secretary of Health and Human Services shall submit a report to Congress on the effect on the program under this title [see Tables for classification] of private contracts entered into under the amendment made by subsection (a) [amending this section and section 1395y of this title]. Such report shall include—  
"(1) analyses regarding—  
"(A) the fiscal impact of such contracts on total Federal expenditures under title XVIII of the Social Security Act [this subchapter] and on out-of-pocket expenditures by medicare beneficiaries for health services under such title; and  
"(B) the quality of the health services provided under such contracts; and  
"(2) recommendations as to whether medicare beneficiaries should continue to be able to enter private contracts under section 1802(b) of such Act [subsec. (b) of this section] (as added by subsection (a)) and if so, what legislative changes, if any should be made to improve such contracts.”  

§ 1395b. Option to individuals to obtain other health insurance protection  
Nothing contained in this subchapter shall be construed to preclude any State from providing, or any individual from purchasing or otherwise securing, protection against the cost of any health services.  


Impact of Increased Investments in Health Research on Future Medicare Costs  

National Bipartisan Commission on the Future of Medicare  
Pub. L. 105–33, title IV, §4021, Aug. 5, 1997, 111 Stat. 347, established National Bipartisan Commission on the Future of Medicare which was directed to review and analyze long-term financial condition of medicare program, identify problems that threaten financial integrity of Federal Hospital Insurance Trust Fund and Federal Supplementary Medical Insurance Trust Fund, analyze potential solutions that will ensure both financial integrity of medicare program and provision of ap-
proper benefits under such program, and make recommendations for, among other things, restoring solvency of Federal Hospital Insurance Trust Fund and financial integrity of Federal Supplementary Medical Insurance Trust Fund, establishing appropriate financial structure of medicare program as a whole, and establishing appropriate balance of benefits covered and benefits to medicare program, further provided for membership of Commission, meetings, personnel and staff matters, powers of Commission, appropriations, submission of final report to Congress not later than Mar. 1, 1969, and termination of Commission 30 days after submission of final report.

EXCLUSION FROM WAGES AND COMPENSATION OF REFUNDS REQUIRED FROM EMPLOYERS TO COMPENSATE FOR Duplicative MEDICARE BENEFITS BY HEALTH CARE BENEFITS PROVIDED BY EMPLOYERS


“(a) OLD-AGE, SURVIVORS, AND DISABILITY, AND HOSPITAL INSURANCE PROGRAMS.—For purposes of title II of the Social Security Act [subchapter II of this chapter] and chapter 21 of the Internal Revenue Code of 1986 [26 U.S.C. 3101 et seq.], the term ‘wages’ shall not include the amount of any refund required under section 421 of the Medicare Catastrophic Coverage Act of 1988 [sec. 421 of Pub. L. 100–360, formerly set out as a note under section 1395u of this title.]


“(c) FEDERAL UNEMPLOYMENT PROGRAMS.—


“(2) RAILROAD UNEMPLOYMENT CONTRIBUTIONS.—For purposes of the Railroad Unemployment Insurance Act (45 U.S.C. 351 et seq.), the term ‘wages’ shall not include the amount of any refund required under section 421 of the Medicare Catastrophic Coverage Act of 1988.


“(d) REPORTING REQUIREMENTS.—Any refund required under section 421 of the Medicare Catastrophic Coverage Act of 1988 shall be reported to the Secretary of the Treasury or his delegate and to the person to whom such refund is made in such manner as the Secretary of the Treasury or his delegate shall prescribe.

“(e) EFFECTIVE DATE.—This section shall apply with respect to refunds provided on or after January 1, 1989.”

UNITED STATES BIPARTISAN COMMISSION ON COMPREHENSIVE HEALTH CARE

Pub. L. 100–360, title IV, §421, July 1, 1988, 102 Stat. 765–768, as amended by Pub. L. 100–647, title VIII, §8414, Nov. 10, 1988, 102 Stat. 3801; Pub. L. 101–239, title VI, §6202, Dec. 19, 1989, 103 Stat. 2473, established the United States Bipartisan Commission on Comprehensive Health Care, also known as the “Claude Pepper Commission” or the “Pepper Commission”, and directed Commission to examine shortcomings in health care delivery and financing mechanisms that limit or prevent access of all individuals in United States to comprehensive health care, and make specific recommendations respecting Federal programs, policies, and financing needed to assure the availability of comprehensive long-term care services for elderly and disabled, as well as comprehensive health care services for all individuals in the United States, and further provided for membership of Commission, staff and consultants, powers, authorization of appropriations, submission of findings and recommendations to Congress not later than Nov. 9, 1989, and for termination of Commission 30 days after submissions to Congress.

MAINTENANCE OF EFFORT REGARDING DUPLICATIVE BENEFITS

Pub. L. 100–360, title IV, §421, July 1, 1988, 102 Stat. 808, as amended by Pub. L. 100–485, title VI, §608(a), Oct. 13, 1988, 102 Stat. 2411, which required employers who had been providing health care benefits to employees that were duplicative part A and part B part benefits to provide the employees with additional benefits equal to the total actuarial value of such duplicative benefits, was repealed by Pub. L. 101–234, title III, §301(a), Dec. 13, 1989, 103 Stat. 1985. [Repeal not applicable to duplicative part A benefits for periods before Jan. 1, 1990, see section 301(e)(1) of Pub. L. 101–234, set out as an Effective Date of 1989 Amendment note under section 1395u of this title.]

TASK FORCE ON LONG-TERM HEALTH CARE POLICIES

Pub. L. 99–272, title IX, §9601, Apr. 7, 1986, 100 Stat. 221, as amended by Pub. L. 100–360, title VI, §601(b)(3), Nov. 10, 1986, 112 Stat. 3286, directed Secretary of Health and Human Services, in consultation with National Association of Insurance Commissioners, to establish Task Force on Long-Term Health Care Policies to develop recommendations for long-term health care policies designed to limit marketing and agent abuse for any duplicative policies, to assure the dissemination of such information to consumers as is necessary to permit informed choice in purchasing policies and to reduce purchase of unnecessary or duplicative coverage, to assure that benefits provided under policies are reasonable in relationship to premiums charged, and to promote development and availability of long-term health care policies which meet these recommendations, and further provided for composition of Task Force, definition of long-term health care policy, assurance of States’ jurisdiction, submission of recommendations to Secretary and Congress not later than 18 months after Apr. 7, 1986, and termination of Task Force 90 days after submission of recommendations.

§1395b–1. Incentives for economy while maintaining or improving quality in provision of health services

(a) Grants and contracts to develop and engage in experiments and demonstration projects

(1) The Secretary of Health and Human Services is authorized, either directly or through grants to public or private agencies, institutions, and organizations or contracts with public or private agencies, institutions, and organizations, to develop and engage in experiments and demonstration projects for the following purposes:

(A) to determine whether, and if so which, changes in methods of payment or reimbursement (other than those dealt with in section 222(a) of the Social Security Amendments of 1972) for health care and services under health programs established by this chapter, including a change to methods based on negotiated rates, would have the effect of increasing the efficiency and economy of health services under such programs through the creation of additional incentives to these ends without adversely affecting the quality of such services;

(B) to determine whether payments for services other than those for which payment may
be made under such programs (and which are incidental to services for which payment may be made under such programs) would, in the judgment of the Secretary, result in more economical provision and more effective utilization of services for which payment may be made under such program, where such services are furnished by organizations and institutions which have the capability of providing—

(i) comprehensive health care services,
(ii) mental health care services (as defined by section 2691(c) of this title),
(iii) ambulatory health care services (including surgical services provided on an outpatient basis), or
(iv) institutional services which may substitute, at lower cost, for hospital care;

(D) to determine whether payments under such programs based on a single combined rate of reimbursement or charge for the teaching activities and patient care which residents, interns, and supervising physicians render in connection with a graduate medical education program in a patient facility would result in more equitable and economical patient care arrangements without adversely affecting the quality of such care;

(E) to determine whether coverage of intermediate care facility services and homemaker services would provide suitable alternatives to posthospital benefits presently provided under this subchapter; such experiment and demonstration projects may include:

(i) counting each day of care in an intermediate care facility as one day of care in a skilled nursing facility, if such care was for a condition for which the individual was hospitalized,

(ii) covering the services of homemakers for a maximum of 21 days, if institutional services are not medically appropriate,

(iii) determining whether such coverage would reduce long-range costs by reducing the lengths of stay in hospitals and skilled nursing facilities, and

(iv) establishing alternative eligibility requirements and determining the probable cost of applying each alternative, if the project suggests that such extension of coverage would be desirable;

(F) to determine whether, and if so which type of, fixed price or performance incentive contract would have the effect of inducing to the greatest degree effective, efficient, and economical performance of agencies and organizations making payment under agreements or contracts with the Secretary for health care and services under health programs established by this chapter;

(G) to determine under what circumstances payment for services would be appropriate and the most appropriate, equitable, and non-inflationary methods and amounts of reimbursement under health care programs established by this chapter for services, which are performed independently by an assistant to a physician, including a nurse practitioner (whether or not performed in the office of or at a place at which such physician is physically present), and—

(i) which such assistant is legally authorized to perform by the State or political subdivision wherein such services are performed, and

(ii) for which such physician assumes full legal and ethical responsibility as to the necessity, propriety, and quality thereof;

(H) to establish an experimental program to provide day-care services, which consist of such personal care, supervision, and services as the Secretary shall by regulation prescribe, for individuals eligible to enroll in the supplemental medical insurance program established under part B of this subchapter and subchapter XIX of this chapter, in day-care centers which meet such standards as the Secretary shall by regulation establish;

(I) to determine whether the services of clinical psychologists may be made more generally available to persons eligible for services under this subchapter and subchapter XIX of this chapter in a manner consistent with quality of care and equitable and efficient administration;

(J) to develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services under the health programs established by this chapter; and

(K) to determine whether the use of competitive bidding in the awarding of contracts, or the use of other methods of reimbursement, under part B of subchapter XI of this chapter would be efficient and effective methods of furthering the purposes of that part.

For purposes of this subsection, ‘‘health programs established by this chapter’’ means the program established by this subchapter and a program established by a plan of a State approved under subchapter XIX of this chapter.

(2) Grants, payments under contracts, and other expenditures made for experiments and demonstration projects under paragraph (1) shall 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 1395i of this title) and from funds appropriated under subchapter XIX of this chapter. Grants and payments under contracts may be made either in advance or by way of reimbursement, as may be determined by the Secretary, and shall be made in such installments and on such conditions as the Secretary may require for services, which are provided.

With respect to any such grant, payment, or other expenditure, the amount to be paid from each of such trust funds (and from funds appropriated under such subchapter XIX

1 See References in Text note below.
of this chapter) shall be determined by the Secretary, giving due regard to the purposes of the experiment or project involved.

(b) Waiver of certain payment or reimbursement requirements; advice and recommendations of specialists preceding experiments and demonstration projects

In the case of any experiment or demonstration project under subsection (a) of this section, the Secretary may waive compliance with the requirements of this subchapter and subchapter XIX of this chapter insofar as such requirements relate to reimbursement or payment on the basis of reasonable cost, or to reimbursement or payment only for such services or items as may be specified in the experiment; and costs incurred in such experiment or demonstration project in excess of the costs which would otherwise be reimbursed or paid under such subchapters may be reimbursed or paid to the extent that such waiver applies to them (with such excess being borne by the Secretary). No experiment or demonstration project shall be engaged in or developed under subsection (a) of this section until the Secretary obtains the advice and recommendations of specialists who are competent to evaluate the proposed experiment or demonstration project as to the soundness of its objectives, the possibilities of securing productive results, the adequacy of resources to conduct the proposed experiment or demonstration project as to the purposes for which experiments and demonstration projects may be carried out for a general statement setting out the increase in efficiency and economy of health services as the purpose of experiments selected by the Secretary, inserted references to demonstration projects, and inserted references to the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund.

Subsec. (b). Pub. L. 92–603, § 222(b)(2), inserted references to demonstration projects and inserted "", or to reimbursement or payment only for such services or items as may be specified in this experiment".

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (a)(1) pursuant to section 509(b) Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98–369 effective July 18, 1984, see section 2331(c) of Pub. L. 98–369, set out as a note under section 1310 of this title.

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by 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, SAVINGS, AND TRANSITIONAL PROVISIONS

For effective date, savings, and transitional provisions relating to amendment by Pub. L. 97–35, see section 2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

COMMUNITY-BASED CARE TRANSITIONS PROGRAM


"(a) IN GENERAL.—The Secretary shall establish a Community-Based Care Transitions Program under which the Secretary provides funding to eligible entities that furnish improved care transition services to high-risk Medicare beneficiaries.

(b) DEFINITIONS.—In this section:

"(1) ELIGIBLE ENTITY.—The term ‘eligible entity’ means the following:

(A) A subsection (d) hospital (as defined in section 1866(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B))) identified by the Secretary as having a high readmission rate, such as under section 1886(q) of the Social Security Act, as added by section 3025.

(B) An appropriate community-based organization that provides care transition services under this section across a continuum of care through arrangements with subsection (d) hospitals (as so de-
fined) to furnish the services described in sub-
section (c)(2)(B)(i) and whose governing body in-
cludes sufficient representation of multiple health
care stakeholders (including consumers).

"(2) HIGH-RISK MEDICARE BENEFICIARY.—The term 'high-risk Medicare beneficiary' means a Medicare
beneficiary who has attained a minimum hierarchical
condition category score, as determined by the Sec-
retary, based on a diagnosis of multiple chronic con-
ditions or other risk factors associated with a hos-
pital readmission or substandard transition into post-
hospitalization care, which may include 1 or more of
the following:

"(A) Cognitive impairment.
"(B) Depression.
"(C) A history of multiple readmissions.
"(D) Any other chronic disease or risk factor as
determined by the Secretary.

"(3) MEDICARE BENEFICIARY.—The term 'Medicare
beneficiary' means an individual who is entitled to
benefits under part A (42 U.S.C. 1395c et seq.) of title
XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) and enrolled under part B (42 U.S.C. 1395 et seq.)
of such title, but not enrolled under part C (42 U.S.C.
1395w–21 et seq.) of such title.

"(4) PROGRAM.—The term 'program' means the pro-
gram conducted under this section.

"(5) READMISSION.—The term 'readmission' has the
meaning given such term in section 1866(a)(3)(E)
of the Social Security Act (42 U.S.C. 1395ww(q)(5)(E)), as
added by section 3025.

"(6) SECRETARY.—The term 'Secretary' means the
Secretary of Health and Human Services.

"(e) REQUIREMENTS.—The program shall be con-
ducted for a 5-year period, beginning January 1,
2011.

"(f) FUNDING.—For purposes of carrying out this sec-
tion, the Secretary of Health and Human Services shall
provide for the transfer, from the Federal Hospital In-
surance Trust Fund under section 1817 of the Social
Security Act (42 U.S.C. 1395s) and the Federal Supple-
mentary Medical Insurance Trust Fund under section
1841 of such Act (42 U.S.C. 1395s), in such proportion as
the Secretary determines appropriate, of $500,000,000,
to the Centers for Medicare & Medicaid Services Program
Management Account for the period of fiscal years 2011
through 2015. Amounts transferred under the preceding
sentence shall remain available until expended.

PILOT TESTING PAY-FOR-PERFORMANCE PROGRAMS FOR
CERTAIN MEDICARE PROVIDERS

961, provided that:

"(a) IN GENERAL.—Not later than January 1, 2016, the
Secretary of Health and Human Services (in this sec-
tion referred to as the 'Secretary') shall, for each pro-
der described in subsection (b), conduct a separate
test of the implementation of a value-based purchasing program under title XVIII of this Act (42 U.S.C. 1395c)
for Medicare-Part B (Medicare) payments to participating
providers, including hospitals, post-acute care facilities,
and organizations providing long-term services and support.

"(b) PROVIDERS DESCRIBED.—The providers described
in this paragraph are the following:

"(1) Psychiatric hospitals (as described in clause (i)
of section 1866(d)(1)(B) of such Act (42 U.S.C. 1395ww(d)(1)(B)) and psychiatric units (as described
in the matter following clause (v) of such section).

"(2) Long-term care hospitals (as described in clause (iv)
of such section).

"(3) Rehabilitation hospitals (as described in clause
(ii) of such section).

"(4) PPS-exempt cancer hospitals (as described in clause (v)
of such section).

"(5) Hospice programs (as defined in section
1861(dd)(2) of such Act (42 U.S.C. 1395x(dd)(2))).

"(c) 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 solely for purposes of carrying out the
pilot programs under this section.

"(d) NO ADDITIONAL PROGRAM EXPENDITURES.—Pay-
ments under this section shall be in addition to other
program expenditures for applicable items and services under title XVIII of the Social Secu-
riety Act for a year shall be in addition to a manner
§ 133(a), July 15, 2008, 122 Stat. 2531, provided that:

"(e) EXPANSION OF PILOT PROGRAM.—The Secretary may, at any point after January 1, 2018, expand the duration and scope of a pilot program conducted under this subsection, to the extent determined appropriate by the Secretary, if—

(1) the Secretary determines that such expansion is expected to—

"(A) reduce spending under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] without reducing the quality of care; or

(B) improve the quality of care and reduce spending;

(2) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce program spending under such title XVIII; and

(3) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under such title XIII (XVIII) for Medicare beneficiaries:'

MEDICARE MEDICAL HOME DEMONSTRATION PROJECT


"(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall establish under title XVIII of the Social Security Act [this subchapter] a medical home demonstration project (in this section referred to as the ‘project’) to redesign the health care delivery system to provide targeted, accessible, continuous and coordinated patient access to personal health information; family-centered care to high-need populations and under which—

(1) care management fees are paid to persons performing services as personal physicians; and

(2) incentive payments are paid to physicians participating in practices that provide services as a medical home under subsection (d).

For purposes of this subsection, the term ‘high-need population’ means individuals with multiple chronic illnesses that require regular medical monitoring, advising, or treatment.

(b) DETAILS.—

(1) DURATION; SCOPE.—Subject to paragraph (3), the project shall operate during a period of three years and shall include urban, rural, and underserved areas in a total of no more than 8 States.

(2) ENCOURAGING PARTICIPATION OF SMALL PHYSICIAN PRACTICES.—The project shall be designed to include the participation of physicians in practices, with fewer than three full-time equivalent physicians as well as physicians in larger practices, particularly in rural and underserved areas.

(3) EXPANSION.—The Secretary may expand the duration and the scope of the project under paragraph (1), to an extent determined appropriate by the Secretary, if the Secretary determines that such expansion will result in any of the following conditions being met:

(A) The expansion of the project is expected to improve the quality of patient care without increasing spending under the Medicare program (not taking into account amounts available under subsection (g));

(B) The expansion of the project is expected to reduce spending under the Medicare program (not taking into account amounts available under subsection (g)) without reducing the quality of patient care.

(c) PERSONAL PHYSICIAN DEFINED.—

"(1) IN GENERAL.—For purposes of this section, the term ‘personal physician’ means a physician (as defined in section 1861(r)(1) of the Social Security Act (42 U.S.C. 1395r(1)(1)) who—

(A) meets the requirements described in paragraph (2); and

(B) performs the services described in paragraph (3).

Nothing in this paragraph shall be construed as preventing such a physician from being a specialist or subspecialist for an individual requiring ongoing care for a specific chronic condition or multiple chronic conditions (such as severe asthma, complex diabetes, cardiovascular disease, rheumatologic disorder) or for an individual with a prolonged illness.

(2) REQUIREMENTS.—The requirements described in this paragraph for a personal physician are as follows:

(A) The physician is a board certified physician who provides first contact and continuous care for individuals under the physician’s care.

(B) The physician has the staff and resources to manage the comprehensive and coordinated health care of each such individual.

(3) SERVICES PERFORMED.—A personal physician shall perform or provide for the performance of at least the following services:

(A) Advocates for and provides ongoing support, oversight, and guidance to implement a plan of care that provides an integrated, coherent, cross-discipline plan for ongoing medical care developed in partnership with patients and including all other physicians furnishing care to the patient involved and other appropriate medical personnel or agencies (such as home health agencies).

(B) Uses evidence-based medicine and clinical decision support tools to guide decision-making at the point-of-care based on patient-specific factors.

(C) Uses health information technology, that may include remote monitoring and patient registries, to monitor and track the health status of patients and to provide patients with enhanced and convenient access to health care services.

(D) Encourages patients to engage in the management of their own health through education and support systems.

(d) MEDICAL HOME DEFINED.—For purposes of this section, the term ‘medical home’ means a physician practice that—

(1) is in charge of targeting beneficiaries for participation in the project; and

(2) is responsible for—

(A) providing safe and secure technology to promote patient access to personal health information;

(B) developing a health assessment tool for the individuals targeted; and

(C) providing training programs for personnel involved in the coordination of care.

(e) PAYMENT MECHANISMS.—

(1) PERSONAL PHYSICIAN CARE MANAGEMENT FEE.—Under the project, the Secretary shall provide for payment under section 1840B of the Social Security Act (42 U.S.C. 1395w-4) of a care management fee to personal physicians providing care management under the project. Under such section and using the relative value scale update committee (RUC) process, the Secretary shall develop a care management fee code for such payments and a value for such code.

(2) MEDICAL HOME SHARING IN SAVINGS.—The Secretary shall provide for payment under the project of a medical home based on the payment methodology applied to physician group practices under section 1866A of the Social Security Act (42 U.S.C. 1395ww-1). Under such methodology, 80 percent of the reductions in expenditures under title XVIII of the Social Security Act [this subchapter] resulting from participation of individuals that are attributable to the medical home (as reduced by the total care management fees paid to the medical home under the project) shall be paid to the medical home. The amount of such reductions in expenditures shall be determined by using assumptions with respect to reductions in the occurrence of health complications, hospitalization rates, medical errors, and adverse drug reactions.
POST-ACUTE CARE PAYMENT REFORM DEMONSTRATION PROGRAM

Pub. L. 110–171, title V, § 5008, Feb. 8, 2006, 120 Stat. 36, provided that:

“(a) Establishment.—

“(1) In general.—By not later than January 1, 2008, the Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall establish a demonstration program for purposes of understanding costs and outcomes across different post-acute care sites. Under such program, with respect to diagnoses specified by the Secretary, an individual who receives treatment from a provider for such a diagnosis shall receive a single comprehensive assessment on the date of discharge from a subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395w(d)(1)(B))) of the needs of the patient and the clinical characteristics of the diagnosis to determine the appropriate placement of such patient in a post-acute care site. The Secretary shall use a standardized patient assessment instrument across all post-acute care sites to measure functional status and other factors during the treatment and at discharge from each provider. Participants in the program shall provide information on the fixed and variable costs for each individual. An additional comprehensive assessment shall be provided at the end of the episode of care.

“(2) Number of sites.—The Secretary shall conduct the demonstration program under this section with sufficient numbers to determine statistically reliable results.

“(3) Duration.—The Secretary shall conduct the demonstration program under this section for a 3-year period.

“(b) 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.; 42 U.S.C. 1396 et seq.) as may be necessary for the purpose of carrying out the demonstration program under this section.

“(c) 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, that includes the results of the program and recommendations for such legislation and administrative action as the Secretary determines to be appropriate.

“(d) Funding.—The Secretary shall provide for the transfer from the Federal Hospital Insurance Trust Fund established under section 1817 of the Social Security Act (42 U.S.C. 1395b–1) of $100,000,000 to carry out the project.

“(h) Application.—Chapter 35 of title 44, United States Code, shall not apply to the conduct of the project.

MEDICARE CARE MANAGEMENT PERFORMANCE DEMONSTRATION


“(a) Establishment.—

“(1) In general.—The Secretary of Health and Human Services shall establish a pay-for-performance demonstration program with physicians to meet the needs of eligible beneficiaries through the adoption and use of health information technology and evidence-based outcomes measures for—

“(A) promoting continuity of care;

“(B) helping stabilize medical conditions;

“(C) preventing or minimizing acute exacerbations of chronic conditions; and

“(D) reducing adverse health outcomes, such as adverse drug interactions related to polypharmacy.

“(2) Sites.—The Secretary shall designate no more than 4 sites at which to conduct the demonstration program under this section, of which—

“(A) two shall be in an urban area;

“(B) one shall be in a rural area; and

“(C) one shall be in a State with a medical school with a Department of Geriatrics that manages rural outreach sites and is capable of managing patients with multiple chronic conditions, one of which is dementia.

“(3) Duration.—The Secretary shall conduct the demonstration program under this section for a 3-year period.

“(4) Consultation.—In carrying out the demonstration program under this section, the Secretary shall consult with private sector and non-profit groups that are undertaking similar efforts to improve quality and reduce avoidable hospitalizations for chronically ill patients.

“(b) Participation.—

“(1) In general.—A physician who provides care for a minimum number of eligible beneficiaries (as specified by the Secretary) may participate in the demonstration program under this section if such physician agrees, to phase-in over the course of the 3-year demonstration period and with the assistance provided under subsection (d)(2), to—

“(A) the use of health information technology to manage the clinical care of eligible beneficiaries consistent with paragraph (3); and

“(B) the electronic reporting of clinical quality and outcomes measures in accordance with requirements established by the Secretary under the demonstration program.

“(2) Special rule.—In the case of the sites referred to in subparagraphs (B) and (C) of subsection (a)(2), a physician who provides care for a minimum number of beneficiaries with two or more chronic conditions, including dementia (as specified by the Secretary), may participate in the program under this section if such physician agrees to the requirements in subparagraphs (A) and (B) of paragraph (1).

“(d) Practice standards.—Each physician participating in the demonstration program under this section must demonstrate the ability—

“(A) to assess each eligible beneficiary for conditions other than chronic conditions, such as impaired cognitive ability and co-morbidities, for the purposes of developing care management requirements;

“(B) to serve as the primary contact of eligible beneficiaries in accessing items and services for which payment may be made under the medicare program;

“(C) to establish and maintain health care information system for such beneficiaries;

“(D) to promote continuity of care across providers and settings;

“(E) to use evidence-based guidelines and meet such clinical quality and outcome measures as the Secretary shall require;

“(F) to promote self-care through the provision of patient education and support for patients or, where appropriate, family caregivers;
“(G) when appropriate, to refer such beneficiaries to community service organizations; and

“(H) to meet such other complex care management requirements as the Secretary may specify.

The guidelines and measures required under subparagraph (E) shall be designed to take into account beneficiaries with multiple chronic conditions.

“(c) Payment Methodology.—Under the demonstration program under this section the Secretary shall pay a per beneficiary amount to each participating physician who meets or exceeds specific performance standards established by the Secretary with respect to the clinical quality and outcome measures reported under subsection (b)(1)(B). Such amount may vary based on different levels of performance or improvement.

“(d) Administration.—

“(1) Use of Quality Improvement Organizations.—The Secretary shall contract with quality improvement organizations or such other entities as the Secretary deems appropriate to enroll physicians and evaluate their performance under the demonstration program under this section.

“(2) Technical Assistance.—The Secretary shall require in such contracts that the contractor be responsible for technical assistance and education as needed to physicians enrolled in the demonstration program under this section for the purpose of aiding their adoption of health information technology, meeting practice standards, and implementing required clinical and outcomes measures.

“(e) Funding.—

“(1) In General.—The Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund established 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 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 estimates would have been paid if the demonstration program under this section was not implemented.

“(f) 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. and 1395 et seq.) as may be necessary for the purpose of carrying out the demonstration program under this section.

“(g) Report.—Not later than 12 months after the date of 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.

“(h) Definitions.—In this section:

“(1) Eligible Beneficiary.—The term ‘eligible beneficiary’ means any individual who—

“(A) is entitled to benefits under part A and enrolled for benefits under part B of title XVIII of the Social Security Act (parts A and B of this subchapter) and is not enrolled in a plan under part C of such title (part C of this subchapter); and

“(B) has one or more chronic medical conditions specified by the Secretary (one of which may be cognitive impairment).

“(2) Health Information Technology.—The term ‘health information technology’ means email communication, clinical alerts and reminders, and other information technology that ensures such functionality, interoperability, and other standards as prescribed by the Secretary.

Demonstration Project for Disease Management for Severely Chronically Ill Medicare Beneficiaries

Pub. L. 106-554, §1(a)(6) [title I, §122], Dec. 21, 2000, 114 Stat. 2763, 2763A-474, provided that the Secretary of Health and Human Services was to conduct a demonstration project under this section to demonstrate the impact on costs and health outcomes of applying disease management to Medicare beneficiaries with diagnosed, advanced-stage congestive heart failure, diabetes, dementia, or coronary heart disease, that the project was to last for not longer than 3 years, and that the Secretary was to submit a final report to Congress not later than 6 months after the project’s completion.

Cancer Prevention and Treatment Demonstration for Ethnic and Racial Minorities

Pub. L. 106-554, §1(a)(6) [title I, §122], Dec. 21, 2000, 114 Stat. 2763, 2763A-476, provided that:

“(a) Demonstration.—

“(1) In General.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall conduct demonstration projects (in this section referred to as ‘demonstration projects’) for the purpose of developing models and evaluating methods that—

“(A) improve the quality of items and services provided to target individuals in order to facilitate reduced disparities in early detection and treatment of cancer;

“(B) improve clinical outcomes, satisfaction, quality of life, and appropriate use of Medicare-covered services and referral patterns among those target individuals with cancer;

“(C) eliminate disparities in the rate of preventive cancer screening measures, such as pap smears and prostate cancer screenings, among target individuals; and

“(D) promote collaboration with community-based organizations to ensure cultural competency of health care professionals and linguistic access for persons with limited English proficiency.

“(2) Target Individual Defined.—In this section, the term ‘target individual’ means an individual of a racial and ethnic minority group, as defined by section 1707 of the Public Health Service Act [section 300u-6 of this title], who is entitled to benefits under part A, and enrolled under part B, of title XVIII of the Social Security Act [parts A and B of this subchapter].

“(b) Program Design.—

“(1) Initial Design.—Not later than 1 year after the date of the enactment of this Act (Dec. 21, 2000), the Secretary shall evaluate best practices in the private sector, community programs, and academic research of methods that reduce disparities among individuals of racial and ethnic minority groups in the prevention and treatment of cancer and shall design the demonstration projects based on such evaluation.

“(2) Number and Project Areas.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall implement at least nine demonstration projects, including the following:

“(A) Two projects for each of the four following major racial and ethnic minority groups:

“(i) American Indians, including Alaska Natives, Eskimos, and Aleuts.

“(ii) Asian Americans and Pacific Islanders.

“(iii) Blacks.

“(iv) Hispanics.

“The two projects must target different ethnic subpopulations.

“(B) One project within the Pacific Islands.

“(C) At least one project each in a rural area and inner-city area.

“(3) Expansion of Projects; Implementation of Demonstration Project Results.—If the initial report under subsection (c) contains an evaluation that demonstration projects—

“(A) reduce expenditures under the Medicare program under title XVIII of the Social Security Act [this subchapter]; or

“(B) do not increase expenditures under the Medicare program and reduce racial and ethnic health disparities in the quality of health care services provided to target individuals and increase satisfaction of beneficiaries and health care providers;
the Secretary shall continue the existing demonstration projects and may expand the number of demonstration projects.

(6) REPORT TO CONGRESS.—
   "(1) IN GENERAL.—Not later than 2 years after the date the Secretary implements the initial demonstration projects, and biannually thereafter, the Secretary shall submit to Congress a report regarding the demonstration projects.
   "(2) CONTENTS OF REPORT.—Each report under paragraph (1) shall include the following:
      "(A) A description of the demonstration projects;
      "(B) An evaluation of—
         "(i) the cost-effectiveness of the demonstration projects;
         "(ii) the quality of the health care services provided to target individuals under the demonstration projects; and
      "(III) beneficiary and health care provider satisfaction under the demonstration projects.
      "(C) Any other information regarding the demonstration projects that the Secretary determines to be appropriate.
   "(d) WAIVER AUTHORITY.—The Secretary shall waive compliance with the requirements of title XVIII of the Social Security Act (this subchapter) to such extent and for such period as the Secretary determines is necessary to conduct demonstration projects.

(7) FUNDING.—
   "(1) DEMONSTRATION PROJECTS.—
      "(A) STATE PROJECTS.—Except as provided in subparagraph (B), the Secretary shall provide for the transfer from the Federal Hospital Insurance Trust Fund and the Federal Supplementary (Medical) Insurance Trust Fund under title XVIII of the Social Security Act (this subchapter), in such proportions as the Secretary determines to be appropriate, of such funds as are necessary for the costs of carrying out the demonstration projects.
      "(B) TERRITORY PROJECTS.—In the case of a demonstration project described in subsection (b)(2)(B), amounts shall be available only as provided in any Federal law making appropriations for the territories.
   "(2) LIMITATION.—In conducting demonstration projects, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the sum of the amount which the Secretary would have paid under the program for the prevention and treatment of cancer if the demonstration projects were not implemented, plus $25,000,000."

LIFESTYLE MODIFICATION PROGRAM DEMONSTRATION


(1) In General.—The Secretary of Health and Human Services shall carry out the demonstration projects, including—
   "(A) 5 projects in urban areas;
   "(B) 3 projects in rural areas; and
   "(C) 1 project within the District of Columbia which is operated by a nonprofit academic medical center that maintains a National Cancer Institute certified comprehensive cancer center.

(2) IMPLEMENTATION OF DEMONSTRATION PROJECT RESULTS.
   "(A) EXPANSION OF PROJECTS.—If the initial report under subsection (c) contains an evaluation that demonstration projects—
      "(i) reduce expenditures under the medicare program; or
      "(ii) do not increase expenditures under the medicare program and increase the quality of health care services provided to target individuals and satisfaction of beneficiaries and health care providers;
   the Secretary shall continue the existing demonstration projects and may expand the number of demonstration projects.
   "(B) IMPLEMENTATION OF DEMONSTRATION PROJECT RESULTS.—If a report under subsection (c) contains an evaluation as described in subparagraph (A), the Secretary may issue regulations to implement, on a permanent basis, the components of the demonstration project that are beneficial to the medicare program.
   "(C) REPORT TO CONGRESS.—

MEnicare coordinated care demonstration project


(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall conduct demonstration projects for the purpose of evaluating methods, such as case management and other models of coordinated care, that—
   "(A) improve the quality of items and services provided to target individuals;
   "(B) reduce expenditures under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) for items and services provided to target individuals;
   "(2) TARGET INDIVIDUAL DEFINED.—In this section, the term ‘target individual’ means an individual that has a chronic illness, as defined and identified by the Secretary, and is enrolled under the fee-for-service program under parts A and B of title XVIII of the Social Security Act (42 U.S.C. 1395c et seq.; 1395j et seq.).

(3) PROGRAM DESIGN.—
   "(1) INITIAL DESIGN.—The Secretary shall evaluate best practices in the private sector of methods of coordinated care for a period of 1 year and design the demonstration project based on such evaluation.
   "(2) NUmBER AND PROJECT AREAS.—Not later than 2 years after the date of enactment of this Act [Aug. 5, 1997], the Secretary shall implement at least 9 demonstration projects, including—
      "(A) 5 projects in urban areas;
      "(B) 3 projects in rural areas; and
      "(C) 1 project within the District of Columbia which is operated by a nonprofit academic medical center that maintains a National Cancer Institute certified comprehensive cancer center.

(4) EXPANSION OF PROJECTS; IMPLEMENTATION OF DEMONSTRATION PROJECT RESULTS.
   "(A) EXPANSION OF PROJECTS.—If the initial report under subsection (c) contains an evaluation that demonstration projects—
      "(i) reduce expenditures under the medicare program; or
      "(ii) do not increase expenditures under the medicare program and increase the quality of health care services provided to target individuals and satisfaction of beneficiaries and health care providers;
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``(1) IN GENERAL.—Not later than 2 years after the Secretary implements the initial demonstration projects under this section, and biannually thereafter, the Secretary shall submit to Congress a report regarding the demonstration projects conducted under this section.

(ii) CONTENTS OF REPORT.—The report in paragraph (1) shall include the following:

(1) A description of the demonstration projects conducted under this section.

(2) An evaluation of—

(a) the cost-effectiveness of the demonstration projects;

(b) the quality of the health care services provided to target individuals under the demonstration projects; and

(c) Any other information regarding the demonstration projects conducted under this section that the Secretary determines to be appropriate.

(d) WAIVER AUTHORITY.—The Secretary shall waive compliance with the requirements of title XVIII of the Social Security Act under title XVI of the Social Security Act [42 U.S.C. 1395 et seq.] to such extent and for such period as the Secretary determines is necessary to conduct demonstration projects.

(3) FUNDING.—

(A) DEMONSTRATION PROJECTS.—

(i) IN GENERAL.—Except as provided in clause (ii), the Secretary shall provide for the transfer from the Federal Hospital Insurance Trust Fund and the Federal Supplementary [Medical] Insurance Trust Fund under title XVIII of the Social Security Act [42 U.S.C. 1395d, 1395c], in such proportions as the Secretary determines to be appropriate, of such funds as are necessary for the costs of carrying out the demonstration projects under this section.

(ii) CANCER HOSPITAL.—In the case of the project described in subsection (b)(2)(C), the Secretary shall provide for the transfer from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Insurance Trust Fund [Medical] under title XVIII of the Social Security Act [42 U.S.C. 1395d, 1395c], in such proportions as the Secretary determines to be appropriate, of such funds as are necessary for the costs of carrying out the demonstration projects under this section.

(B) LIMITATION.—In conducting the demonstration project under this subsection, 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 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 (c).

INFORMATICS, TELEMEDICINE, AND EDUCATION DEMONSTRATION PROJECT


(a) PURPOSE AND AUTHORIZATION.—

(1) IN GENERAL.—Not later than 9 months after the date of enactment of this section [Aug. 5, 1997], the Secretary of Health and Human Services shall provide for a demonstration project described in paragraph (2). The Secretary shall make an award for such project not later than 3 months after the date of the enactment of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 [Nov. 29, 1999]. The Secretary shall accept the proposal judged to be the best technical proposal as of such date of enactment without the need for additional review or resubmission of proposals.

(2) DESCRIPTION OF PROJECT.—

(A) IN GENERAL.—The demonstration project described in this paragraph is a single demonstration project to use eligible health care provider telemedicine networks to apply high-capacity computing and advanced networks to improve primary care (and prevent health care complications) to Medicare beneficiaries with diabetes mellitus who are residents of medically underserved rural areas or residents of medically underserved inner-city areas that qualify as Federally designated medically underserved areas or health professional shortage areas at the time of enrollment of beneficiaries under the project.

(B) MEDICALLY UNDERSERVED DEFINED.—As used in this paragraph, the term ‘medically underserved’ has the meaning given such term in section 330(b)(3) of the Public Health Service Act (42 U.S.C. 254b(b)(3)).

(C) WAIVER.—The Secretary shall waive such provisions of title XVIII of the Social Security Act [this subchapter] as may be necessary to provide for payment for services under the project in accordance with subsection (d).

(3) DURATION OF PROJECT.—The project shall be conducted over a 8-year period.

(4) OBJECTIVES OF PROJECT.—The objectives of the project include the following:

(A) Improving patient access to and compliance with appropriate care guidelines for individuals with diabetes mellitus through direct telecommunications link with information networks in order to improve patient quality-of-life and reduce overall health care costs.

(B) Developing a curriculum to train health professionals (particularly primary care health professionals) in the use of medical informatics and telecommunications.

(C) Demonstrating the application of advanced technologies, such as video-conferencing from a patient’s home, remote monitoring of a patient’s medical condition, interventional informatics, and applying individualized, automated care guidelines, to assist primary care providers in assisting patients with diabetes in a home setting.

(D) Application of medical informatics to residents with limited English language skills.

(5) Developing standards in the application of telemedicine and medical informatics.

(6) Developing a model for the cost-effective delivery of primary and related care both in a managed care environment and in a fee-for-service environment.

(E) ELIGIBLE HEALTH CARE PROVIDER TELEMEDICINE NETWORK DEFINED.—For purposes of this section, the term ‘eligible health care provider telemedicine network’ means a consortium that includes at least one tertiary care hospital (but no more than 2 such hospitals), at least one medical school, no more than 4 facilities in rural or urban areas, and at least one regional telecommunications provider and that meets the following requirements:

(1) The consortium is located in an area with a high concentration of medical schools and tertiary care facilities in the United States and has appropriate arrangements (within or outside the consortium) with such schools and facilities, universities, and telecommunications providers, in order to conduct the project.

(2) The consortium submits to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including a description of the use to which the consortium would apply any amounts received under the project.

(3) The consortium guarantees that it will be responsible for payment for all costs of the project that
are not paid under this section and that the maximum amount of payment that may be made to the consortium under this section shall not exceed the amount specified in subsection (a)(4).”

“(d) COVERAGE AS MEDICARE PART B SERVICES.—

“(1) IN GENERAL.—Subject to the succeeding provisions of this subsection, services related to the treatment or management of (including prevention of complications from) diabetes for Medicare beneficiaries furnished under the project shall be considered to be services covered under part B of title XVIII of the Social Security Act [part B of this chapter].

“(2) PAYMENTS.—

“(A) IN GENERAL.—Subject to paragraph (3), payment for such services shall be made for the costs that are related to the provision of such services. In computing such costs, the Secretary shall include costs described in subparagraph (B), but may not include costs described in subparagraph (C).

“(B) COSTS THAT MAY BE INCLUDED.—The costs described in this subparagraph are the permissible costs (as recognized by the Secretary) for the following:

(i) The acquisition of telemedicine equipment for use in patients' homes or at sites providing health care to patients located in medically underserved areas.

(ii) Curriculum development and training of health professionals in medical informatics and telemedicine.

(iii) Payment of telecommunications costs (including salaries and maintenance of equipment), including costs of telecommunications between patients' homes and the eligible network and between the network and other entities under the arrangements described in subsection (c)(1).

(iv) Payments to practitioners and providers under the Medicare programs.

(C) COSTS NOT INCLUDED.—The costs described in this subparagraph are costs for any of the following:

(i) The purchase or installation of transmission equipment (other than such equipment used by health professionals for activities related to the project).

(ii) The establishment or operation of a telecommunications common carrier network.

(iii) Construction (except for minor renovations related to the installation of reimbursable equipment) or the acquisition or building of real property.

“(3) LIMITATION.—The total amount of the payments that may be made under this section shall not exceed $60,000,000 for the period of the project (described in subsection (a)(4)).

“(4) COST-SHARING.—The project may not impose cost-sharing on a Medicare beneficiary for the receipt of services under the project. Project costs will cover all costs to Medicare beneficiaries and providers related to participation in the project.

“(e) REPORTS.—The Secretary shall submit to the Committee on Ways and Means and the Committee on Committee on Energy and Commerce [now Committee on Energy and Commerce] of the House of Representatives and the Committee on Finance of the Senate interim reports on the project and a final report on the project within 6 months after the conclusion of the project. The final report shall include an evaluation of the impact of the use of telemedicine and medical informatics on improving access of Medicare beneficiaries to health care services, on reducing the costs of such services, and on improving the quality of life of such beneficiaries.

“(f) DEFINITIONS.—For purposes of this section:

“(1) INTERVENTIONAL INFORMATICS.—The term ‘interventional informatics’ means using information technology and virtual reality technology to intervene in patient care.

“(2) MEDICAL INFORMATICS.—The term ‘medical informatics’ means the storage, retrieval, and use of biomedical and related information for problem solving and decision-making through computing and communications technologies.

“(3) PROJECT.—The term ‘project’ means the demonstration project under this section.

CLARIFICATION OF SECRETARIAL WAIVER AUTHORITY FOR RURAL HOSPITAL DEMONSTRATIONS


VOLUNTEER SENIOR AIDES DEMONSTRATION PROJECTS FOR BASIC MEDICAL ASSISTANCE AND SUPPORT TO FAMILIES WITH DISABLED OR ILL CHILDREN


“(a) NUMBER OF PROJECTS.—In order to determine whether, and if so, the extent to which, the use of volunteer senior aides to provide basic medical assistance and support to families with moderately or severely disabled or chronically ill children contributes to reducing the costs of care for such children, not more than 10 communities may conduct demonstration projects under this section.

“(b) DUTIES OF THE SECRETARY.—

“(1) CONSIDERATION OF APPLICATIONS.—The Secretary of Health and Human Services [now Health and Human Services] shall consider all applications received from communities desiring to conduct demonstration projects under this section.

“(2) APPROVAL OF CERTAIN APPLICATIONS.—The Secretary shall approve not more than 10 applications to conduct demonstration projects which appear likely to contribute significantly to the achievement of the purpose of this section.

“(3) GRANTS.—The Secretary shall make grants to each community the application of which to conduct a demonstration project under this section is approved by the Secretary to assist the community in carrying out the project.

“(c) REQUIREMENTS.—Each community receiving a grant with respect to a demonstration project under this section shall conduct the project in accordance with such requirements as the Secretary may prescribe.

“(d) LIMITATION ON AUTHORIZATION OF APPROPRIATIONS.—For grants under this section, there are authorized to be appropriated to the Secretary of Health and Human Services not to exceed—

(1) $1,000,000 for each of the fiscal years 1990 and 1991; and

(2) $2,000,000 for each of the fiscal years 1992, 1993, and 1994.

“(e) EFFECTIVE DATE.—This section shall take effect on October 1, 1989.”

TREATMENT OF CERTAIN NURSING EDUCATION PROGRAMS


“(a) DEMONSTRATION OF JOINT NURSING GRADUATE EDUCATION PROGRAMS.—

“(1) The Secretary of Health and Human Services shall provide for demonstration programs under this subsection in each of 5 hospitals for cost reporting periods beginning on or after July 1, 1989, and before July 1, 1994.

“(2) Under each demonstration project, subject to paragraph (4), the reasonable costs incurred by a hos-
hospital pursuant to a written agreement with an educational institution for the activities described in paragraph (3) conducted as part of an approved educational program that—

"(A) involves a substantial clinical component (as determined by the Secretary), and

"(B) leads to a master's or doctoral degree in nursing,

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 approved educational program (other than an approved graduate medical education program).

"(3) The activities described in this paragraph are the activities for which the reasonable costs of conducting such activities are allowable under title XVIII of the Social Security Act if conducted under a hospital-operated approved educational program (other than an approved graduate medical education program), but only to the extent such activities are directly related to the operation of the educational program conducted pursuant to the written agreement between the hospital and the educational institution.

"(4) The amount paid under a demonstration program under this subsection to a hospital for a cost reporting period may not exceed $200,000.

"(b) Joint Undergraduate Education Program.—In the case of a hospital which (1) was paid under a waiver under section 492 of the Social Security Amendments of 1967 [section 492 of Pub. L. 90–248, enacting this section and amending section 1395f of this title] and section 222 of the Social Security Amendments of 1972 [section 222 of Pub. L. 92–603, amending this section and section 1395f of this title and enacting provisions set out below], which waiver expired on September 30, 1985, and (2) during its cost reporting period beginning in fiscal year 1985 and for each subsequent cost reporting period, has been and is associated with, and has incurred and incurs substantial costs with respect to, a nursing college with which it has shared and shares common directors, educational activities of the nursing college shall be considered to be educational activities operated directly by such hospital for purposes of title XVIII of the Social Security Act [this subchapter], and shall be allowable as reasonable costs under such title and reimbursed under such title on the same basis as if they were allowable direct costs of a hospital-operated approved educational program (other than an approved graduate medical education program), for hospital cost reporting periods beginning in fiscal years 1986 through 1991.

RESEARCH ON LONG-TERM CARE SERVICES FOR MEDICARE BENEFICIARIES


ADJUSTMENT OF CONTRACTS WITH PREPAID HEALTH PLANS

For requirement that Secretary of Health and Human Services modify contracts with health maintenance organizations under subsec. (a) of this section and section 222(a) of Pub. L. 92–603, set out below, as to apply to such organizations and contracts the requirements imposed by the amendments made by Pub. L. 100–360, see section 222 of Pub. L. 100–360, set out as a note under section 1395mm of this title.

CASE MANAGEMENT DEMONSTRATION PROJECTS


"(1) In general.—Notwithstanding any other provision of law, the Secretary of Health and Human Services shall resume the 3 case management demonstration projects described in paragraph (2) and approved under section 425 of the Medicare Catastrophic Coverage Act of 1988 [Pub. L. 100–203, formerly set out below] (in this subsection referred to as 'MCCA').

"(2) Project Descriptions.—The demonstration projects referred to in paragraph (1) are:

"(A) the project proposed to be conducted by Providence Hospital for case management of the elderly at risk for acute hospitalization as described in Project No. 18–P–99375–01;

"(B) the project proposed to be conducted by the Iowa Foundation for Medical Care to study patients with chronic congestive conditions to reduce repeated hospitalizations of such patients as described in Project No. P–99399–4–01; and

"(C) the project proposed to be conducted by Key Care Health Resources, Inc., to examine the effects of case management on 2,500 high cost medicare beneficiaries as described in Project No. P–99399–4–01.

"(3) Terms and Conditions.—Except as provided in paragraph (4), the demonstration projects resumed pursuant to paragraph (1) shall be subject to the same terms and conditions established under section 425 of MCCA. In determining the 2-year duration period of a project resumed pursuant to paragraph (1), the Secretary may not take into account any period of time for which the project was in effect under section 425 of MCCA.

"(4) Authorization of Appropriations.—Notwithstanding section 425(g) of MCCA, there are authorized to be appropriated for administrative costs in carrying out the demonstration projects resumed pursuant to paragraph (1) $2,000,000 in each of fiscal years 1991 and 1992.

Pub. L. 100–360, title IV, §425, July 1, 1988, 102 Stat. 813, which directed Secretary of Health and Human Services to establish 4 demonstration projects under which an appropriate entity agreed to provide case management services, was repealed by Pub. L. 101–234, title III, §301(a), Dec. 13, 1989, 103 Stat. 185.

DEMONSTRATION PROJECTS WITH RESPECT TO CHRONIC VENTILATOR-DEPENDENT UNITS IN HOSPITALS

Pub. L. 100–360, title IV, §429, July 1, 1988, 102 Stat. 817, as amended by Pub. L. 100–647, title VII, §8404(a), Nov. 10, 1988, 102 Stat. 3800, directed Secretary of Health and Human Services, in consultation with the Prospective Payment Assessment Commission, to provide for at least 5 demonstration projects, for at least 3 years each, to review appropriateness of classifying chronic ventilator-dependent units in hospitals as rehabilitation units.

RESEARCH AND DEMONSTRATION PROJECTS ON RURAL AND INNER-CITY HEALTH ISSUES


"(A) Set Aside for Issues of Health Care in Rural Areas and in Inner-City Areas.—Not less than ten percent of the total amounts annually appropriated to, and expended by, the Health Care Financing Administration for the conduct of research and demonstration projects in fiscal years 1986, 1989, and 1990 shall be expended for research and demonstration projects relating exclusively or substantially to rural health issues, including (but not limited to) the impact of the payment methodology under section 1866(d) of the Social Security Act [section 1395ww(d) of this title] on the financial viability of small rural hospitals, the effect of medicare payment policies on the ability of rural areas (and rural hospitals in particular) to attract and retain physicians and other health professionals, the appropriateness of medicare conditions of participation and
staffing requirements for small rural hospitals, and the impact of Medicare policies on access to (and the quality of) health care in rural areas.

"(2) Not less than ten percent of the total amounts annually appropriated to, and expended by, the Health Care Financing Administration for the conduct of research and demonstration projects in fiscal years 1988, 1989, and 1990 shall be expended for research and demonstration projects relating exclusively or substantially to issues of providing health care in inner-city areas, including (but not limited to) the impact of the payment methodology under section 1862(d) of the Social Security Act on the financial viability of inner-city hospitals and the impact of Medicare policies on access to and the quality of health care in inner-city areas.

"(b) AGENDA.—The Secretary of Health and Human Services shall establish an agenda of research and demonstration projects, relating exclusively or substantially to rural health issues or to inner-city health issues, that are in progress or have been proposed, and shall include such agenda in the annual report submitted pursuant to section 1875(b) of the Social Security Act [section 1395w(b) of this title]. The agenda shall be accompanied by a statement setting forth the amounts that have been obligated and expended with respect to such projects in the current and most recently completed fiscal years.

ALZHEIMER'S DISEASE DEMONSTRATION PROJECTS

Pub. L. 99–99, title IX, §9312, Apr. 21, 1986, 100 Stat. 205, as amended by Pub. L. 100–504, title IV, §4164(a)(6), Nov. 5, 1990, 104 Stat. 1338–101; Pub. L. 100–636, title XIII, §13532, Aug. 10, 1990, 103 Stat. 151, required Secretary of Health and Human Services to conduct at least 5 and no more than 10 demonstration projects, each over a period of 5 years, to determine effectiveness, cost, and impact on health status and functioning of providing comprehensive services for individuals entitled to benefits under this chapter who are victims of Alzheimer's disease or related disorders and to report to Congress upon completion of the projects.

SPECIAL 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 9222(c) of Pub. L. 99–272, as amended, set out as a note under section 1395ww of this title.

EXTENSION OF CERTAIN MEDICARE MUNICIPAL HEALTH SERVICES DEMONSTRATION PROJECTS


"(a) The Secretary of Health and Human Services shall extend through December 31, 1997, approval of four municipal health services demonstration projects (located in Baltimore, Cincinnati, Milwaukee, and San Jose) authorized under section 402(a) of the Social Security Amendments of 1967 [subsec. (a) of this section]. The Secretary shall submit a report to Congress on the waiver program with respect to the quality of health care, beneficiary costs, costs to the Medicaid program, and other payers, access to care, outcomes, beneficiary satisfaction, utilization differences among the different populations served by the projects, and such other factors as may be appropriate. Subject to subsection (c), the Secretary may further extend such demonstration projects through December 31, 1998, where the Secretary determines that the project is in progress or has been proposed and the Secretary determines that the extension of such demonstration projects is in the public interest.

"(b) The project referred to in subsection (a) is the statewide demonstration project established in the State of New Jersey under section 402 of the Social Security Amendments of 1967, as amended by section 192(b) of the Social Security Amendments of 1987 [42 U.S.C. §402(b) (this section), which project provides for payments to hospitals in the State on a prospective basis ending on the date of the enactment of the Balanced Budget Act of 1997 [Aug. 5, 1997].

"(b) The Secretary shall work with each such demonstration project to develop a transition plan, to be submitted to the Committee on Ways and Means and the Committee on Commerce of the House of Representatives and the Committee on Finance of the Senate by March 31, 1998, for the orderly transition of demonstration projects and the project participants to a non-demonstration project health care delivery system, such as through integration with a private or public health plan, including a Medicaid managed care or Medicare-Choice plan.

"(c) A demonstration project under subsection (a) which does not develop and submit a transition plan under subsection (b) by March 31, 1998, or, if later, 6 months after the date of the enactment of the Balanced Budget Act of 1997 [Aug. 5, 1997], shall be discontinued as of December 31, 1998. The Secretary shall provide appropriate technical assistance to assist in the transition so that disruption of medical services to project participants may be minimized.''

[References to Medicare-Choice deemed to refer to Medicare Advantage, see section 201(b) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.]

DEMONSTRATION PROGRAM FOR REDUCTION OF DISABILITY AND DEPENDENCY THROUGH PROVISION OF PREVENTIVE HEALTH SERVICES UNDER MEDICARE

Pub. L. 99–272, title IX, §9314, Apr. 7, 1986, 100 Stat. 194, as amended by Pub. L. 99–99, title IX, §9344(d), Oct. 21, 1986, 100 Stat. 2358–101; Pub. L. 101–508, title IV, §4164(a)1(a) [title VI, §633], Dec. 21, 1990, 104 Stat. 1388–100, required Secretary of Health and Human Services to establish a 5-year demonstration program designed to reduce disability and dependency through the provision of preventive health services to individuals entitled to benefits under this subchapter and to submit reports to Congress including a final report on the project not later than April 1, 1996.

PAYMENT FOR COSTS OF HOSPITAL-BASED MOBILE INTENSIVE CARE UNITS

Section 2330 of Pub. L. 98–369 provided that:

"(a)(1) In the case of a project described in subsection (b), the Secretary of Health and Human Services shall provide, except as provided in paragraph (2), that the amount of payments to hospitals covered under the project during the period described in paragraph (3) shall include payments for their operation of hospital-based mobile intensive care units (as defined by State statute) if the State provides satisfactory assurances that the total amount of payments to such hospitals under titles XVIII and XIX of the Social Security Act [this subchapter and subchapter XIX of this chapter] under the demonstration project (including any such additional amount of payments) would not exceed the total amount of payments which would have been paid under such titles if the demonstration project were not in effect.

"(2) Paragraph (1) shall not apply if the State in which the project is located notifies the Secretary, within 30 days after the date of the enactment of this section [July 18, 1984], that the State does not want paragraph (1) to apply to that project.

"(3) The period referred to in paragraph (1) begins on the date of the enactment of this section and continues so long as the Secretary continues the Statewide waiver referred to in subsection (b), but in no case ends earlier than 90 days after the date final regulations to implement section 1886(c) of the Social Security Act [section 1395ww(c) of this title] are published.

"(b) The project referred to in subsection (a) is the statewide demonstration project established in the State of New Jersey under section 402 of the Social Security Amendments of 1967, as amended by section 192(b) of the Social Security Amendments of 1987 [42 U.S.C. §402(b) (this section), which project provides for payments to hospitals in the State on a prospective basis…]
basis and related to a classification of patients by diagnosis-related groups.

“(c) Payment for services described in this section shall be considered to be payments for services under part A of title XVIII of the Social Security Act [part A of this subchapter].”

CONTINUATION OF SECRETARY’S AUTHORITY REGARDING EXPERIMENTS AND DEMONSTRATION PROJECTS

Pub. L. 98–21, title VI, §603(b), Apr. 20, 1983, 97 Stat. 168, provided that:

“(1) Except as provided in paragraph (2), the amendments made by this title [amending sections 1320a–1, 1323c–2, 1395f, 1396i–1, 1396n, 1395r, 1395v, 1396w, 1396x, 1396y, 1396z–6, 1396cc, 1396mm, 1396rr, 1396sw, and 1396xx of this title, enacting provisions set out as notes under this section and sections 1395f, 1395x, 1395y, 1395cc, and 1396sw of this title, and amending provisions set out as a note under section 1395x of this title] shall not affect the authority of the Secretary to develop, carry out, or continue experiments and demonstration projects.

“(2) The Secretary shall provide that, upon the request of a State which has a demonstration project, for payment of hospitals under title XVIII of the Social Security Act [this subchapter] approved under section 402(a) of the Social Security Amendments of 1967 [subsec. (a) of this section] or section 222(a) of the Social Security Amendments of 1972 [set out as a note below], which (A) is in effect as of March 1, 1983, and (B) was entered into after August 1982 or (upon the request of another party to demonstration project agreement), the terms of the demonstration agreement shall be modified so that the demonstration project is not required to maintain the rate of increase in Medicare hospital costs in that State below the national rate of increase in Medicare hospital costs.”

ALTERNATIVE CARE DEMONSTRATION PROJECTS IN HOSPITALS SHORT OF SKILLED NURSING FACILITIES

Pub. L. 98–21, title VI, §603(d), Apr. 20, 1983, 97 Stat. 168, provided that: “The Secretary shall conduct demonstrations with hospitals in areas with critical shortages of skilled nursing facilities to study the feasibility of providing alternative systems of care or methods of payment.”

CONTINUATION OF HOSPICE DEMONSTRATION PROJECTS; REPORT TO CONGRESS

Section 122(h), formerly §122(h), of Pub. L. 97–248, as redesignated and amended by Pub. L. 97–448, title III, §309(a)(6), (e), Jan. 12, 1983, 96 Stat. 2408, 2410, provided that:

“(1) No provision of this law which has the effect of restricting the time period of a hospice demonstration project in effect on July 15, 1982, pursuant to section 402(a) of the Social Security Amendments of 1967 [subsec. (a) of this section], the Secretary of Health and Human Services, upon request of the hospice involved, shall permit continuation of the project until November 1, 1983, or, if later, the date on which payments can first be made to any hospice program under the amendments made by this section.

“(2) Prior to September 30, 1983, the Secretary shall submit to Congress a report on the effectiveness of demonstration projects referred to in paragraph (1), including an evaluation of the cost-effectiveness of hospice care, the reasonableness of the 40-percent cap amount for hospice care as provided in section 1814(a) of the Social Security Act [section 1395l of this title] (as added by this section), proposed methodology for determining such cap amount, proposed standards for requiring and measuring the maintenance of effort for utilizing volunteers as required under section 1861(dd) of such Act [section 1395x(dd) of this title], an evaluation of physician reimbursement for services furnished as a part of hospice care and for services furnished to individuals receiving hospice care but which are not reimbursed as a part of the hospice care, and any proposed legislative changes in the hospice care provisions of title XVIII of such Act [this subchapter].

“(3)(A) Notwithstanding the provisions of paragraph (1), the Secretary of Health and Human Services, upon request of the hospice involved, shall permit continuation of a hospice demonstration project described in paragraph (1) until September 30, 1986, if the hospice involved in such demonstration project does not provide hospice care directly but acts as a channeling agency for the provision of hospice care.

“(B) During the period after the date on which a hospice demonstration project described in subparagraph (A) would otherwise have terminated under the provisions of paragraph (1), and prior to September 30, 1986, any such hospice demonstration project shall be subject to the same requirements as are imposed under the hospice program provided for under the amendments made by this section (amending sections 1395c to 1395f, 1395h, and 1395x to 1395cc of this title and section 231f of Title 45, Railroads, and enacting provisions set out as notes under sections 1395c and 1395f of this title) with respect to reimbursement on a cost basis for services required by the requirement that certain benefits be provided directly by the hospice involved.”

STATE MEDICARE HOSPITAL REIMBURSEMENT DEMONSTRATION PROJECT LIMITATION


STUDY OF NEED FOR DUAL PARTICIPATION OF SKILLED NURSING FACILITIES


DEMONSTRATION PROJECTS FOR PHYSICIAN-DIRECTED CLINICS IN URBAN MEDICALLY UNDERSERVED AREAS; REPORT SUBMITTED NO LATER THAN JANUARY 1, 1981

Pub. L. 95–210, §3, Dec. 13, 1977, 91 Stat. 1489, required the Secretary to provide, through demonstration projects, reimbursement on a cost basis for services provided by physician-directed clinics in urban medically underserved areas for which payment may be made under this subchapter and, notwithstanding any other provision of this subchapter, for services provided by a physician assistant or nurse practitioner employed by such clinics which would otherwise be covered under this subchapter if provided by a physician. The Secretary was to evaluate the relative advantages and disadvantages of reimbursement on the basis of costs and fee-for-service for physician-directed clinics employing a physician assistant or nurse practitioner, the appropriate methodology for determining the compensation for physician services on a cost basis for the purposes of reimbursement of services provided in such clinics, the appropriate definition for such clinics, the appropriate criteria to use for the purposes of designating urban medically underserved areas, and such other possible changes in the provisions of this subchapter as might be appropriate for the efficient and cost-effective reimbursement of services provided in such clinics. Grants, payments under contracts, and other expenditures made for demonstration projects were to be made in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. The Secretary was to submit to the Congress, no later than Jan. 1, 1981, a complete detailed report on the demonstration projects.

SCOPE OF GRANTS FOR EXPERIMENTS AND DEMONSTRATION PROJECTS TO DETERMINE METHODS FOR PROSPECTIVE PAYMENTS TO HOSPITALS, SKILLED NURSING FACILITIES, AND OTHER PROVIDERS OF SERVICES

Pub. L. 94–182, title I, §107, Dec. 31, 1975, 89 Stat. 1053, provided that: “Nothing contained in section 222(a) of...”
Public Law 92–603 [set out below] shall be construed to preclude or prohibit the Secretary of Health, Education, and Welfare [now Health and Human Services] from including in any grant otherwise authorized to be made under such section moneys which are to be used for payments, to a participant in a demonstration or experiment with respect to which the grant is made, for or on account of costs incurred or services performed by such participant for a period prior to the date that the project of such participant is placed in operation, if—

‘‘(1) the applicant for such grant is a State or an agency thereof,

‘‘(2) such participant is an individual practice association which has been in existence for at least 3 years prior to the date of enactment of this section [Dec. 31, 1975] and which has in effect a contract with such State (or an agency thereof), entered into prior to the date on which such grant is approved by the Secretary, under which such association will, for a period which begins before and ends after the date such grant is so approved, provide health care services for individuals entitled to care and services under the State plan of such State which is approved under title XIX of the Social Security Act [subchapter XIX of this chapter],

‘‘(3) the purpose of the inclusion of the project of such association is to test the utility of a particular rate-setting methodology, designed to be employed in prepaid health plans, in an individual practice association operation, and

‘‘(4) the applicant for such grant affirms that the use of moneys from such grant to make such payments to such individual practice association is necessary or useful in assuring that such association will be able to continue in operation and carry out the project described in clause (3).’’

EXPERIMENTS AND DEMONSTRATION PROJECTS TO DETERMINE METHODS FOR PROSPECTIVE PAYMENTS TO HOSPITALS, SKILLED NURSING FACILITIES, AND OTHER PROVIDERS OF SERVICES FOR CARE AND SERVICES FURNISHED; SCOPE; WAIVER OF PAYMENT REQUIREMENTS; SOURCE AND MANNER OF PAYMENTS FOR GRANTS, PAYMENTS UNDER CONTRACTS, REPORTS TO CONGRESS


‘‘(1) the Secretary of Health, Education, and Welfare [now Health and Human Services], directly or through contracts with, or grants to, public or private agencies or organizations, shall develop and carry out experiments and demonstration projects designed to determine the relative advantages and disadvantages of various alternative methods of making payment on a prospective basis to hospitals, skilled nursing facilities, and other providers of services for care and services provided under title XIX of the Social Security Act [this subchapter] and under State plans approved under title XIX of such Act [subchapter XIX of this chapter], including alternative methods for classifying providers, for establishing prospective rates of payment, and for implementing on a gradual, selective, or other basis the establishment of a prospective payment system, in order to stimulate such providers through positive (or negative) financial incentives to use their facilities and personnel more efficiently and thereby to reduce the total costs of the health programs involved without adversely affecting the quality of services by containing or lowering the rate of increase in provider costs that has been and is being experienced under the existing system of retrospective cost reimbursement.

‘‘(2) The experiments and demonstration projects developed under paragraph (1) shall be of sufficient scope and shall be carried out on a wide enough scale to permit a thorough evaluation of the alternative methods of prospective payment under consideration while giving assurance that the results derived from the experiments and projects will obtain generally in the operation of the programs involved (without committing such programs to the adoption of any prospective payment system either locally or nationally).

‘‘(3) In the case of any experiment or demonstration project under paragraph (1), the Secretary may waive compliance with the requirements of titles XVIII and XIX of the Social Security Act (this subchapter and subchapter XIX of this chapter) insofar as such requirements relate to methods of payment for services provided; and costs incurred in such experiment or project in excess of those which would otherwise be reimbursed or paid under such titles [subchapters] may be reimbursed or paid to the extent that such waiver applies to them (with such excess being borne by the Secretary).

No experiment or demonstration project shall be developed or carried out under paragraph (1) until the Secretary obtains the advice and recommendations of specialists who are competent to evaluate the proposed experiment or project as to the soundness of its objectives, the possibilities of securing productive results, the adequacy of resources to conduct it, and its relationship to other similar experiments or projects already completed or in process; and no such experiment or project shall be actually placed in operation unless at least 30 days prior thereto a written report, prepared for purposes of notification and information only, containing a full and complete description thereof has been transmitted to the Committees on Ways and Means of the House of Representatives and to the Committee on Finance of the Senate.

‘‘(4) Grants, payments under contracts, and other expenditures made for experimental and demonstration projects under this subsection shall be made in appropriate part from the Federal Hospital Insurance Trust Fund (established by section 1817 of the Social Security Act (section 1395f of this title)) and the Federal Supplementary Medical Insurance Trust Fund (established by section 1841 of the Social Security Act (section 1395t of this title)) and from funds appropriated under title XIX of such Act [subsection XIX of this chapter]. Grants and payments under contracts may be made either in advance or by way of reimbursement, as may be determined by the Secretary, and shall be made in such installments and on such conditions as the Secretary finds necessary to carry out the purpose of this subsection. With respect to any such grant, payment, or other expenditure, the amount to be paid from each of such trust funds (and from funds appropriated under such title XIX) shall be determined by the Secretary, giving due regard to the purposes of the experiment or project involved.

‘‘(5) The Secretary shall submit to the Congress no later than July 1, 1974, a full report on the experiments and demonstration projects carried out under this subsection and on the experience of other programs with respect to prospective reimbursement together with any related data and materials which he may consider appropriate. Such report shall include detailed recommendations with respect to the specific methods which could be used in the full implementation of a system of prospective payment to providers of services under the programs involved.’’

§ 1395b–2. Notice of medicare benefits; medicare and medigap information

(a) Notice of medicare benefits

The Secretary shall prepare (in consultation with groups representing the elderly and with health insurers) and provide for distribution of a notice containing—

(1) a clear, simple explanation of the benefits available under this subchapter and the major categories of health care for which benefits are not available under this subchapter,

(2) the limitations on payment (including deductibles and coinsurance amounts) that are imposed under this subchapter, and
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(3) a description of the limited benefits for long-term care services available under this subchapter and generally available under State plans approved under subchapter XIX of this chapter.

Such notice shall be mailed annually to individuals entitled to benefits under part A or part B of this subchapter and when an individual applies for benefits under part A of this subchapter or enrolls under part B of this subchapter.

(b) Medicare and medigap information

The Secretary shall provide information via a toll-free telephone number on the programs under this subchapter. The Secretary shall provide, through the toll-free telephone number 1-800-MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the toll-free number listed for general information and assistance in the annual notice under subsection (a) of this section instead of the listing of numbers of individual contractors.


1994—Pub. L. 103–432 inserted "medicare and medigap information" in section catchline, designated existing provisions as subsec. (a), and added subsec. (b).

EFFECTIVE DATE OF 1997 AMENDMENT

Section 4311(a)(2) of Pub. L. 105–33 provided that: "The amendment made by this subsection [amending this section] shall apply to notices provided on or after January 1, 1998.

EFFECTIVE DATE OF 1994 AMENDMENT


EFFECTIVE DATE

Section 4312 of Pub. L. 103–432 provided that: "The Secretary of Health and Human Services shall first distribute the notice required by the amendment made by subsection (a) [enacting this section] not later than January 31, 1999."

MONITORING ACCURACY


"(A) STUDY.—The Comptroller General of the United States shall conduct a study to monitor the accuracy and consistency of information provided to individuals entitled to benefits under part A [probably means part A of title XVIII of the Social Security Act which is classified to part A 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, through the toll-free telephone number 1-800-MEDICARE, including an assessment of whether the information provided is sufficient to answer questions of such individuals. In conducting the study, the Comptroller General shall examine the education and training of the individuals providing information through such number.

"(B) REPORT.—Not later than 1 year 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 subparagraph (A)."

STATE REGULATORY PROGRAMS

For provisions relating to changes required to conform State regulatory programs to amendments by section 171 of Pub. L. 103–432, see section 171(m) of Pub. L. 103–432, set out as a note under section 1395s of this title.

DEMONSTRATION PROJECTS

Section 4316(b) of Pub. L. 101–508 provided that: "The Secretary of Health and Human Services is authorized to conduct demonstration projects in up to 5 States for the purpose of establishing statewide toll-free telephone numbers for providing information on medicare benefits, medicare supplemental policies available in the State, and benefits under the State medicare program.

NOTICE OF CHANGES UNDER REPEAL OF MEDICARE CATASTROPHIC COVERAGE

(D) other issues deemed appropriate by the Secretary.

The beneficiary assistance program also shall provide such other services as the Secretary deems appropriate to increase beneficiary understanding of, and confidence in, the medicare program and to improve the relationship between beneficiaries and the program.

(d) Educational material

The Secretary, through the Administrator of the Centers for Medicare & Medicaid Services, shall develop appropriate educational materials and other appropriate techniques to assist employees in carrying out this section.

(e) Notice to beneficiaries

The Secretary shall take such steps as are necessary to assure that medicare-eligible beneficiaries and the general public are made aware of the beneficiary assistance program.

(f) Report

The Secretary shall include, in an annual report transmitted to the Congress, a report on the beneficiary assistance program and on other health insurance informational and counseling services made available to medicare-eligible individuals. The Secretary shall include in the report recommendations for such changes as may be desirable to improve the relationship between the medicare program and medicare-eligible individuals.


CODIFICATION

Section was enacted as part of the Omnibus Budget Reconciliation Act of 1990, and not as part of the Social Security Act which comprises this chapter.

AMENDMENTS


MEDICARE ENROLLMENT ASSISTANCE


“(a) ADDITIONAL FUNDING FOR STATE HEALTH INSURANCE ASSISTANCE PROGRAMS.—

“(1) GRANTS.—

“(A) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall use amounts made available under subparagraph (B) to make grants to States for State health insurance assistance programs receiving assistance under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (42 U.S.C. 1395i–4).

“(B) FUNDING.—For purposes of making grants under this subsection, 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) and the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395i), in the same proportion as the Secretary determines under section 1833(f) of such Act (42 U.S.C. 1395w–23(f)), to the Centers for Medicare & Medicaid Services Program Management Account—

“(i) for fiscal year 2009, of $7,500,000; and

“(ii) for the period of fiscal years 2010 through 2012, of $15,000,000.
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Amounts appropriated under this subparagraph shall remain available until expended.

(2) AMOUNT OF GRANTS.—The amount of a grant to a State under this subparagraph from the total amount made available under paragraph (1) shall be equal to the sum of the amount allocated to the State under paragraph (3)(A) and the amount allocated to the State under subparagraph (3)(B).

(3) ALLOCATION TO STATES.—

(A) ALLOCATION BASED ON PERCENTAGE OF LOW-INCOME BENEFICIARIES.—The amount allocated to a State under this subparagraph from the total amount made available under paragraph (1) shall be based on the number of individuals who meet the requirement under subsection (a)(3)(A)(i) of section 1860D–14 of the Social Security Act (42 U.S.C. 1395w–114) but who have not enrolled to receive a subsidy under such section 1860D–14 relative to the total number of individuals who meet the requirement under such subsection (a)(3)(A)(i) in each State, as estimated by the Secretary.

(B) ALLOCATION BASED ON PERCENTAGE OF RURAL BENEFICIARIES.—The amount allocated to a State under this subparagraph from 1⁄3 of the total amount made available under paragraph (1) shall be based on the number of part D eligible individuals (as defined in section 1860D–3(a)(3)(A) of such Act (42 U.S.C. 1395w–114)) residing in a rural area relative to the total number of such individuals in each State, as estimated by the Secretary.

(4) PORTION OF GRANT BASED ON PERCENTAGE OF LOW-INCOME BENEFICIARIES TO BE USED TO PROVIDE OUTREACH TO INDIVIDUALS WHO MAY BE SUBSIDY ELIGIBLE INDIVIDUALS OR ELIGIBLE FOR THE MEDICARE SAVINGS PROGRAM.—Each grant awarded under this subsection with respect to amounts allocated under paragraph (3)(A) shall be used to provide outreach to individuals who may be subsidy eligible individuals (as defined in section 1860D–1(a)(3)(A) of such Act) for the Medicare Savings Program (as defined in section 1860D–14(a)(3)(A) of the Social Security Act (42 U.S.C. 1395w–114)) or eligible for the Medicare Savings Program (as defined in subsection (f)).

(4) ADDITIONAL FUNDING FOR AREA AGENCIES ON AGING.—

(A) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Aging, shall make grants to States for area agencies on aging (as defined in section 102 of the Older Americans Act of 1965 (42 U.S.C. 3002)) and Native American tribes and Native American programs (as defined in section 102 of the Older Americans Act of 1965 (42 U.S.C. 3001 et seq.)).

(B) FUNDING.—For purposes of making grants under this subsection, 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) and the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395z–1) in the same proportion as the Secretary determines under section 1853(f) of such Act (42 U.S.C. 1395w–21(f)) to the Administration on Aging—

(1) for fiscal year 2009, of $7,500,000; and

(2) for the period of fiscal years 2010 through 2012, of $15,000,000.

Amounts appropriated under this subparagraph shall remain available until expended.

(2) AMOUNT OF GRANT AND ALLOCATION TO STATES BASED ON PERCENTAGE OF LOW-INCOME AND RURAL BENEFICIARIES.—The amount of a grant to a State under this subsection from the total amount made available under paragraph (1) shall be determined in the same manner as the amount of a grant to a State under subsection (a), from the total amount made available under paragraph (1) of such subsection, determined under paragraphs (2) and subparagraphs (A) and (B) of paragraph (3) of such subsection.

(3) REQUIRED USE OF FUNDS.—(A) ALL FUNDS.—Subject to subparagraph (B), each grant awarded under this subsection shall be used to provide outreach to eligible Medicare beneficiaries regarding the benefits available under title XVIII of the Social Security Act (this subchapter).

(B) OUTREACH TO INDIVIDUALS WHO MAY BE SUBSIDY ELIGIBLE INDIVIDUALS OR ELIGIBLE FOR THE MEDICARE SAVINGS PROGRAM.—Subsection (a)(4) shall apply to each grant awarded under this subsection in the same manner as it applies to a grant under subsection (a).

(c) ADDITIONAL FUNDING FOR AGING AND DISABILITY RESOURCE CENTERS.—

(A) IN GENERAL.—The Secretary shall make grants to Aging and Disability Resource Centers under the Aging and Disability Resource Center grant program that are established centers under such program on the date of the enactment of this Act (July 15, 2008).

(B) FUNDING.—For purposes of making grants under this subsection, 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) and the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395z–1), in the same proportion as the Secretary determines under section 1853(f) of such Act (42 U.S.C. 1395w–21(f)), to the Administration on Aging—

(1) for fiscal year 2009, of $5,000,000; and

(2) for the period of fiscal years 2010 through 2012, of $10,000,000.

Amounts appropriated under this subparagraph shall remain available until expended.

(2) REQUIRED USE OF FUNDS.—(A) Each grant awarded under this subsection shall be used to provide outreach to individuals regarding the benefits available under the Medicare prescription drug benefit under part D of title XVIII of the Social Security Act [part D of this subchapter] and under the Medicare Savings Program.

(B) COORDINATION OF EFFORTS TO INFORM OLDER AMERICANS ABOUT BENEFITS AVAILABLE UNDER FEDERAL AND STATE PROGRAMS.—

(1) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Aging, in cooperation with related Federal agency partners, shall make a grant to, or enter into a contract with, a qualified, experienced entity under which the entity shall—

(A) maintain and update web-based decision support tools, and integrated, person-centered systems, designed to inform older individuals (as defined in section 102 of the Older Americans Act of 1965 (42 U.S.C. 3002)) about the full range of benefits for which the individuals may be eligible under Federal and State programs;

(B) utilize cost-effective strategies to find older individuals with the greatest economic need (as defined in such section 102) and inform the individuals with the greatest economic need and informing the individuals of the programs; and

(D) provide, in collaboration with related Federal agency partners administering the Federal programs, training and technical assistance on the most effective outreach, screening, and follow-up strategies for the Federal and State programs.

(2) FUNDING.—For purposes of making a grant or entering into a contract under paragraph (1), 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) and the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395z–1) in the same proportion as the Secretary determines under section 1853(f) of such Act (42 U.S.C. 1395w–21(f)) to the Administration on Aging—

(1) for fiscal year 2009, of $5,000,000; and
“(1) for the period of fiscal years 2010 through 2012, of $5,000,000. Amounts appropriated under this subparagraph shall remain available until expended.

“(e) REPROGRAMMING FUNDS FROM MEDICARE, MEDICAID, AND SCHIP EXTENSION ACT OF 2007.—The Secretary shall only use the $5,000,000 in funds allocated to make grants to States for Area Agencies on Aging and Aging Disability and Resource Centers for the period of fiscal years 2008 through 2009 under section 118 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Pub. L. 109–171) (121 Stat. 2508) for the sole purpose of providing outreach to individuals regarding the benefits available under the Medicare prescription drug benefit under part D of title XVIII of the Social Security Act (part D of this subchapter). The Secretary shall re-publish the request for proposals issued on April 17, 2008, in order to comply with the preceding sentence.

“(D) MEDICARE SAVINGS PROGRAM DEFINED.—For purposes of this section, the term ‘Medicare Savings Program’ means the program of medical assistance for payment of the cost of medicare cost-sharing under the Medicare program pursuant to sections 1922(a)(10)(E) and 1933 of the Social Security Act (42 U.S.C. 1396a(a)(10)(E), 1396u–3).

“(g) SECRETARIAL AUTHORITY TO ENLIST SUPPORT IN CONDUCTING CERTAIN OUTREACH ACTIVITIES.—The Secretary may request that an entity awarded a grant under this section support the conduct of outreach activities aimed at preventing disease and promoting wellness. Notwithstanding any other provision of this section, an entity may use a grant awarded under this subsection (probably should be “section”) to support the conduct of activities described in the preceding sentence.

Beneficiary Outreach Demonstration Program


“(a) IN GENERAL.—The Secretary of Health and Human Services shall establish a demonstration program in (in this section referred to as the ‘demonstration program’) under which medicare specialists employed by the Department of Health and Human Services shall establish a demonstration program (in this section referred to as the ‘demonstration program’). In conducting the demonstration program in rural areas to participate in the demonstration program.

“(2) Assistance for rural beneficiaries.—The Secretary shall provide for the selection of at least 2 rural areas to participate in the demonstration program. In conducting the demonstration program in such rural areas, the Secretary shall provide for medicare specialists to travel among local offices in such rural areas, the Secretary shall provide for medicare specialists to travel among local offices in a rural area on a scheduled basis.

“(c) Duration.—The demonstration program shall be conducted over a 3-year period.

“(d) Evaluation and report.—

“(1) Evaluation.—The Secretary shall provide for an evaluation of the demonstration program. Such evaluation shall include an analysis of—

“(A) utilization of, and satisfaction of those individuals referred to in subsection (a) with the assistance provided under the program; and

“(B) the cost-effectiveness of providing beneficiary assistance through out-stationing medicare specialists at local offices of the Social Security Administration.

“(2) Report.—The Secretary shall submit to Congress a report on such evaluation and shall include in such report recommendations regarding the feasibility of permanently out-stationing medicare specialists at local offices of the Social Security Administration.”

QUALIFIED MEDICARE BENEFICIARY OUTREACH

Pub. L. 103–432, title I, §154, Oct. 31, 1994, 108 Stat. 4637, 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 establish and implement a method for obtaining information from newly eligible medicare beneficiaries that may be used to determine whether such beneficiaries may be eligible for medical assistance for medicare cost-sharing under State medicaid plans as qualified medicare beneficiaries, and for transmitting such information to the State in which such a beneficiary resides.’’

§1395b–4. Health insurance information, counseling, and assistance grants

(a) Grants

The Secretary of Health and Human Services (in this section referred to as the ‘‘Secretary’’) shall make grants to States with approved State regulatory programs under section 1395ss of this title, that submit applications to the Secretary that meet the requirements of this section for the purpose of providing information, counseling, and assistance relating to the procurement of adequate and appropriate health insurance coverage to individuals who are eligible to receive benefits under this subchapter (in this section referred to as ‘‘eligible individuals’’). The Secretary shall prescribe regulations to establish a minimum level of funding for a grant issued under this section.

(b) Grant applications

(1) In submitting an application under this section, a State may consolidate and coordinate an application that consists of parts prepared by more than one agency or department of such State.

(2) As part of an application for a grant under this section, a State shall submit an plan for a State-wide health insurance information, counseling, and assistance program. Such program shall—

(A) establish or improve upon a health insurance information, counseling, and assistance program that provides counseling and assistance to eligible individuals in need of health insurance information, including—

(i) information that may assist individuals in obtaining benefits and filing claims under this subchapter and subchapter XIX of this chapter;

(ii) policy comparison information for medicare supplemental policies (as described in section 1395ss(g)(1) of this title) and information that may assist individuals in filing claims under such medicare supplemental policies;

(iii) information regarding long-term care insurance; and

(iv) information regarding other types of health insurance benefits that the Secretary determines to be appropriate;

(B) in conjunction with the health insurance information, counseling, and assistance program described in subparagraph (A), establish a system of referral to appropriate Federal or
State departments or agencies for assistance with problems related to health insurance coverage (including legal problems), as determined by the Secretary;

(C) provide for a sufficient number of staff positions (including volunteer positions) necessary to provide the services of the health insurance information, counseling, and assistance program;

(D) provide assurances that staff members (including volunteer staff members) of the health insurance information, counseling, and assistance program have no conflict of interest in providing the counseling described in subparagraph (A);

(E) provide for the collection and dissemination of timely and accurate health care information to staff members;

(F) provide for training programs for staff members (including volunteer staff members);

(G) provide for the coordination of the exchange of health insurance information between the staff of departments and agencies of the State government and the staff of the health insurance information, counseling, and assistance program;

(H) make recommendations concerning consumer issues and complaints related to the provision of health care to agencies and departments of the State government and the Federal Government responsible for providing or regulating health insurance;

(I) establish an outreach program to provide the health insurance information and counseling described in subparagraph (A) and the referrals described in subparagraph (B) to eligible individuals; and

(J) demonstrate, to the satisfaction of the Secretary, an ability to provide the counseling and assistance required under this section.

(c) Special grants

(1) A State that is conducting a health insurance information, counseling, and assistance program that is substantially similar to a program described in subsection (b)(2) of this section shall, as a requirement for eligibility for a grant under this section, demonstrate, to the satisfaction of the Secretary, that such State shall maintain the activities of such program at least at the level that such activities were conducted immediately preceding the date of the issuance of any grant during the period of time covered by such grant under this section.

(2) If the Secretary determines that the existing health insurance information, counseling, and assistance program is substantially similar to a program described in subsection (b)(2) of this section, the Secretary may waive some or all of the requirements described in such subsection and issue a grant to the State for the purpose of increasing the number of services offered by the health insurance information, counseling, and assistance program, experimenting with new methods of outreach in conducting such program, or expanding such program to geographic areas of the State not previously served by the program.

(d) Criteria for issuing grants

In issuing a grant under this section, the Secretary shall consider—

(1) the commitment of the State to carrying out the health insurance information, counseling, and assistance program described in subsection (b)(2) of this section, including the level of cooperation demonstrated—

(A) by the office of the chief insurance regulator of the State, or the equivalent State entity;

(B) other officials of the State responsible for overseeing insurance plans issued by nonprofit hospital and medical service associations; and

(C) departments and agencies of such State responsible for—

(i) administering funds under subchapter XIX of this chapter, and

(ii) administering funds appropriated under the Older Americans Act [42 U.S.C. 3001 et seq.];

(2) the population of eligible individuals in such State as a percentage of the population of such State; and

(3) in order to ensure the needs of rural areas in such State, the relative costs and special problems associated with addressing the special problems of providing health care information, counseling, and assistance eligible individuals residing in rural areas of such State.

(e) Annual State report

A State that receives a grant under this section shall, not later than 180 days after receiving such grant, and annually thereafter during the period of the grant, issue a report to the Secretary that includes information concerning—

(1) the number of individuals served by the health insurance information, counseling and assistance program of such State;

(2) an estimate of the amount of funds saved by the State, and by eligible individuals in the State, in the implementation of such program; and

(3) the problems that eligible individuals in such State encounter in procuring adequate and appropriate health care coverage.

(f) Report to Congress

Beginning with 1992, and annually thereafter, the Secretary shall issue a report to the Committee on Finance of the Senate, the Special Committee on Aging of the Senate, the Committee on Ways and Means of the House of Representatives, and the Committee on Energy and Commerce of the House of Representatives that—

(1) summarizes the allocation of funds authorized for grants under this section and the expenditure of such funds;

(2) outlines the problems that eligible individuals encounter in procuring adequate and appropriate health care coverage;

(3) makes recommendations that the Secretary determines to be appropriate to address the problems described in paragraph (3); and

(4) in the case of the report issued 2 years after November 5, 1990, evaluates the effectiveness of counseling programs established under

1So in original. Probably should be preceded by “to”.

2So in original. Probably should be paragraph “(2)”.

3So in original. Probably should be preceded by “to”. 
this program, and makes recommendations regarding continued authorization of funds for these purposes.

(g) Authorization of appropriations for grants

There are authorized to be appropriated, in equal parts from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund, $10,000,000 for each of fiscal years 1991, 1992, 1993, 1994, 1995, and 1996, to fund the grant programs described in this section.


REFERENCES IN TEXT


Amendments


1994—Subsec. (b)(2)(A)(xi), (b)(2)(C), inserted closing parenthesis after “of this title”.

Subsec. (b)(2)(D). Pub. L. 103–432, § 171(i)(2), substituted “counseling” for “services” before “described in subparagraph (A)”, “referrals” for “assistance”.

Subsec. (d)(1). Pub. L. 103–432, § 171(i)(4), struck out “eligible individuals residing in rural areas” for “to the rural areas”.

Subsec. (e). Pub. L. 103–432, § 171(i)(6)(A), (B), in introductory provisions, substituted “this section” for “subsections (d) of this section” and “and annually thereafter during the period of the grant, issue a report” for “and annually thereafter, issue an annual report”.


Pub. L. 103–432, § 171(i)(8)(B), and Pub. L. 103–437, § 15(b)(2), made identical amendments, redesignating subsec. (f), relating to authorization of appropriations for grants, as (g).


Subsec. (f)(2) to (5). Pub. L. 103–432, § 171(i)(7), in subsec. (f), relating to report to Congress, redesignated pars. (3) to (5) as (2) to (4), respectively, and struck out former par. (2) which read as follows: “summarizes the scope and content of training conferences convened under this section.”.

Subsec. (g). Pub. L. 103–432, § 171(i)(8)(B), and Pub. L. 103–437, § 15(b)(2), made identical amendments, redesignating subsec. (f), relating to authorization of appropriations for grants, as (g).

Change of Name


Effective Date of 1994 Amendment

Amendment by Pub. L. 103–432 effective as if included in the enactment of Pub. L. 103–442, set out as a note under section 1395ss of this title.

Demonstration To Improve Care To Previously Uninsured


“(a) Establishment.—Within one year after the date of the enactment of this Act (July 15, 2008), the Secretary (in this section referred to as the ‘Secretary’) shall establish a demonstration project to determine the greatest needs and most effective methods of outreach to Medicare beneficiaries who were previously uninsured.

“(b) Scope.—The demonstration shall be in no fewer than 10 sites, and shall include state health insurance assistance programs, community health centers, community-based organizations, community health workers, and other service providers under parts A, B, and C of title XVIII of the Social Security Act [parts A, B, and C of this subchapter]. Grantees that are plans operating under part C shall document that enrollees who were previously uninsured receive the ‘Welcome to Medicare’ physical exam.

“(c) Duration.—The Secretary shall conduct the demonstration project for a period of 2 years.

“(d) Report and Evaluation.—The Secretary shall conduct an evaluation of the demonstration and not later than 1 year after the completion of the project shall submit to Congress a report including the following:

“(1) An analysis of the effectiveness of outreach activities targeting beneficiaries who were previously uninsured, such as revising outreach and enrollment materials (including the potential for use of video information), providing one-on-one counseling, working with community health workers, and amending the Medicare and You handbook;

“(2) The effect of such outreach on beneficiary access to care, utilization of services, efficiency and cost-effectiveness of health care delivery, patient satisfaction, and select health outcomes.”

State Regulatory Programs

For provisions relating to changes required to conform State regulatory programs to amendments by section 171 of Pub. L. 103–432, see section 171(m) of Pub. L. 103–432, set out as a note under section 1395ss of this title.

§ 1395b–5. Beneficiary incentive programs


(b) Program to collect information on fraud and abuse

(1) Establishment of program

Not later than 3 months after August 21, 1996, the Secretary shall establish a program
under which the Secretary shall encourage individuals to report to the Secretary information on individuals and entities who are engaging in or who have engaged in acts or omissions which constitute grounds for the imposition of a sanction under section 1320a-7, 1320a-7a, or 1320a-7b of this title, or who have otherwise engaged in fraud and abuse against the Medicare program under this subchapter for which there is a sanction provided under law. The program shall discourage provision of, and not consider, information which is frivolous or otherwise not relevant or material to the imposition of such a sanction.

(2) Payment of portion of amounts collected

If an individual reports information to the Secretary under the program established under paragraph (1) which serves as the basis for the collection by the Secretary or the Attorney General of any amount of at least $100 (other than any amount paid as a penalty under section 1320a-7b of this title), the Secretary may pay a portion of the amount collected to the individual (under procedures similar to those applicable under section 7623 of the Internal Revenue Code of 1986 to payments to individuals providing information on violations of such Code).

(c) Program to collect information on program efficiency

(1) Establishment of program

Not later than 3 months after August 21, 1996, the Secretary shall establish a program under which the Secretary shall encourage individuals to submit to the Secretary suggestions on methods to improve the efficiency of the Medicare program.

(2) Payment of portion of program savings

If an individual submits a suggestion to the Secretary under the program established under paragraph (1) which is adopted by the Secretary and which results in savings to the program, the Secretary may make a payment to the individual of such amount as the Secretary considers appropriate.

(3) Specific topics to be reviewed

Specifically, the Commission shall review, with respect to the Medicare+Choice program under part C of this subchapter, the following:

(i) The methodology for making payment to plans under such program, including the making of differential payments and the distribution of differential updates among different payment areas.

(ii) The mechanisms used to adjust payments for risk and the need to adjust such mechanisms to take into account health status of beneficiaries.

(iii) The implications of risk selection both among Medicare+Choice organizations and between the Medicare+Choice option and the original Medicare fee-for-service option.

(iv) The development and implementation of mechanisms to assure the quality of care for those enrolled with Medicare+Choice organizations.

(v) The impact of the Medicare+Choice program on access to care for Medicare beneficiaries.

(vi) Other major issues in implementation and further development of the Medicare+Choice program.

1 So in original.
(B) Original medicare fee-for-service system

Specifically, the Commission shall review payment policies under parts A and B of this subchapter, including—

(i) the factors affecting expenditures for the efficient provision of services in different sectors, including the process for updating hospital, skilled nursing facility, physician, and other fees,
(ii) payment methodologies, and
(iii) their relationship to access and quality of care for medicare beneficiaries.

(C) Interaction of medicare payment policies with health care delivery generally

Specifically, the Commission shall review the effect of payment policies under this subchapter on the delivery of health care services other than under this subchapter and assess the implications of changes in health care delivery in the United States and in the general market for health care services on the medicare program.

(3) Comments on certain secretarial reports

If the Secretary submits to Congress (or a committee of Congress) a report that is required by law and that relates to payment policies under this subchapter, the Secretary shall transmit a copy of the report to the Commission. The Commission shall review the report and, not later than 6 months after the date of submittal of the Secretary’s report to Congress, shall submit to the appropriate committees of Congress written comments on such report. Such comments may include such recommendations as the Commission deems appropriate.

(4) Review and comment on the Independent Payment Advisory Board or Secretarial proposal

If the Independent Payment Advisory Board (as established under subsection (a) of section 1395kkk of this title) or the Secretary submits a proposal to the Commission under such section in a year, the Commission shall review the proposal and, not later than March 1 of that year, submit to the appropriate committees of Congress written comments on such proposal. Such comments may include such recommendations as the Commission deems appropriate.

(5) Agenda and additional reviews

The Commission shall consult periodically with the chairmen and ranking minority members of the appropriate committees of Congress regarding the Commission’s agenda and progress towards achieving the agenda. The Commission may conduct additional reviews, and submit additional reports to the appropriate committees of Congress, from time to time on such topics relating to the program under this subchapter as may be requested by such chairmen and members and as the Commission deems appropriate.

(6) Availability of reports

The Commission shall transmit to the Secretary a copy of each report submitted under this subsection and shall make such reports available to the public.

(7) Appropriate committees of Congress

For purposes of this section, the term “appropriate committees of Congress” means the Committees on Ways and Means and Commerce of the House of Representatives and the Committee on Finance of the Senate.

(8) Voting and reporting requirements

With respect to each recommendation contained in a report submitted under paragraph (1), each member of the Commission shall vote on the recommendation, and the Commission shall include, by member, the results of that vote in the report containing the recommendation.

(9) Examination of budget consequences

Before making any recommendations, the Commission shall examine the budget consequences of such recommendations, directly or through consultation with appropriate expert entities.

(9) Review and annual report on Medicaid and commercial trends

The Commission shall review and report on aggregate trends in spending, utilization, and financial performance under the medicare program under subchapter XIX and the private market for health care services with respect to providers for which, on an aggregate national basis, a significant portion of revenue or services is associated with the medicare program. Where appropriate, the Commission shall conduct such review in consultation with the Medicaid and CHIP Payment and Access Commission established under section 1396 of this title (in this section referred to as “MACPAC”).

(10) Coordinate and consult with the Federal Coordinated Health Care Office

The Commission shall coordinate and consult with the Federal Coordinated Health Care Office established under section 2081 of the Patient Protection and Affordable Care Act before making any recommendations regarding payment policies subject to the dual eligible individual.

(11) Interaction of Medicaid and Medicare

The Commission shall consult with MACPAC in carrying out its duties under this section, as appropriate. Responsibility for analysis of and recommendations to change medicare policy regarding medicare beneficiaries, including medicare beneficiaries who are dually eligible for medicare and medicaid, shall rest with the Commission. Responsibility for analysis of and recommendations to change medicare policy regarding medicaid beneficiaries, including medicaid beneficiaries who are dually eligible for medicare and medicaid, shall rest with MACPAC.

(e) Membership

(1) Number and appointment

The Commission shall be composed of 17 members appointed by the Comptroller General.

<sup>3</sup> So in original. Two pars. (9) have been enacted.

<sup>4</sup> See References in Text note below.
§ 1395b–6

TITLE 42—THE PUBLIC HEALTH AND WELFARE

(2) Qualifications

(A) In general

The membership of the Commission 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.

(B) Inclusion

The membership of the Commission 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.

(C) 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 membership of the Commission.

(D) Ethical disclosure

The Comptroller General shall establish a system for public disclosure by members of the Commission of financial and other potential conflicts of interest relating to such members. Members of the Commission shall be treated as employees of Congress for purposes of applying title I of the Ethics in Government Act of 1978 (Public Law 95–521).

(3) Terms

(A) In general

The terms of members of the Commission shall be for 3 years except that the Comptroller General shall designate staggered terms for the members first appointed.

(B) Vacancies

Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office. A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

(4) Compensation

While serving on the business of the Commission (including traveltime), a member of the Commission shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Sched-

ule under section 5315 of title 5; and while so serving away from home and the member's regular place of business, a member may be allowed travel expenses, as authorized by the Chairman of the Commission. Physicians serving as personnel of the Commission may be provided a physician comparability allowance by the Commission in the same manner as Government physicians may be provided such an allowance by an agency under section 5948 of title 5, and for such purpose subsection (i) of such section shall apply to the Commission in the same manner as it applies to the Tennessee Valley Authority. 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.

(5) Chairman; Vice Chairman

The Comptroller General shall designate a member of the Commission, at the time of appointment of the member as Chairman and a member as Vice Chairman for that term of appointment, except that in the case of vacancy of the Chairmanship or Vice Chairmanship, the Comptroller General may designate another member for the remainder of that member's term.

(6) Meetings

The Commission shall meet at the call of the Chairman.

(d) Director and staff; experts and consultants

Subject to such review as the Comptroller General deems necessary to assure the efficient administration of the Commission, the Commission may—

(1) employ and fix the compensation of an Executive Director (subject to the approval of the Comptroller General) and such other personnel as may be necessary to carry out its duties (without regard to the provisions of title 5 governing appointments in the competitive service); (2) seek such assistance and support as may be required in the performance of its duties from appropriate Federal departments and agencies;

(3) enter into contracts or make other arrangements, as may be necessary for the conduct of the work of the Commission (without regard to section 6101 of title 41); (4) make advance, progress, and other payments which relate to the work of the Commission; (5) provide transportation and subsistence for persons serving without compensation; and (6) prescribe such rules and regulations as it deems necessary with respect to the internal organization and operation of the Commission.

(e) Powers

(1) Obtaining official data

The Commission 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 Chairman, the head of that department or agency shall furnish that information to the Commission on an agreed upon schedule.
(2) Data collection
In order to carry out its functions, the Commission shall—
(A) utilize existing information, both published and unpublished, where possible, collected and assessed either by its own staff or under other arrangements made in accordance with this section; and
(B) carry out, or award grants or contracts for, original research and experimentation, where existing information is inadequate, and
(C) adopt procedures allowing any interested party to submit information for the Commission’s use in making reports and recommendations.

(3) Access of GAO to information
The Comptroller General shall have unrestricted access to all deliberations, records, and nonproprietary data of the Commission, immediately upon request.

(4) Periodic audit
The Commission shall be subject to periodic audit by the Comptroller General.

(f) Authorization of appropriations

(1) Request for appropriations
The Commission shall submit requests for appropriations in the same manner as the Comptroller General submits requests for appropriations, but amounts appropriated for the Commission shall be separate from amounts appropriated for the Comptroller General.

(2) Authorization
There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this section. Sixty percent of such appropriation shall be payable from the Federal Hospital Insurance Trust Fund, and 40 percent of such appropriation shall be payable from the Federal Supplementary Medical Insurance Trust Fund.


2000—Subsec. (b)(1)(D). Pub. L. 106–554, §1(a)(6) [title V, §544(a)(1)], substituted “June 15 of each year,” for “June 1 of each year (beginning with 1998),”.


References in Text
Parts A, B, and C of this subchapter, referred to in subsec. (b)(2), (B), are classified to sections 1395c et seq., 1395 et seq., and 1395w–21 et seq., respectively, of this title.
paragraph (1) [amending this section] shall take effect on January 1, 2004.”

**Effective Date of 2000 Amendment**


**Effective Date of 1999 Amendment**

Amendment by Pub. L. 106–113 effective in determining conversion factor under section 1395w–4(d) of this title for years beginning with 2001 and not applicable to or affecting any update (or any update adjustment factor) for any year before 2001, see section 1000(a)(6) [title II, §211(d)] of Pub. L. 106–113, set out as a note under section 1395w–4 of this title.

**Effective Date; Transition; Transfer of Functions**

Section 4022(c) of Pub. L. 105–33 provided that:

“(1) IN GENERAL.—The Comptroller General shall first provide for appointment of members to the Medicare Payment Advisory Commission (in this subsection referred to as ‘MedPAC’) by not later than September 30, 1997.

“(2) TRANSITION.—As quickly as possible after the date a majority of members of MedPAC are first appointed [Oct. 1, 1997, see 62 FR 52313], the Comptroller General, in consultation with the Prospective Payment Assessment Commission (in this subsection referred to as ‘ProPAC’) and the Physician Payment Review Commission (in this subsection referred to as ‘PPRC’), shall provide for the termination of the ProPAC and the PPRC. As of the date of termination of the respective Commissions [Nov. 1, 1997, see 62 FR 59556], the amendments made by paragraphs (1) and (2), respectively, of subsection (b) [amending sections 1395w–4, 1395y, and 1395ww of this title and repealing section 1395w–1 of this title] become effective. The Comptroller General, to the extent feasible, shall provide for the transfer to the MedPAC of assets and staff of the ProPAC and the PPRC, without any loss of benefits or seniority by virtue of such transfers. Fund balances available to the ProPAC or the PPRC for any period shall be available to the MedPAC for such period for like purposes.

“(3) CONTINUING RESPONSIBILITY FOR REPORTS.—The MedPAC shall be responsible for the preparation and submission of reports required by law to be submitted (and which have not been submitted by the date of establishment of the MedPAC) by the ProPAC and the PPRC. As of the date of termination of the MedPAC, the MedPAC shall, and, for this purpose, any reference in law to either such Commission is deemed, after the appointment of the MedPAC, to refer to the MedPAC.”

**Appointment of Experts in Prescription Drugs**

Pub. L. 108–173, title VII, §735(e)(2), Dec. 8, 2003, 117 Stat. 2354, provided that: “The Comptroller General of the United States shall ensure that the membership of the Commission [Medicare Payment Advisory Commission] complies with the amendment made by paragraph (1) [amending this section] with respect to appointments made on or after the date of the enactment of this Act [Dec. 8, 2000].”

**MedPAC Analysis of Impact of Volume on Per Unit Cost of Rural Hospitals With Psychiatric Units**


“(1) in such study an analysis of the impact of volume on the per unit cost of rural hospitals with psychiatric units; and

“(2) in its report under subsection (b) of such section a recommendation on whether special treatment for such hospitals may be warranted.”

**MedPAC Study on Complexity of Medicare Program and Levels of Burdens Placed on Providers Through Federal Regulation**


“(1) STUDY.—The Medicare Payment Advisory Commission shall undertake a comprehensive study to review the regulatory burdens placed on all classes of health care providers under parts A and B of the Medicare program under title XVIII of the Social Security Act [this subchapter] and to determine the costs these burdens impose on the nation’s health care system. The study shall also examine the complexity of the current regulatory system and its impact on providers.

“(2) REPORT.—Not later than December 31, 2001, the Commission shall submit to Congress one or more reports on the study conducted under paragraph (1). The report shall include recommendations regarding—

“(A) how the Health Care Financing Administration can reduce the regulatory burdens placed on patients and providers; and

“(B) legislation that may be appropriate to reduce the complexity of the Medicare program, including improvement of the rules regarding billing, compliance, and fraud and abuse.”

**MedPAC Report**

Pub. L. 106–113, div. B, §1000(a)(6) [title III, §312(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A–365, provided that: “The Medicare Payment Advisory Commission shall include in its report submitted to Congress in March of 2001 recommendations regarding the appropriateness of the initial residency period used under section 1886(h)(5)(F) of the Social Security Act (42 U.S.C. 1395vv(h)(5)(F)) for other residency training programs in a specialty that require preliminary years of study in another specialty.”

**MedPAC Study of Rural Providers**


“(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study of rural providers furnishing items and services for which payment is made under title XVIII of the Social Security Act [this subchapter]. Such study shall examine and evaluate the adequacy and appropriateness of the categories of special payments (and payment methodologies) established for rural hospitals under the Medicare program, and the impact of such categories on beneficiary access and quality of health care services.

“(b) REPORT.—Not later than 18 months after the date of the enactment of this Act (Nov. 29, 1999), the Medicare Payment Advisory Commission shall submit to Congress a report on the study conducted under subsection (a).”

**Quality Improvement Standards**

Pub. L. 106–113, div. B, §1000(a)(6) [title V, §520(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A–386, provided that:

“(1) STUDY.—The Medicare Payment Advisory Commission shall conduct a study on the appropriate quality improvement standards that should apply to—

“(A) each type of Medicare+Choice plan described in section 1811(a)(2) of the Social Security Act (42 U.S.C. 1395w–21(a)(2)), including each type of Medicare+Choice plan that is a coordinated care plan (as described in subparagraph (A) of such section); and

“(B) the original Medicare fee-for-service program under parts A and B [sic] title XVIII of such Act (42 U.S.C. 1395 et seq.) [parts A and B of this subchapter].

“(2) CONSIDERATIONS.—Such study shall specifically examine the effects, costs, and feasibility of requiring entities, physicians, and other health care providers
that provide items and services under the original medicare fee-for-service program to comply with quality standards and related reporting requirements that are comparable to the quality standards and related reporting requirements that are applicable to Medicare+Choice organizations.

(3) REPORT.—Not later than 2 years after the date of the enactment of this Act [Nov. 29, 1999], such Commission shall submit a report to Congress on the study conducted under this subsection, together with any recommendations for legislation that it determines to be appropriate as a result of such study.’’

INITIAL TERMS OF ADDITIONAL MEMBERS


‘‘(1) IN GENERAL.—For purposes of staggering the initial terms of members of the Medicare Payment Advisory Commission (under section 1805(c)(3) of such Act [42 U.S.C. 1395b–6(c)(3)(B)], the initial terms of the two additional members of the Commission provided for by the amendment under subsection (a) [amending this section] are as follows:

‘‘(A) One member shall be appointed for one year.

‘‘(B) One member shall be appointed for two years.

‘‘(2) COMMENCEMENT OF TERMS.—Such terms shall begin on May 1, 1999.’’

INFORMATION INCLUDED IN ANNUAL RECOMMENDATIONS

Section 4804(c) of Pub. L. 105–33 provided that: ‘‘The Medicare Payment Advisory Commission shall include in its annual report under section 1805(b)(1)(B) of the Social Security Act [subsecs. (b)(1)(B) of this section] recommendations on the methodology and level of payments made to PACE providers under sections 1894(d) and 1894(d) of such Act [sections 1395k–4(d)(1) and 1396u–4(d) of this title] and on the treatment of private, for-profit entities as PACE providers.’’

§ 1395b–7. Explanation of medicare benefits

(a) In general

The Secretary shall furnish to each individual for whom payment has been made under this subchapter (or would be made without regard to any deductible) a statement which—

(1) lists the item or service for which payment has been made and the amount of such payment for each item or service; and

(2) includes a notice of the individual’s right to request an itemized statement (as provided in subsection (b) of this section).

(b) Request for itemized statement for medicare items and services

(1) In general

An individual may submit a written request to any physician, provider, supplier, or any other person (including an organization, agency, or other entity) for an itemized statement for any item or service provided to such individual by such person with respect to which payment has been made under this subchapter.

(2) 30-day period to furnish statement

(A) In general

Not later than 30 days after the date on which a request under paragraph (1) has been made, a person described in such paragraph shall furnish an itemized statement describing each item or service provided to the individual requesting the itemized statement.

(B) Penalty

Whoever knowingly fails to furnish an itemized statement in accordance with sub-paragraph (A) shall be subject to a civil money penalty of not more than $100 for each such failure. Such penalty 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.

(3) Review of itemized statement

(A) In general

Not later than 90 days after the receipt of an itemized statement furnished under paragraph (1), an individual may submit a written request for a review of the itemized statement to the Secretary.

(B) Specific allegations

A request for a review of the itemized statement shall identify—

(1) specific items or services that the individual believes were not provided as claimed, or

(ii) any other billing irregularity (including duplicate billing).

(4) Findings of Secretary

The Secretary shall, with respect to each written request submitted under paragraph (3), determine whether the itemized statement identifies specific items or services that were not provided as claimed or any other billing irregularity (including duplicate billing) that has resulted in unnecessary payments under this subchapter.

(5) Recovery of amounts

The Secretary shall take all appropriate measures to recover amounts unnecessarily paid under this subchapter with respect to a statement described in paragraph (4).


EFFECTIVE DATE

Section 4311(b)(3) of Pub. L. 105–33 provided that:

‘‘(A) STATEMENT BY SECRETARY.—Paragraph (1) of section 1806(a) of the Social Security Act [subsec. (a)(1) of this section], as added by paragraph (1), and the repeal made by paragraph (2) [amending section 1395b–5 of this title] shall take effect on the date of the enactment of this Act [Aug. 5, 1997].

‘‘(B) ITEMIZED STATEMENT.—Paragraph (2) of section 1806(a) and section 1806(b) of the Social Security Act [subsecs. (a)(2) and (b) of this section], as so added, shall take effect not later than January 1, 1999.’’

INCLUSION OF ADDITIONAL INFORMATION IN NOTICES TO BENEFICIARIES ABOUT SKILLED NURSING FACILITY BENEFITS


‘‘(a) IN GENERAL.—The Secretary [of Health and Human Services] shall provide that in medicare beneficiary notices provided (under section 1866(a) of the Social Security Act, 42 U.S.C. 1395l–7(a)) with respect to the provision of post-hospital extended care services under part A of title XVIII of the Social Security Act [part A of this subchapter], there shall be included information on the number of days of coverage of such services remaining under such part for the medicare beneficiary and spell of illness involved.

‘‘(b) EFFECTIVE DATE.—Subsection (a) shall apply to notices provided during calendar quarters beginning more than 6 months after the date of the enactment of this Act [Dec. 8, 2003].’’
§ 1395b–8. Chronic care improvement

(a) Implementation of chronic care improvement programs

(1) In general

The Secretary shall provide for the phased-in development, testing, evaluation, and implementation of chronic care improvement programs in accordance with this section. Each such program shall be designed to improve clinical quality and beneficiary satisfaction and achieve spending targets with respect to expenditures under this subchapter for targeted beneficiaries with one or more threshold conditions.

(2) Definitions

For purposes of this section:

(A) Chronic care improvement program

The term “chronic care improvement program” means a program described in paragraph (1) that is offered under an agreement under subsection (b) or (c) of this section.

(B) Chronic care improvement organization

The term “chronic care improvement organization” means an entity that has entered into an agreement under subsection (b) or (c) of this section to provide, directly or through contracts with subcontractors, a chronic care improvement program under this section. Such an entity may be a disease management organization, health insurer, integrated delivery system, physician group practice, a consortium of such entities, or any other legal entity that the Secretary determines appropriate to carry out a chronic care improvement program under this section.

(C) Care management plan

The term “care management plan” means a plan established under subsection (d) of this section for a participant in a chronic care improvement program.

(D) Threshold condition

The term “threshold condition” means a chronic condition, such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), or other diseases or conditions, as selected by the Secretary as appropriate for the establishment of a chronic care improvement program.

(E) Targeted beneficiary

The term “targeted beneficiary” means, with respect to a chronic care improvement program, an individual who—

(i) is entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter, but not enrolled in a plan under part C of this subchapter;

(ii) has one or more threshold conditions covered under such program; and

(iii) has been identified under subsection (d)(1) of this section as a potential participant in such program.

(3) Construction

Nothing in this section shall be construed as—

(A) expanding the amount, duration, or scope of benefits under this subchapter;

(B) providing an entitlement to participate in a chronic care improvement program under this section;

(C) providing for any hearing or appeal rights under section 1395ff, 1395oo of this title, or otherwise, with respect to a chronic care improvement program under this section;

(D) providing benefits under a chronic care improvement program for which a claim may be submitted to the Secretary by any provider of services or supplier (as defined in section 1395x(d) of this title).

(b) Developmental phase (Phase I)

(1) In general

In carrying out this section, the Secretary shall enter into agreements consistent with subsection (f) of this section with chronic care improvement organizations for the development, testing, and evaluation of chronic care improvement programs using randomized controlled trials. The first such agreement shall be entered into not later than 12 months after December 8, 2003.

(2) Agreement period

The period of an agreement under this subsection shall be for 3 years.

(3) Minimum participation

(A) In general

The Secretary shall enter into agreements under this subsection in a manner so that chronic care improvement programs offered under this section are offered in geographic areas that, in the aggregate, consist of areas in which at least 10 percent of the aggregate number of Medicare beneficiaries reside.

(B) Medicare beneficiary defined

In this paragraph, the term “Medicare beneficiary” means an individual who is entitled to benefits under part A of this subchapter, enrolled under part B of this subchapter, or both, and who resides in the United States.

(4) Site selection

In selecting geographic areas in which agreements are entered into under this subsection, the Secretary shall ensure that each chronic care improvement program is conducted in a geographic area in which at least 10,000 targeted beneficiaries reside among other individuals entitled to benefits under part A of this subchapter, enrolled under part B of this subchapter, or both, to serve as a control population.

(5) Independent evaluations of Phase I programs

The Secretary shall contract for an independent evaluation of the programs conducted under this subsection. Such evaluation shall be done by a contractor with knowledge of chronic care management programs and demonstrated experience in the evaluation of such programs. Each evaluation shall include an assessment of the following factors of the programs:
(A) Quality improvement measures, such as adherence to evidence-based guidelines and rehospitalization rates.
(B) Beneficiary and provider satisfaction.
(C) Health outcomes.
(D) Financial outcomes, including any cost savings to the program under this subchapter.

c(e) Expanded implementation phase (Phase II)

(1) In general
With respect to chronic care improvement programs conducted under subsection (b) of this section, if the Secretary finds that the results of the independent evaluation conducted under subsection (b)(6) of this section indicate that the conditions specified in paragraph (2) have been met by a program (or components of such program), the Secretary shall enter into agreements consistent with subsection (f) of this section to expand the implementation of the program on a national basis. Such expansion shall begin not earlier than 2 years after the program is implemented under subsection (b) of this section and not later than 6 months after the date of completion of such program.

(2) Conditions for expansion of programs
The conditions specified in this paragraph are, with respect to a chronic care improvement program conducted under subsection (b) of this section for a threshold condition, that the program is expected to—
(A) improve the clinical quality of care;
(B) improve beneficiary satisfaction; and
(C) achieve targets for savings to the program under this subchapter specified by the Secretary in the agreement within a range determined to be appropriate by the Secretary, subject to the application of budget neutrality with respect to the program and not taking into account any payments by the organization under the agreement under the program for risk under subsection (f)(3)(B) of this section.

(3) Independent evaluations of Phase II programs
The Secretary shall carry out evaluations of programs expanded under this subsection as the Secretary determines appropriate. Such evaluations shall be carried out in the similar manner as is provided under subsection (b)(5) of this section.

(d) Identification and enrollment of prospective program participants

(1) Identification of prospective program participants
The Secretary shall establish a method for identifying targeted beneficiaries who may benefit from participation in a chronic care improvement program.

(2) Initial contact by Secretary
The Secretary shall communicate with each targeted beneficiary concerning participation in a chronic care improvement program. Such communication may be made by the Secretary and shall include information on the following:
(A) A description of the advantages to the beneficiary in participating in a program.
(B) Notification that the organization offering a program may contact the beneficiary directly concerning such participation.
(C) Notification that participation in a program is voluntary.
(D) A description of the method for the beneficiary to participate or for declining to participate and the method for obtaining additional information concerning such participation.

(3) Voluntary participation
A targeted beneficiary may participate in a chronic care improvement program on a voluntary basis and may terminate participation at any time.

(e) Chronic care improvement programs

(1) In general
Each chronic care improvement program shall—
(A) have a process to screen each targeted beneficiary for conditions other than threshold conditions, such as impaired cognitive ability and co-morbidities, for the purposes of developing an individualized, goal-oriented care management plan under paragraph (2);
(B) provide each targeted beneficiary participating in the program with such plan; and
(C) carry out such plan and other chronic care improvement activities in accordance with paragraph (3).

(2) Elements of care management plans
A care management plan for a targeted beneficiary shall be developed with the beneficiary and shall, to the extent appropriate, include the following:
(A) A designated point of contact responsible for communications with the beneficiary and for facilitating communications with other health care providers under the plan.
(B) Self-care education for the beneficiary (through approaches such as disease management or medical nutrition therapy) and education for primary caregivers and family members.
(C) Education for physicians and other providers and collaboration to enhance communication of relevant clinical information.
(D) The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment.
(E) The provision of information about hospice care, pain and palliative care, and end-of-life care.

(3) Conduct of programs
In carrying out paragraph (1)(C) with respect to a participant, the chronic care improvement organization shall—
(A) guide the participant in managing the participant’s health (including all co-morbidities, relevant health care services, and pharmaceutical needs) and in performing activities as specified under the elements of the care management plan of the participant;

(B) use decision-support tools such as evidence-based practice guidelines or other criteria as determined by the Secretary; and

(C) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

(4) Additional responsibilities

(A) Outcomes report

Each chronic care improvement organization offering a chronic care improvement program shall monitor and report to the Secretary, in a manner specified by the Secretary, on health care quality, cost, and outcomes.

(B) Additional requirements

Each such organization and program shall comply with such additional requirements as the Secretary may specify.

(5) Accreditation

The Secretary may provide that chronic care improvement programs and chronic care improvement organizations that are accredited by qualified organizations (as defined by the Secretary) may be deemed to meet such requirements under this section as the Secretary may specify.

(f) Terms of agreements

(1) Terms and conditions

(A) In general

An agreement under this section with a chronic care improvement organization shall contain such terms and conditions as the Secretary may specify consistent with this section.

(B) Clinical, quality improvement, and financial requirements

The Secretary may not enter into an agreement with such an organization under this section for the operation of a chronic care improvement program unless—

(i) the program and organization meet the requirements of subsection (e) of this section and such clinical, quality improvement, financial, and other requirements as the Secretary deems to be appropriate for the targeted beneficiaries to be served; and

(ii) the organization demonstrates to the satisfaction of the Secretary that the organization is able to assume financial risk for performance under the agreement (as applied under paragraph (3)(B)) with respect to payments made to the organization under such agreement through available reserves, reinsurance, withholds, or such other means as the Secretary determines appropriate.

(2) Manner of payment

Subject to paragraph (3)(B), the payment under an agreement under—

(A) subsection (b) of this section shall be computed on a per-member per-month basis; or

(B) subsection (c) of this section may be on a per-member per-month basis or such other basis as the Secretary and organization may agree.

(3) Application of performance standards

(A) Specification of performance standards

Each agreement under this section with a chronic care improvement organization shall specify performance standards for each of the factors specified in subsection (c)(2) of this section, including clinical quality and spending targets under this subchapter, against which the performance of the chronic care improvement organization under the agreement is measured.

(B) Adjustment of payment based on performance

(i) In general

Each such agreement shall provide for adjustments in payment rates to an organization under the agreement insofar as the Secretary determines that the organization failed to meet the performance standards specified in the agreement under subparagraph (A).

(ii) Financial risk for performance

In the case of an agreement under subsection (b) or (c) of this section, the agreement shall provide for a full recovery for any amount by which the fees paid to the organization under the agreement exceed the estimated savings to the programs under this subchapter attributable to implementation of such agreements.

(4) Budget neutral payment condition

Under this section, the Secretary shall ensure that the aggregate sum of medicare program benefit expenditures for beneficiaries participating in chronic care improvement programs and funds paid to chronic care improvement organizations under this section, shall not exceed the medicare program benefit expenditures that the Secretary estimates would have been made for such targeted beneficiaries in the absence of such programs.

(g) Funding

(1) Subject to paragraph (2), there are 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 to provide for agreements with chronic care improvement programs under this section.

(2) In no case shall the funding under this section exceed $100,000,000 in aggregate increased expenditures under this subchapter (after taking into account any savings attributable to the operation of this section) over the 3-fiscal-year period beginning on October 1, 2003.


References in Text

Parts A, B, and C of this subchapter, referred to in subsecs. (a)(2)(E)(1) and (b)(3)(B), (4), are classified to
sections 1395c et seq., 1395j et seq., and 1395w–21 et seq., respectively, of this title.

**Demonstration Project for Consumer-Directed Chronic Outpatient Services**


"(a) Establishment.—"

"(1) In general.—Subject to the succeeding provisions of this section, the Secretary [of Health and Human Services] shall establish demonstration projects (in this section referred to as ‘demonstration projects’) under which the Secretary shall evaluate methods that improve the quality of care provided to individuals with chronic conditions and that reduce expenditures that would otherwise be made under the medicare program on behalf of such individuals for such chronic conditions, such methods to include permitting those beneficiaries to direct their own health care needs and services.

"(2) Individuals with chronic conditions defined.—In this section, the term ‘individuals with chronic conditions’ means an individual entitled to benefits under part A of title XVIII of the Social Security Act [part A of this subchapter], and enrolled under part B of such title [part B of this subchapter], but who is not enrolled under part C of such title [part C of this subchapter] who is diagnosed as having one or more chronic conditions (as defined by the Secretary), such as diabetics.

"(b) Design of Projects.—"

"(1) Evaluation before implementation of project.—"

"(A) In general.—In establishing the demonstration projects under this section, the Secretary shall evaluate best practices employed by group health plans and practices under State plans for medical assistance under the medicare program under title XIX of the Social Security Act [subchapter XIX of this chapter], as well as best practices in the private sector or other areas, of methods that permit patients to self-direct the provision of personal care services. The Secretary shall evaluate such practices for a 1-year period and, based on such evaluation, shall design the demonstration project.

"(B) Requirement for estimate of budget neutral costs.—As part of the evaluation under subparagraph (A), the Secretary shall evaluate the costs of furnishing care under the projects. The Secretary may not implement the demonstration projects under this section unless the Secretary determines that the costs of providing care to individuals with chronic conditions under the project will not exceed the costs, in the aggregate, of furnishing care to such individuals under title XVIII of the Social Security Act [this subchapter], that would otherwise be paid with respect to demonstration projects for the period of the project.

"(2) Scope of services.—The Secretary shall determine the appropriate scope of personal care services that would apply under the demonstration projects.

"(c) Voluntary Participation.—Participation of providers of services and suppliers, and of individuals with chronic conditions, in the demonstration projects shall be voluntary.

"(d) Demonstration Projects Sites.—Not later than 2 years after the date of the enactment of this Act [Dec. 8, 2003], the Secretary shall conduct a demonstration project in at least one area that the Secretary determines has a population of individuals entitled to benefits under part A of title XVIII of the Social Security Act [part A of this subchapter], and enrolled under part B of such title [part B of this subchapter], with a rate of incidence of diabetes that significantly exceeds the national average rate of all areas.

"(e) Evaluation and Report.—"

"(1) Evaluations.—The Secretary shall conduct evaluations of the clinical and cost effectiveness of the demonstration projects.

"(2) Reports.—Not later than 2 years after the commencement of the demonstration projects, and biannually thereafter, the Secretary shall submit to Congress a report on the evaluation, and shall include in the report the following:

"(A) An analysis of the patient outcomes and costs of furnishing care to the individuals with chronic conditions participating in the projects as compared to such outcomes and costs to other individuals for the same health conditions.

"(B) Evaluation of patient satisfaction under the demonstration projects.

"(C) Such recommendations regarding the extension, expansion, or termination of the projects as the Secretary determines appropriate.

"(f) Waiver Authority.—The Secretary shall waive compliance with the requirements of title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] to such extent and for such period as the Secretary determines is necessary to conduct demonstration projects.

"(g) Authorization of Appropriations.—(1) 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. 1395cc].

"(2) There are authorized to be appropriated from such Trust Fund such sums as may be necessary for the Secretary to enter into contracts with appropriate organizations for the design [sic], implementation, and evaluation of the demonstration project.

"(3) In no case may expenditures under this section exceed the aggregate expenditures that would otherwise have been made for the provision of personal care services.’’

**Reports**

Pub. L. 108–173, title VII, §721(b), Dec. 8, 2003, 117 Stat. 2346, provided that: "The Secretary [of Health and Human Services] shall submit to Congress 2 additional biennial reports on the chronic care improvement programs conducted under such section. The first such report shall be submitted not later than 2 years after the report is submitted under paragraph (2). Each such report shall include information on—"

"(A) the scope of implementation (in terms of both regions and chronic conditions) of the chronic care improvement programs;

"(B) the design of the programs; and

"(C) the improvements in health outcomes and financial efficiencies that result from such implementation.’’

**Chronically Ill Medicare Beneficiary Research, Data, Demonstration Strategy**

shall develop a plan to improve quality of care and reduce the cost of care for chronically ill Medicare beneficiaries.

“(b) PLAN REQUIREMENTS.—The plan will utilize existing data and identify data gaps, develop research initiatives, and propose intervention demonstration programs to provide better health care for chronically ill Medicare beneficiaries. The plan shall—

“(1) integrate existing data sets including, the Medicare Current Beneficiary Survey (MCBS), Minimum Data Set (MDS), Outcome and Assessment Information Set (OASIS), data from Quality Improvement Organizations (QIO), and claims data;

“(2) identify any new data needs and a methodology to address new data needs;

“(3) plan for the collection of such data in a data warehouse; and

“(4) develop a research agenda using such data.

“(c) CONSULTATION.—In developing the plan under this section, the Secretary shall consult with experts in the fields of care for the chronically ill (including clinicians).

“(d) IMPLEMENTATION.—Not later than 2 years after the date of the enactment of this Act [Dec. 8, 2003], the Secretary shall implement the plan developed under this section. The Secretary may contract with appropriate entities to implement such plan.

“(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary such sums as may be necessary in fiscal years 2004 and 2005 to carry out this section.”

§ 1395b–9. Provisions relating to administration

(a) Coordinated administration of Medicare prescription drug and Medicare Advantage programs

(1) In general

There is within the Centers for Medicare & Medicaid Services a center to carry out the duties described in paragraph (3).

(2) Director

Such center shall be headed by a director who shall report directly to the Administrator of the Centers for Medicare & Medicaid Services.

(3) Duties

The duties described in this paragraph are the following:

(A) The administration of parts C and D of this subchapter.

(B) The provision of notice and information under section 1395b–2 of this title.

(C) Such other duties as the Secretary may specify.

(4) Deadline

The Secretary shall ensure that the center is carrying out the duties described in paragraph (3) by not later than January 1, 2008.

(b) Employment of management staff

(1) In general

The Secretary may employ, within the Centers for Medicare & Medicaid Services, such individuals as management staff as the Secretary determines to be appropriate. With respect to the administration of parts C and D of this subchapter, such individuals shall include individuals with private sector expertise in negotiations with health benefits plans.

(2) Eligibility

To be eligible for employment under paragraph (1) an individual shall be required to have demonstrated, by their education and experience (either in the public or private sector), superior expertise in at least one of the following areas:

(A) The review, negotiation, and administration of health care contracts.

(B) The design of health care benefit plans.

(C) Actuarial sciences.

(D) Compliance with health plan contracts.

(E) Consumer education and decision making.

(F) Any other area specified by the Secretary that requires specialized management or other expertise.

(3) Rates of payment

(A) Performance-related pay

Subject to subparagraph (B), the Secretary shall establish the rate of pay for an individual employed under paragraph (1). Such rate shall take into account expertise, experience, and performance.

(B) Limitation

In no case may the rate of compensation determined under subparagraph (A) exceed the highest rate of basic pay for the Senior Executive Service under section 5332(b) of title 5.

(c) Medicare Beneficiary Ombudsman

(1) In general

The Secretary shall appoint within the Department of Health and Human Services a Medicare Beneficiary Ombudsman who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under this subchapter.

(2) Duties

The Medicare Beneficiary Ombudsman shall—

(A) receive complaints, grievances, and requests for information submitted by individuals entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, with respect to any aspect of the Medicare program;

(B) provide assistance with respect to complaints, grievances, and requests referred to in subparagraph (A), including—

(i) assistance in collecting relevant information for such individuals, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, MA organization, or the Secretary;

(ii) assistance to such individuals with any problems arising from disenrollment from an MA plan under part C of this subchapter; and

(iii) assistance to such individuals in presenting information under section 1395r(i)(4)(C) of this title (relating to income-related premium adjustment); and

(C) submit annual reports to Congress and the Secretary that describe the activities of

1 So in original. A closing parenthesis probably should precede the semicolon.
the Office and that include such recommendations for improvement in the administration of this subchapter as the Ombudsman determines appropriate.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

(3) Working with health insurance counseling programs

To the extent possible, the Ombudsman shall work with health insurance counseling programs (receiving funding under section 1395b–4 of this title) to facilitate the provision of information to individuals entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both regarding MA plans and changes to those plans. Nothing in this paragraph shall preclude further collaboration between the Ombudsman and such programs.


REFERENCES IN TEXT

Parts A, B, C, and D of this subchapter, referred to in text, are classified to sections 1395c et seq., 1395j et seq., 1395w–21 et seq., and 1395w–101 et seq., respectively, of this title.

AMENDMENTS


DEADLINE FOR APPOINTMENT

Pub. L. 108–173, title IX, §§ 923(b), Dec. 8, 2003, 117 Stat. 2394, provided that: “By 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 appoint the Medicare Beneficiary Ombudsman under section 1808(c) of the Social Security Act [subsec. (c) of this section], as added by subsection (a).”

§ 1395b–10. Addressing health care disparities

(a) Evaluating data collection approaches

The Secretary shall evaluate approaches for the collection of data under this subchapter, to be performed in conjunction with existing quality reporting requirements and programs under this subchapter, that allow for the ongoing, accurate, and timely collection and evaluation of data on disparities in health care services and performance on the basis of race, ethnicity, and gender. In conducting such evaluation, the Secretary shall consider the following objectives:

(1) Protecting patient privacy.
(2) Minimizing the administrative burdens of data collection and reporting on providers and health plans participating under this subchapter.
(3) Improving Medicare program data on race, ethnicity, and gender.

(b) Reports to Congress

(1) Report on evaluation

Not later than 18 months after July 15, 2008, the Secretary shall submit to Congress a report on the evaluation conducted under subsection (a). Such report shall, taking into consideration the results of such evaluation—

(A) identify approaches (including defining methodologies) for identifying and collecting and evaluating data on health care disparities on the basis of race, ethnicity, and gender for the original Medicare fee-for-service program under parts A and B, the Medicare Advantage program under part C, and the Medicare prescription drug program under part D;
(B) include recommendations on the most effective strategies and approaches to reporting HEDIS quality measures as required under section 1395w–22(e)(3) of this title and other nationally recognized quality performance measures, as appropriate, on the basis of race, ethnicity, and gender.

(2) Reports on data analyses

Not later than 4 years after July 15, 2008, and 4 years thereafter, the Secretary shall submit to Congress a report that includes recommendations for improving the identification of health care disparities for Medicare beneficiaries based on analyses of the data collected under subsection (c).

(c) Implementing effective approaches

Not later than 24 months after July 15, 2008, the Secretary shall implement the approaches identified in the report submitted under subsection (b) for the ongoing, accurate, and timely collection and evaluation of data on health care disparities on the basis of race, ethnicity, and gender.


REFERENCES IN TEXT

Parts A, B, C, and D, referred to in subsec. (b)(1)(A), are classified to sections 1395c et seq., 1395j et seq., 1395w–21 et seq., and 1395w–101 et seq., respectively, of this title.

PART A—HOSPITAL INSURANCE BENEFITS FOR AGED AND DISABLED

§ 1395c. Description of program

The insurance program for which entitlement is established by sections 426 and 426–1 of this title provides basic protection against the costs of hospital, related post-hospital, home health services, and hospice care in accordance with this part for (1) individuals who are age 65 or over and are eligible for retirement benefits under subchapter II of this chapter (or would be eligible for such benefits if certain government employment were covered employment under such subchapter) or under the railroad retirement system on the basis of a disability, and (3) certain individuals who do not meet the conditions specified in either clause (1) or (2) but who are medically determined to have end stage renal disease.

AMENDMENTS

1989—Pub. L. 101–234 repealed Pub. L. 100–360, §104(d)(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.

1988—Pub. L. 100–360 substituted “inpatient hospital services, extended care services” for “hospital, related post-hospital”.


1984—Pub. L. 97–248, §122(a)(1), substituted “home health services, and hospice care” for “and home health services”.

1982—Pub. L. 97–248, §278(b)(3), inserted “(or would have been entitled to such benefits if certain Federal employment were covered employment under such subchapter)” after “subchapter II of this chapter” in cl. (1), and inserted “(or would have been so entitled to such benefits if certain Federal employment were covered employment under such subchapter)” after “subchapter II of this chapter” in cl. (2).


1979—Pub. L. 96–473 substituted “are entitled for” for “are entitled to”.

1978—Pub. L. 96–355 substituted “not less than 24 months” for “not less than 24 consecutive months”.

1972—Pub. L. 92–603 designated existing provisions as cl. (1) and added cl. (2).

EFFECTIVE DATE OF 1989 AMENDMENT

Section 101(d) of Pub. L. 101–234 provides that: “The provisions of this section amending this section and sections 1395d, 1395e, 1395f, 1395k, 1395x, 1395cc, and 1395st of this title, enacting provisions set out as notes under sections 1395x, 1395d, and 1395st of this title, and amending provisions set out as notes under sections 1395xw of this title] shall take effect January 1, 1990, except that the amendments made by subsection (c) [amending provisions set out as a note under section 1395xw of this title] shall be effective as if included in the enactment of MCCCA (Pub. L. 100–360).”

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by 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 services 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.

EFFECTIVE DATE OF 1986 AMENDMENT

Amendment by Pub. L. 99–272 effective after Mar. 31, 1986, with no individual to be considered under disability for any period beginning before Apr. 1, 1986, for purposes of hospital insurance benefits, see section 13203(d)(2) of Pub. L. 99–272, set out as a note under section 419 of this title.

EFFECTIVE DATE OF 1982 AMENDMENT

Section 122(h)(1) of Pub. L. 97–248, as amended by Pub. L. 99–272, title IX, §9213(a), Apr. 7, 1986, 100 Stat. 168, provided that: “The amendments made by this section [amending this section and sections 1395d to 1395f, 1395x, and 1395st to 1395cc of this title and section 231l of Title 45, Railroads, and enacting provisions set out as notes under sections 1395x, 1395d, and 1395st of this title] apply to hospice care provided on or after November 1, 1983.”


EFFECTIVE DATE OF 1980 AMENDMENTS

Amendment by Pub. L. 96–499 effective with respect to services furnished on or after July 1, 1981, see section 930(e)(1) of Pub. L. 96–499, set out as a note under section 1395x of this title.


Amendment by Pub. L. 96–265 applicable with respect to hospital insurance or supplementary medical insurance benefits for services provided on or after first day of sixth month which begins after June 9, 1980, see section 103(e) of Pub. L. 96–265, set out as a note under section 426 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, 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.

ADVISORY COUNCIL TO STUDY COVERAGE OF DISABLED UNDER THIS SUBCHAPTER

Pub. L. 90–248, title I, §140, Jan. 2, 1968, 81 Stat. 854, directed Secretary of Health, Education, and Welfare to appoint an Advisory Council to study need for coverage of disabled under the health insurance programs of this subchapter, directed Council to submit a report on such study to Secretary by Jan. 1, 1969, and directed Secretary in turn to transmit such report to Congress, resulting in termination of Council’s existence.

REIMBURSEMENT OF CHARGES UNDER PART A FOR SERVICES TO PATIENTS ADMITTED PRIOR TO 1968 TO CERTAIN HOSPITALS

Pub. L. 90–248, title I, §142, Jan. 2, 1968, 81 Stat. 855, provided that: “(a) Notwithstanding any provision of title XVIII of the Social Security Act [this subchapter] an individual who is entitled to hospital insurance benefits under section 1861 of such Act (section 1395x of this title) may, subject to subsections (b) and (c), receive, on the basis of an itemized bill, reimbursement for charges for him for inpatient hospital services (as defined in section 1861(r) of such Act (section 1395x of this title), but without regard to subsection (e) of such section) furnished by, or under arrangements (as defined in section 1861(w) of
such Act (section 1395x(w) of this title) with, a hospital if—

“(1) the hospital did not have an agreement in effect under section 1866 of such Act (section 1395cc of this title) but would have been eligible for payment under part A of title XVIII of such Act (this part) with respect to such services if at the time such services were furnished the hospital had such an agreement in effect;

“(2) the hospital (A) meets the requirements of paragraphs (5) and (7) of section 1861(e) of such Act (section 1395x(e) of this title), (B) is not primarily engaged in providing the services described in section 1861(k)(1)(A) of such Act (section 1395x(k)(1)(A) of this title), and (C) is primarily engaged in providing, by or under the supervision of individuals referred to in paragraph (1) of section 1861(r) of such Act (section 1395x(r) of this title), to inpatients (i) diagnostic services and therapeutic services for medical diagnosis, treatment, and care, and (ii) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;

“(3) the hospital shall not meet the requirements that must be met to permit payment to the hospital under part A of title XVIII of such Act (this part); and

“(4) an application is filed (submitted in such form and manner and by such person, and containing and supported by such information, as the Secretary shall by regulations prescribe) for reimbursement before January 1, 1969.

“(b) Payments under this section may not be made for inpatient hospital services (as described in subsection (a)) furnished to an individual—

“(1) prior to January 1, 1966;

“(2) after December 31, 1967, unless furnished with respect to an admission to the hospital prior to January 1, 1968, and

“(3) for more than—

“(A) 90 days in any spell of illness, but only if (i) prior to January 1, 1969, the hospital furnishing such services entered into an agreement under section 1866 of the Social Security Act (section 1395cc of this title) and (ii) the hospital’s plan for utilization review, as provided for in section 1861(k) of such Act (section 1395x(k) of this title), has, in accordance with section 1814 of such Act (section 1395f(d) of this title), been applied to the services furnished such individual, or

“(B) 20 days in any spell of illness, if the hospital did not meet the conditions of clauses (i) and (ii) of subparagraph (A).

“(c) The amounts payable in accordance with subsection (a) with respect to inpatient hospital services shall, subject to paragraph (2) of this subsection, be paid from the Federal Hospital Insurance Trust Fund in amounts equal to 60 percent of the hospital’s reasonable charges for routine services furnished in the accommodations occupied by the individual or in semi-private accommodations (as defined in section 1861(v)(4) of the Social Security Act (section 1395x(v)(4) of this title)) which are less, plus 80 percent of the hospital’s reasonable charges for ancillary services. If separate charges for routine and ancillary services are not made by the hospital, reimbursement may be based on two-thirds of the hospital’s reasonable charges for the services received but not to exceed the charges which would have been made if the patient had occupied semi-private accommodations (as so defined). For purposes of the preceding provisions of this paragraph, the term ‘routine services’ shall mean the regular room, dietary, and nursing services, minor medical and surgical supplies and the use of equipment and facilities for which a separate charge is not customarily made; the term ‘ancillary services’ shall mean those special services for which charges are customarily made in addition to routine services.

“(2) Before applying paragraph (1), payments made under this section shall be reduced to the extent provided for under section 1813 of the Social Security Act (section 1395z of this title) in the case of benefits payable to providers of services under part A of title XVIII of such Act (this part).

“(d) For the purposes of this section—

“(1) the 90-day period, referred to in subsection (b)(3)(A), shall be reduced by the number of days of inpatient hospital services furnished to such individual during the spell of illness, referred to therein, and with respect to which he was entitled to have payment made under part A of title XVIII of the Social Security Act (this part);

“(2) the 20-day period, referred to in subsection (b)(3)(B) shall be reduced by the number of days in excess of 70 days of inpatient hospital services furnished during the spell of illness, referred to therein, and with respect to which individual was entitled to have payment made under such part A (this part);

“(3) the term ‘spell of illness’ shall have the meaning assigned to it by subsection (a) of section 1861 of such Act (section 1395x(a) of this title) except that the term ‘inpatient hospital services’ as it appears in such subsection shall have the meaning assigned to it by subsection (a) of this section.”

§ 1395d. Scope of benefits

(a) Entitlement to payment for inpatient hospital services, post-hospital extended care services, home health services, and hospice care

The benefits provided to an individual by the insurance program under this part shall consist of entitlement to have payment made on his behalf or, in the case of payments referred to in section 1395f(d)(2) of this title to him (subject to the provisions of this part) for—

(1) inpatient hospital services or inpatient critical access hospital services for up to 150 days during any spell of illness minus 1 day for each day of such services in excess of 90 received during any preceding spell of illness (if such individual was entitled to have payment for such services made under this part unless he specifies in accordance with regulations of the Secretary that he does not desire to have such payment made);

(2)(A) post-hospital extended care services for up to 100 days during any spell of illness, and (B) to the extent provided in subsection (f) of this section, extended care services that are not post-hospital extended care services;

(3) in the case of individuals not enrolled in part B of this subchapter, home health services, and in the case of individuals so enrolled, post-institutional home health services furnished during a home health spell of illness for up to 100 visits during such spell of illness;

(4) in lieu of certain other benefits, hospice care with respect to the individual during up to two periods of 90 days each and an unlimited number of subsequent periods of 60 days each with respect to which the individual makes an election under subsection (d)(1) of this section; and

(5) for individuals who are terminally ill, have not made an election under subsection (d)(1) of this section, and have not previously received services under this paragraph, services that are furnished by a physician (as defined in section 1395xx(r)(1) of this title) who is either the medical director or an employee of a hospice program and that—

(A) consist of—

(i) an evaluation of the individual’s need for pain and symptom management, in-
§ 1395d

(1) The Secretary shall provide for coverage, under clause (B) of subsection (a)(2) of this section, of extended care services which are not usual circumstances as the Secretary may provide, if an individual makes such an election for a period with respect to a particular hospice program, the individual shall be deemed to have waived all rights to have payment made under this subchapter with respect to—

(i) hospice care provided by another hospice program (other than under arrangements made by the particular hospice program) during the period, and

(ii) services furnished during the period that are determined (in accordance with guidelines of the Secretary) to be—

(I) related to the treatment of the individual’s condition with respect to which a diagnosis of terminal illness has been made or

(II) equivalent to (or duplicative of) hospice care;

except that clause (ii) shall not apply to physicians’ services furnished by the individual’s attending physician (if not an employee of the hospice program) or to services provided by (or under arrangements made by) the hospice program.

(B) After an individual makes such an election with respect to a 90-day period or a subsequent 60-day period, the individual may revoke the election during the period, in which case—

(i) the revocation shall act as a waiver of the right to have payment made under this part for any hospice care benefits for the remaining time in such period and (for purposes of subsection (a)(4) of this section and subparagraph (A)) the individual shall be deemed to have been provided such benefits during such entire period, and

(ii) the individual may at any time after the revocation execute a new election for a subsequent period, if the individual otherwise is entitled to hospice care benefits with respect to such a period.

(C) An individual may, once in each such period, change the hospice program with respect to which the election is made and such change shall not be considered a revocation of an election under subparagraph (B).

(D) For purposes of this subchapter, an individual’s election with respect to a hospice program shall no longer be considered to be in effect with respect to that hospice program after the date the individual’s revocation or change of election with respect to that election takes effect.

(e) Services taken into account

For purposes of subsections (b) and (c) of this section, inpatient hospital services, inpatient psychiatric hospital services, and post-hospital extended care services shall be taken into account only if payment is or would be, except for this section or the failure to comply with the request and certification requirements of or under section 1395f(a) of this title, made with respect to such services under this part.

(f) Coverage of extended care services without regard to three-day prior hospitalization requirement

(1) The Secretary shall provide for coverage, under clause (B) of subsection (a)(2) of this section, of extended care services which are not

incluing the individual’s need for hospice care; and

(ii) counseling the individual with respect to hospice care and other care options; and

(B) may include advising the individual regarding advanced care planning.

(b) Services not covered

Payment under this part for services furnished an individual during a spell of illness may not (subject to subsection (c) of this section) be made for—

(1) inpatient hospital services furnished to him during such spell after such services have been furnished to him for 150 days during such spell minus 1 day for each day of inpatient hospital services in excess of 90 received during any preceding spell of illness (if such individual was entitled to have payment for such services made under this part unless he specifies in accordance with regulations of the Secretary that he does not desire to have such payment made);

(2) post-hospital extended care services furnished to him during such spell after such services have been furnished to him for 100 days during such spell; or

(3) inpatient psychiatric hospital services furnished to him after such services have been furnished to him for a total of 190 days during his lifetime.

Payment under this part for post-institutional home health services furnished an individual during a home health spell of illness may not be made for such services beginning after such services have been furnished for a total of 100 visits during such spell.

(c) Inpatients of psychiatric hospitals

If an individual is an inpatient of a psychiatric hospital on the first day of the first month for which he is entitled to benefits under this part, the days on which he was an inpatient of such a hospital in the 150-day period immediately before such first day shall be included in determining the number of days limit under subsection (b)(1) of this section insofar as such limit applies to (1) inpatient psychiatric hospital services, or

(2) inpatient hospital services for an individual who is an inpatient primarily for the diagnosis or treatment of mental illness (but shall not be included in determining such number of days limit insofar as it applies to other inpatient hospital services or in determining the 190-day limit under subsection (b)(3) of this section).

(d) Hospice care; election; waiver of rights; revocation; change of election

(1) Payment under this part may be made for hospice care provided with respect to an individual only during two periods of 90 days each and an unlimited number of subsequent periods of 60 days each during the individual’s lifetime and only, with respect to each such period, if the individual makes an election under this paragraph to receive hospice care under this part provided by, or under arrangements made by, a particular hospice program instead of certain other benefits under this subchapter.

(2)(A) Except as provided in subparagraphs (B) and (C) and except in such exceptional and unusual circumstances as the Secretary may provide, if an individual makes such an election for a period with respect to a particular hospice program, the individual shall be deemed to have waived all rights to have payment made under this subchapter with respect to—

(i) hospice care provided by another hospice program (other than under arrangements made by the particular hospice program) during the period, and

(ii) services furnished during the period that are determined (in accordance with guidelines of the Secretary) to be—

(I) related to the treatment of the individual’s condition with respect to which a diagnosis of terminal illness has been made or

(II) equivalent to (or duplicative of) hospice care;

except that clause (ii) shall not apply to physicians’ services furnished by the individual’s attending physician (if not an employee of the hospice program) or to services provided by (or under arrangements made by) the hospice program.

(B) After an individual makes such an election with respect to a 90-day period or a subsequent 60-day period, the individual may revoke the election during the period, in which case—

(i) the revocation shall act as a waiver of the right to have payment made under this part for any hospice care benefits for the remaining time in such period and (for purposes of subsection (a)(4) of this section and subparagraph (A)) the individual shall be deemed to have been provided such benefits during such entire period, and

(ii) the individual may at any time after the revocation execute a new election for a subsequent period, if the individual otherwise is entitled to hospice care benefits with respect to such a period.

(C) An individual may, once in each such period, change the hospice program with respect to which the election is made and such change shall not be considered a revocation of an election under subparagraph (B).

(D) For purposes of this subchapter, an individual’s election with respect to a hospice program shall no longer be considered to be in effect with respect to that hospice program after the date the individual’s revocation or change of election with respect to that election takes effect.

(e) Services taken into account

For purposes of subsections (b) and (c) of this section, inpatient hospital services, inpatient psychiatric hospital services, and post-hospital extended care services shall be taken into account only if payment is or would be, except for this section or the failure to comply with the request and certification requirements of or under section 1395f(a) of this title, made with respect to such services under this part.

(f) Coverage of extended care services without regard to three-day prior hospitalization requirement

(1) The Secretary shall provide for coverage, under clause (B) of subsection (a)(2) of this section, of extended care services which are not
post-hospital extended care services at such time and for so long as the Secretary determines, and under such terms and conditions (described in paragraph (2)) as the Secretary finds appropriate, that the inclusion of such services will not result in any increase in the total of payments made under this subchapter and will not alter the acute care nature of the benefit described in subsection (a)(2) of this section.

(2) The Secretary may provide—

(A) for such limitations on the scope and extent of services described in subsection (a)(2)(B) of this section and on the categories of individuals who may be eligible to receive such services, and

(B) notwithstanding sections 1385f, 1395x(v), and 1385ww of this title, for such restrictions and alternatives on the amounts and methods of payment for services described in such subsection, as may be necessary to carry out paragraph (1).

(g) “Spells of illness” defined

For definitions of “spell of illness”, and for definitions of other terms used in this part, see section 1395x of this title.


REFERENCES IN TEXT

Part B of this subchapter, referred to in subsec. (a)(3), is classified to section 1395x et seq. of this title.

AMENDMENTS

2003—Subsec. (a)(3). Pub. L. 108–173, § 736(c)(1), substituted “in the case of individuals not” for “for individuals not” and “in the case of individuals so” for “for individuals so”.


Subsec. (a)(3). Pub. L. 105–33, § 4611(a)(1), substituted “for individuals not enrolled in part B of this subchapter, home health services, and for individuals so enrolled, post-institutional home health services furnished during a home health spell of illness for up to 100 visits during such spell of illness” for “home health services”.

Subsec. (a)(4). Pub. L. 105–33, § 4443(a), substituted “an unlimited number of subsequent periods of 60 days each” for “a subsequent period of 30 days, and a subsequent extension period”.


Subsec. (d)(1). Pub. L. 105–33, § 4443(a), substituted “and an unlimited number of subsequent periods of 60 days each” for “a subsequent period of 30 days, and a subsequent extension period”.

Subsec. (d)(2)(B). Pub. L. 105–33, § 4443(b)(1), substituted “60-day period or a subsequent 60-day period” for “90- or 30-day period or a subsequent extension period”.

1994—Subsec. (a)(1). Pub. L. 103–432 substituted “inpatient hospital services or inpatient rural primary care hospital services” for “inpatient hospital services” before “for up to 150 days” and “such services” for “inpatient hospital services” before “in excess of 90” and struck out “and inpatient rural primary care hospital services” after “such payment made”.

1990—Subsec. (a)(4). Pub. L. 101–508, § 4006(a)(1), substituted “90 days each, a subsequent period of 30 days, and a subsequent extension period” for “90 days each and one subsequent period of 30 days”.

Subsec. (d)(1). Pub. L. 101–508, § 4006(a)(2)(A), substituted “90 days each, a subsequent period of 30 days, and a subsequent extension period during the individual’s lifetime” for “90 days each and one subsequent period of 30 days during the individual’s lifetime”.

Subsec. (d)(2)(B). Pub. L. 101–508, § 4006(a)(2)(B), substituted “a 90- or 30-day period or a subsequent extension period” for “a 90- or 30-day period”.

1989—Subsec. (a). Pub. L. 101–234 repealed Pub. L. 100–360, § 101(i), 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.


Subsecs. (b) to (d)(1), (2)(B), (e) to (g). Pub. L. 101–234 repealed Pub. L. 100–360, § 101(i), 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.

1985—Subsec. (a). Pub. L. 100–360, § 101(1), struck out former pars. (1) to (4) and added new pars. (1) to (4) which read as follows:

“(1) inpatient hospital services;

“(2) extended care services for up to 150 days during any calendar year;

“(3) home health services; and

“(4) in lieu of certain other benefits, hospice care with respect to the individual during up to two periods of 90 days each, a subsequent period of 30 days, and a subsequent extension period with respect to which the individual makes an election under subsection (d)(1) of this section.”

Subsec. (b). Pub. L. 100–360, § 101(2), amended subsec. (b) generally, striking out par. (1) and renumbering and amending pars. (2) and (3) as (1) and (2), respectively.

Subsec. (c). Pub. L. 100–360, § 101(3), amended subsec. (c) generally, substituting pars. (1) to (4) limiting periods for inpatients of psychiatric hospitals for former single paragraph.

Subsec. (d)(1). Pub. L. 100–360, § 101(4)(A), substituted “a subsequent period of 30 days, and a subsequent extension period” for “and one subsequent period of 30 days”.


Subsec. (f). Pub. L. 100–360, § 101(6), struck out subsec. (f) which provided coverage of extended care services without regard to three-day prior hospitalization requirement.

Subsec. (g). Pub. L. 100–360, § 101(8), struck out subsec. (g) which cross-referenced section 1395x of this title for definitions of “spell of illness” and other terms used in this part.
to services" for "or to other than services" after "(if
not an employee of the hospice program)".
existing provisions as subpar. (A) and added sub-
par. (B).
(d).
(f) and redesignated former subsec. (f) as (g).
which related to alcohol detoxification facility serv-
ces.
1980—Subsec. (a)(3). Pub. L. 96–499, §930(b), substi-
tuted "home health services" for "post-hospital
home health services for up to 100 visits (during
the one year period described in section 1395x(n) of this
title) after the beginning of one spell of illness and before
the beginning of the next".
d which authorized payment for post-hospital home
health services furnished an individual only during the
one year period described in section 1395x(n) of this
title following his most recent hospital discharge
which met the requirements of such section and only
for the first 100 visits in such period.
Subsec. (e). Pub. L. 96–499, §930(d), substituted "sub-
sections (b) and (c)" for "subsections (b), (c), and (d)"
and "and post-hospital extended care services" for
"post-hospital extended care services, and post-hospital
home health services".
1968—Subsec. (a). Pub. L. 90–248, §143(b), inserted "or,
in the case of payments referred to in section 1395f(d)(2)
of this title to him" after "on his behalf" in text pre-
ceding par. (1).
Subsec. (a)(1). Pub. L. 90–248, §137(a)(1), increased the maximum duration of benefits from 90 to 150
days minus 1 day for each day of inpatient hospital services
in excess of 90 received during any preceding spell of
illness (if such individual was entitled to have payment
for such services made under this part unless he specifies
that he does not desire to have such payment made).
(4) which provided for payment for outpatient
hospital diagnostic services.
Subsec. (b)(1). Pub. L. 90–248, §137(a)(2), changed the limitation on payments from 90 to 150 days minus 1 day
for each day of inpatient hospital services in excess of
90 received during any preceding spell of illness (if such
individual was entitled to have payment for such serv-
cices made under this part unless he specifies that he
does not desire to have such payment made).
Subsec. (c). Pub. L. 90–248, §138(a), increased the limit
from 90 to 150 days so that if an individual was an inpa-
tient of a psychiatric or tuberculosis hospital on the
first day of the first month for which he is entitled to
benefits, the days he was an inpatient in the 150-day pe-
riod immediately before such first day are included in
determining the limit under subsec. (b)(1) insofar as
such limit applies to (1) inpatient psychiatric hospital
services and inpatient tuberculosis hospital services, or
(2) inpatient hospital services for an individual who is
an inpatient primarily for the diagnosis or treatment of
mental illness or tuberculosis (but are not included in
determining such limit as it applies to other inpa-
tient hospital services or in determining the 190-day
limit under subsec. (b)(3)).
Pub. L. 90–248, §146(a), provided that the limitation of allowable days of inpatient hospital services will not
apply to services provided to an inpatient of a tuber-
culosus hospital.

Effective Date of 2003 Amendment
2580, provided that: "The amendments made by this
section [amending this section and sections 1395f and
1395x of this title] shall apply to services provided by a
hospice program on or after January 1, 2005."
this subtitle, insofar as they eliminate the requirement (under section 1212(a)(2) of the Social Security Act [subsec. (a)(2) of this section]) that extended care services are only covered under title XVIII of such Act [this subchapter] if they are post-hospital extended care services, shall only apply to extended care services furnished pursuant to an admission to a skilled nursing facility occurring on or after January 1, 1989.

**Effective Date of 1983 Amendment**
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 930(c)(2) of Pub. L. 97–248, set out as a note under section 426–1 of this title.

**Effective Date of 1982 Amendment**
Amendment by section 122(b) of Pub. L. 97–248 applicable to hospice care provided on or after Nov. 1, 1983, see section 122(h)(1) of Pub. L. 97–248, as amended, set out as a note under section 1395c of this title.

**Effective Date of 1981 Amendment**
Section 2211(a) of Pub. L. 97–35 provided that: “The amendments made by this section [amending this section and sections 1320c–3, 1320c–4, 1320c–7, 1395f, and 1395x of this title] shall become effective with respect to services furnished after the date of enactment of this Act [Aug. 13, 1981].”

**Effective Date of 1980 Amendment**
Amendment by section 930(b)–(d) of Pub. L. 96–499 effective with respect to services furnished on or after July 1, 1981, see section 930(e)(1) of Pub. L. 96–499, set out as a note under section 1390x of this title.

**Effective Date of 1980 Amendment**
Section 821(e) of Pub. L. 96–499 provided that: “The amendments made by subsections (a) through (d) of this section [amending this section and sections 1395f and 1395x of this title] shall become effective on April 1, 1981.”

**Effective Date of 1968 Amendment**
Section 129(d) of Pub. L. 90–248 provided that: “The amendments made by this section [amending this section and sections 1395d, 1395e, 1395f, 1395k, 1395l, 1395m, 1395x, and 1395cc of this title and section 228d–2 of Title 45, Railroads] shall apply with respect to services furnished after March 31, 1968, except that subsection (c)(5) of such section [amending section 1395f of this title] shall become effective with respect to services furnished after the date of enactment of this Act [Jan. 2, 1968].”

Section 137(c) of Pub. L. 90–248 provided that: “The amendments made by subsections (a) and (b) [amending this section and section 1395e of this title] shall apply with respect to services furnished after December 31, 1967.”

Section 138(b) of Pub. L. 90–248 provided that: “The amendments made by subsection (a) [amending this section] shall apply with respect to payment for services furnished after December 31, 1967.”

Section 143(d) of Pub. L. 90–248 provided that: “The provisions made by subsection (a) of this section [amending section 1395x of this title] shall become effective as of July 1, 1966, and the provisions made by subsections (b) and (c) of this section [amending this section and section 1395f of this title] shall apply to services furnished with respect to admissions occurring after December 31, 1967, and to outpatient hospital diagnostic services furnished after December 31, 1967, and before April 1, 1968.”

Section 146(b) of Pub. L. 90–248 provided that: “The amendments made by subsection (a) [amending this section] shall apply with respect to payment for services furnished after December 31, 1967.”

**Medicare Hospice Concurrent Care Demonstration Program**

“(a) Establishment.—

“(1) In general.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall establish a Medicare Hospice Concurrent Care demonstration program at participating hospice programs under which Medicare beneficiaries are furnished, during the same period, hospice care and any other items or services covered under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) from funds otherwise paid under such title to such hospice programs.

“(2) Duration.—The demonstration program under this section shall be conducted for a 3-year period.

“(3) Sites.—The Secretary shall select not more than 15 hospice programs at which the demonstration program under this section shall be conducted. Such hospice programs shall be located in urban and rural areas.

“(b) Independent Evaluation and Reports.—

“(1) Independent Evaluation.—The Secretary shall provide for the conduct of an independent evaluation of the demonstration program under this section. Such independent evaluation shall determine whether the demonstration program has improved patient care, quality of life, and cost-effectiveness for Medicare beneficiaries participating in the demonstration program.

“(2) Reports.—The Secretary shall submit to Congress a report containing the results of the evaluation conducted under paragraph (1), together with such recommendations as the Secretary determines appropriate.

“(c) Budget Neutrality.—With respect to the 3-year period of the demonstration program under this section, the Secretary shall ensure that the aggregate expenditures under title XVIII (42 U.S.C. 1395 et seq.) for such period shall not exceed the aggregate expenditures that would have been expended under such title if the demonstration program under this section had not been implemented.”

**Protecting Home Health Benefits**

**Rural Hospice Demonstration Project**

“(a) In General.—The Secretary (of Health and Human Services) shall conduct a demonstration project for the delivery of hospice care to Medicare beneficiaries in rural areas. Under the project Medicare beneficiaries who are unable to receive hospice care in the facility for lack of an appropriate caregiver are provided such care in a facility of 20 or fewer beds which offers, within its walls, the full range of services provided by hospice programs under section 1861(dd) of the Social Security Act (42 U.S.C. 1395x(dd)).

“(b) Scope of Project.—The Secretary shall conduct the project under this section with respect to no more than 3 hospice programs over a period of not longer than 5 years each.

“(c) Compliance With Conditions.—Under the demonstration project—

“(1) the hospice program shall comply with otherwise applicable requirements, except that it shall not be required to offer services outside of the home or to meet the requirements of section 1861(dd)(2)(A)(ii)(I) of the Social Security Act [section 1395x(dd)(2)(A)(ii)(I) of this title]; and
"(2) payments for hospice care shall be made at the rates otherwise applicable to such care under title XVIII of such Act [this subchapter]. The Secretary may require the program to comply with such additional quality assurance standards for its provision of services in its facility as the Secretary deems appropriate."

"(d) Report.—Upon completion of the project, the Secretary shall submit a report to Congress on the project and shall include in the report recommendations regarding extension of such project to hospice programs serving rural areas."

"(2) the extent to which hospitals provide notice to Medicare beneficiaries in accordance with applicable requirements before they use the 60 lifetime reserve days described in section 1812(a)(1) of the Social Security Act (42 U.S.C. 1395d(a)(1)); and

"(2) the appropriateness and feasibility of hospitals providing a notice to such beneficiaries before they completely exhaust such lifetime reserve days."

"(a) In General.—The Medicare Payment Advisory Commission shall conduct a study to examine the factors affecting the use of hospice benefits under the Medicare program under title XVIII of the Social Security Act [this subchapter], including a delay in the time (relative to death) of entry into a hospice program, and differences in such use between urban and rural hospice programs and based upon the presenting condition of the patient."

"(b) Report.—Not later than 18 months after the date of the enactment of this Act [Dec. 8, 2003], the Inspector General of the Department of Health and Human Services shall submit a report to Congress on—

"(1) the extent to which hospitals provide notice to Medicare beneficiaries in accordance with applicable requirements before they use the 60 lifetime reserve days described in section 1812(a)(1) of the Social Security Act (42 U.S.C. 1395d(a)(1)); and

"(2) the appropriateness and feasibility of hospitals providing a notice to such beneficiaries before they completely exhaust such lifetime reserve days."

"(a) In General.—The Medicare Payment Advisory Commission shall conduct a study to examine the factors affecting the use of hospice benefits under the Medicare program under title XVIII of the Social Security Act [this subchapter], including a delay in the time (relative to death) of entry into a hospice program, and differences in such use between urban and rural hospice programs and based upon the presenting condition of the patient."

"(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 deems appropriate."

"(1) The amount payable for inpatient hospital services or inpatient critical access hospital services furnished to an individual during any spell of illness shall be reduced by a deduction equal to the inpatient hospital deductible or, if less, the charges imposed with respect to such individual for such services, except that, if the customary charges for such services are greater than the charges so imposed, such customary charges shall be considered to be the charges so imposed. Such amount shall be further reduced by a coinsurance amount equal to—

(A) one-fourth of the inpatient hospital deductible for each day (before the 91st day) on which such individual is furnished such services during such spell of illness after such services have been furnished to him for 60 days during such spell; and

(B) one-half of the inpatient hospital deductible for each day (before the day following the last day for which such individual is entitled to payment made on his behalf for inpatient hospital services or inpatient critical access hospital services during such spell of illness) on which such individual is furnished such services during such spell of illness after such services have been furnished to him for 90 days during such spell; except that the reduction under this sentence for any day shall not exceed the charges imposed for that day with respect to such individual for such services (and for this purpose, if the customary charges for such services are greater than the charges so imposed, such customary charges shall be considered to be the charges so imposed)."


(A) In General.—For purposes only of computing the monthly premium under section 1839 of the Social Security Act (42 U.S.C. 1395w), the monthly actuarial rate for enrollees age 65 and over shall be computed as though any reference in paragraph (1) of this subsection to 2002 were a reference to 2003 and as if the following proportions were substituted for the proportions specified in paragraph (2):

(i) For 1998, 1⁄6,

(ii) For 1999, 1⁄5,

(iii) For 2000, 1⁄4,

(iv) For 2001, 1⁄3,

(v) For 2002, 1⁄2,

(vi) For 2003, 1⁄3.

(B) No Impact on Government Contribution.—Subparagraph (A) does not apply in determining the amount of the Government contribution under section 1844 of the Social Security Act (42 U.S.C. 1395w)."

"(A) one-fourth of the inpatient hospital deductible for each day (before the 91st day) on which such individual is furnished such services during such spell of illness after such services have been furnished to him for 60 days during such spell; and

(B) one-half of the inpatient hospital deductible for each day (before the day following the last day for which such individual is entitled to payment made on his behalf for inpatient hospital services or inpatient critical access hospital services during such spell of illness) on which such individual is furnished such services during such spell of illness after such services have been furnished to him for 90 days during such spell; except that the reduction under this sentence for any day shall not exceed the charges imposed for that day with respect to such individual for such services (and for this purpose, if the customary charges for such services are greater than the charges so imposed, such customary charges shall be considered to be the charges so imposed)."


(A) In General.—For purposes only of computing the monthly premium under section 1839 of the Social Security Act (42 U.S.C. 1395w), the monthly actuarial rate for enrollees age 65 and over shall be computed as though any reference in paragraph (1) of this subsection to 2002 were a reference to 2003 and as if the following proportions were substituted for the proportions specified in paragraph (2):

(i) For 1998, 1⁄6,

(ii) For 1999, 1⁄5,

(iii) For 2000, 1⁄4,

(iv) For 2001, 1⁄3,

(v) For 2002, 1⁄2,

(vi) For 2003, 1⁄3.

(B) No Impact on Government Contribution.—Subparagraph (A) does not apply in determining the amount of the Government contribution under section 1844 of the Social Security Act (42 U.S.C. 1395w)."

"For provisions repealing amendment by section 101 of Pub. L. 100–360, restoring or reviving this section as if section 101 of Pub. L. 100–360 had not been enacted, and providing a transition period for Medicare beneficiaries with respect to inpatient hospital services and extended care services provided on or after Jan. 1, 1990, and providing an exception to such restoration for certain hospice care, see section 101(a)–(d)(2) of Pub. L. 101–234, set out as a note under section 1395n of this title."
individual shall be further reduced by a deduction equal to the expenses incurred for the first three pints of whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished to the individual during each calendar year, except that such deductible for such blood shall in accordance with regulations be appropriately reduced to the extent that there has been a replacement of such blood (or equivalent quantities of packed red blood cells, as so defined); and for such purposes blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual shall be deemed replaced when the institution or other person furnishing such blood (or such equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is made under this sentence. 

(b) The deductible under subparagraph (A) for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1395(b)(1) of this title to blood or blood cells furnished the individual in the year.

(3) The amount payable for post-hospital extended care services furnished an individual during any spell of illness shall be reduced by a coinsurance amount equal to one-eighth of the inpatient hospital deductible for each day (before the 101st day) on which he is furnished such services after such services have been furnished to him for 20 days during such spell.

(4)(A) The amount payable for hospice care shall be reduced—

(i) in the case of drugs and biologicals provided on an outpatient basis by (or under arrangements made by) the hospice program, by a coinsurance amount equal to an amount (not to exceed $5 per prescription) determined in accordance with a drug copayment schedule (established by the hospice program) which is related to, and approximates 5 percent of, the cost of the drug or biological to the program, and

(ii) in the case of respite care provided by (or under arrangements made by) the hospice program, by a coinsurance amount equal to 5 percent of the amount estimated by the hospice program (in accordance with regulations of the Secretary) to be equal to the amount of payment under section 1395f(i) of this title to that program for respite care;

except that the total of the coinsurance required under clause (ii) for an individual may not exceed for a hospice coinsurance period the inpatient hospital deductible applicable for the year in which the period began. For purposes of this subparagraph, the term "hospice coinsurance period" means, for an individual, a period of consecutive days beginning with the first day for which an election under section 1395d(d) of this title is in effect for the individual and ending with the close of the first period of 14 consecutive days on each of which such an election is not in effect for the individual.

(B) During the period of an election by an individual under section 1395d(d)(1) of this title, no copayments or deductibles other than those under subparagraph (A) shall apply with respect to services furnished to such individual which constitute hospice care, regardless of the setting in which such services are furnished.

(b) Inpatient hospital deductible; application

(1) The inpatient hospital deductible for 1987 shall be $520. The inpatient hospital deductible for any succeeding year shall be an amount equal to the inpatient hospital deductible for the preceding calendar year, changed by the Secretary’s best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1395ww(b)(3)(B) of this title) which are applied under section 1395ww(d)(3)(A) of this title for discharges in the fiscal year that begins on October 1 of such preceding calendar year, and adjusted to reflect changes in real case mix (determined on the basis of the most recent case mix data available). Any amount determined under the preceding sentence which is not a multiple of $4 shall be rounded to the nearest multiple of $4 (or, if it is midway between two multiples of $4, to the next higher multiple of $4).

(2) The Secretary shall promulgate the inpatient hospital deductible and all coinsurance amounts under this section between September 1 and September 15 of the year preceding the year to which they will apply.

(3) The inpatient hospital deductible for a year shall apply to—

(A) the deduction under the first sentence of subsection (a)(1) of this section for the year in which the first day of inpatient hospital services or inpatient critical access hospital services occurs in a spell of illness, and

(B) to the coinsurance amounts under subsection (a) of this section for inpatient hospital services, inpatient critical access hospital services, hospice care, and post-hospital extended care services furnished in that year.

Amendments


1994—Subsec. (a)(1). Pub. L. 103–432, § 102(g)(2), substituted “inpatient hospital services or inpatient rural primary care hospital services” for “inpatient hospital services” in introductory provisions and in subpar. (B).

Subsec. (b)(3)(A). Pub. L. 103–432, § 102(g)(2), substituted “inpatient hospital services or inpatient rural primary care hospital services” for “inpatient hospital services”.  

Statutory Authority

Subsec. (b)(3)(B). Pub. L. 103–432, §102(g)(3), substituted “inpatient hospital services, inpatient rural primary care hospital services” for “inpatient hospital services”.

1989—Subsecs. (a)(1) to (3), (b)(3), Pub. L. 101–234 repealed Pub. L. 100–360, §102, subject to an exception for blood donation, and provided that the provisions of law repealed by such section are reenacted or revived as if such section had not been enacted, see 1988 Amendment notes below.

1988—Subsec. (a)(1) to (3), Pub. L. 100–360, §102(1), amended pars. (1) to (3) generally, revising and reorganizing former pars. (1)(A), (B), (2), and (3), as par. (1), consisting of subpars. (A) to (D), and pars. (2) and (3), each consisting of subpars. (A) and (B).


Subsec. (b)(3). Pub. L. 100–360, §102(2), struck out par. (3) which related to application of deductible.

1987—Subsec. (b)(1), Pub. L. 100–203, §4002(f)(3), as added by Pub. L. 100–360, §411(b)(1)(H)(ii), substituted “Secretary’s best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1395ww(b)(3)(B) of this title) which are applied for ‘applicable percentage increase as defined in section 1395ww(b)(3)(B) of this title’ which is applied”.

1986—Subsec. (b), Pub. L. 99–509 amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows:

“(1) The inpatient hospital deductible which shall be applicable for the purposes of subsection (a) of this section shall be $40 in the case of any spell of illness beginning before 1969.

(2) The Secretary shall, between July 1 and September 15 of 1968, and of each year thereafter, determine and promulgate the inpatient hospital deductible which shall be applicable for the purposes of subsection (a) of this section in the case of any inpatient hospital services or post-hospital extended care services furnished during the succeeding calendar year. Such inpatient hospital deductible shall be equal to $45 multiplied by the ratio of (A) the current average per diem rate for inpatient hospital services for the calendar year preceding the promulgation, to (B) the current average per diem rate for such services for 1966. Any amount determined under the preceding sentence which is not a multiple of $4 shall be rounded to the nearest multiple of $4 (or, if it is midway between two multiples of $4, to the next higher multiple of $4). The current average per diem rate for any year shall be determined by the Secretary on the basis of the best information available to him (at the time the determination is made) as to the amounts paid under this part on account of inpatient hospital services furnished during such year, by hospitals which have agreements in effect under section 1395c of this title, to individuals who are entitled to hospital insurance benefits under section 122 of this title, plus the amount which would have been so paid but for subsection (a)(1) of this section.”

Subsec. (b)(2). Pub. L. 99–272 substituted “September 15” for “October 1”.


1981—Subsec. (b)(2). Pub. L. 97–35 substituted “any inpatient hospital services or post-hospital extended care services furnished during the succeeding calendar year”.

Such inpatient hospital deductible shall be equal to $45” for “any spell of illness beginning during the succeeding calendar year. Such inpatient hospital deductible shall be equal to $40”.

1988—Subsec. (a)(1), Pub. L. 90–248, §137(b), designated existing provisions as subpar. (A) and added subpar. (B) and the exception provision that the reduction for any day shall not exceed the charges for that day.

Subsec. (a)(2). Pub. L. 90–248, §135(a), made the three pint deductible applicable also to equivalent quantities of packed red blood cells, as defined by the Secretary under regulations.

Subsec. (a)(3)(A). Pub. L. 90–248, §129(c)(3), struck out par. (2) which provided for reduction of amount payable for outpatient hospital diagnostic services furnished an individual during a diagnostic study, and redesignated pars. (3) and (4) as (2) and (3), respectively.

Subsec. (b)(1), (2). Pub. L. 90–248, §129(a), struck out diagnostic studies from application of inpatient hospital deductible.

Effective Date of 1997 Amendment
Amendment by 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.

Effective Date of 1989 Amendment

Effective Date of 1988 Amendment
Amendment by section 102 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 103(a) of Pub. L. 100–360, set out as a note under section 1395f of this title.


Effective Date of 1986 Amendments
Section 9301(b) of Pub. L. 99–509 provided that: “The amendment made by subsection (a) [amending this section] shall apply to inpatient hospital services and post-hospital extended care services furnished on or after January 1, 1987, and to the monthly premium (under part A of title XVIII of the Social Security Act (this part)) for months beginning with January 1987.”

Section 9125(b) of Pub. L. 99–272 provided that: “The amendment made by this section [amending this section] shall apply to calendar years after 1965.”

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(b)(3) of Pub. L. 97–248, as amended, set out as a note under section 1395c of this title.

Effective Date of 1981 Amendment
Section 2131(b) of Pub. L. 97–35 provided that: “The amendment made by subsection (a) [amending this section] is effective for inpatient hospital services or post-hospital extended care services furnished on or after January 1, 1982.”

Section 2132(b) of Pub. L. 97–35 provided that: “The amendments made by subsection (a) [amending this section] shall apply to inpatient hospital services and post-hospital extended care services furnished in calendar years beginning with calendar year 1982.”

Effective Date of 1968 Amendment
Amendment by section 129(c)(3), (4) of Pub. L. 90–248 applicable with respect to services furnished after Mar. 31, 1968, see section 122(d) of Pub. L. 90–248, set out as a note under section 1395f of this title.

Section 133(d) of Pub. L. 90–248 provided that: “The amendments made by this section [amending this section and sections 1393 and 1395ccc of this title] shall apply with respect to the payment for blood (or packed red blood cells) furnished an individual after December 31, 1967.”

Amendment by section 137(b) of Pub. L. 90–248 applicable with respect to services furnished after Dec. 31, 1967, see section 137(c) of Pub. L. 90–248, set out as a note under section 1395d of this title.
REPEAL OF 1988 EXPANSION OF MEDICARE PART A BENEFITS


“(a) IN GENERAL—

“(1) GENERAL RULE.—Except as provided in paragraph (2), sections 101, 102, and 104(d) (other than paragraph (7) of the Medicare Catastrophic Coverage Act of 1988 (Public Law 100–360) [amending this section and sections 1395c, 1395d, 1395f, 1395k, 1395x, 1395cc, and 1395tt of this title] (in this Act referred to as ‘MCCA’) are repealed, and the provisions of law amended or repealed by such sections are restored or revived as if such section had not been enacted.

“(2) EXCLUSION FOR BLOOD DEDUCTION.—The repeal of section 102(a)(1) of MCCA [amending this section (relating to deductibles and coinsurance under part A)] shall not apply, but only insofar as such section amended paragraph (2) of section 1813(a) of the Social Security Act [subsec. (a)(2) of this section] (relating to a deduction for blood).

“(b) TRANSITION PROVISIONS FOR MEDICARE BENEFICIARIES.—

“(1) INPATIENT HOSPITAL SERVICES AND POST-HOSPITAL EXTENDED CARE SERVICES.—In applying sections 1812 and 1813 of the Social Security Act [section 1395d of this title and this section], as restored by subsection (a)(1), with respect to inpatient hospital services and extended care services provided on or after January 1, 1990—

“(A) no day before January 1, 1990, shall be counted in determining the beginning (or period) of a spell of illness;

“(B) with respect to the limitation (other than the limitation under section 1812(c) of such Act [section 1395d(c) of this section]) on such services provided in a spell of illness, days of such services before January 1, 1990, shall not be counted, except that days of inpatient hospital services before January 1, 1989, which were applied with respect to an individual after receiving 90 days of services in a spell of illness (commonly known as ‘lifetime reserve days’) shall be counted;

“(C) the limitation of coverage of extended care services to post-hospital extended care services shall not apply to an individual receiving such services from a skilled nursing facility during a continuous period beginning before (and including) January 1, 1990, until the end of the period of 30 consecutive days in which the individual is not provided inpatient hospital services or extended care services; and

“(D) the inpatient hospital deductible under section 1813(a)(1) of such Act [subsec. (a)(1) of this section] shall not apply—

“(i) in the case of an individual who is receiving inpatient hospital services during a continuous period beginning before (and including) January 1, 1990, with respect to the spell of illness beginning on such date, if such a deductible was imposed on the individual for a period of hospitalization during 1989;

“(ii) for a spell of illness beginning during January 1990, if such a deductible was imposed on the individual for a period of hospitalization that began in December 1989; and

“(iii) in the case of a spell of illness of an individual that began before January 1, 1990,

“(2) HOSPICE CARE.—The restoration of section 1812(a)(4) of the Social Security Act [section 1395d(a)(4) of this title], effected by subsection (a)(1), shall not apply to hospice care provided during the subsequent period (described in such section as in effect on December 31, 1989) with respect to which an election has been made before January 1, 1990.

“(b) Section 4008(m)(1) of Pub. L. 101–508 provided that amendment by that section to section 101(b)(1)(B) of Pub. L. 101–234, set out above, is effective as if included in enactment of Medicare Catastrophic Coverage Repeal Act of 1989, Pub. L. 101–234.]

HOLD HARMLESS PROVISIONS; APPLICATION OF SUBSECTION (A)(1) AND (2)


“(1) subsection (a)(1) of such Act [subsec. (a)(1) of this section] (as amended by this subtitle [subtitle A (§§ 101–104) of title I of Pub. L. 100–360]) shall not apply to services furnished during that spell of illness during 1989, and

“(B) if that individual begins a period of hospitalization (as defined in such section) during 1989 after the end of that spell of illness, the first period of hospitalization during 1989 that begins after that spell of illness shall be considered to be (for purposes of such section) the first period of hospitalization that begins during that year; and

“(2) the amount of any deductible under section 1813(a)(2) of such Act (as amended by this subtitle) shall be reduced during that spell of illness during 1989 to the extent the deductible under such section was applied during the spell of illness.”

PROMULGATION OF NEW DEDUCTIBLE

Section 9301(c) of Pub. L. 99–509 directed Secretary of Health and Human Services to provide, within 30 days after Oct. 21, 1986, for publication of inpatient hospital deductible, coinsurance amounts for inpatient hospital services and post-hospital extended care services, and monthly part A premiums for 1987, as modified under the amendment of this section made by subsection (a).

§ 1395f. Conditions of and limitations on payment for services

(a) Requirement of requests and certifications

Except as provided in subsections (d) and (g) of this section and in section 1395mm of this title, payment for services furnished an individual may be made only to providers of services which are eligible therefor under section 1395cc of this title and only if—

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner, and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period ending 1 calendar year after the date of service;

(2) a physician, or, in the case of services described in subparagraph (B), a physician, or a nurse practitioner, a clinical nurse specialist, or a physician assistant (as those terms are defined in section 1395x(aa)(5) of this title) who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician,2 or, in the case of services described in subparagraph (C), a physician enrolled under section 1395cc(e) of this title, certifies (and recertifies, where such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided

2So in original.
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inpatient hospital services not later than the certifications shall be required in each case of by regulations, except that the first of such re-certifications shall be required in each case of inpatient hospital services not later than the 20th day of such period that—

(A) in the case of inpatient psychiatric hospital services, such services are or were required to be given on an inpatient basis, by or under the supervision of a physician, for the psychiatric treatment of an individual; and (I) such treatment can or could reasonably be expected to improve the condition for which such treatment is or was necessary or (ii) inpatient diagnostic study is or was medically required and such services are or were necessary for such purposes;

(B) in the case of post-hospital extended care services, such services are or were required to be given because the individual needs or needed on a daily basis skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services, which as a practical matter can only be provided in a skilled nursing facility on an inpatient basis, for any of the conditions with respect to which he was receiving inpatient hospital services (or services which would constitute inpatient hospital services if the institution met the requirements of paragraphs (f) and (g) of section 1395x(aa)(5) of this title) prior to transfer to the skilled nursing facility or for a condition requiring such extended care services which arose after such transfer and while he was still in the facility for treatment of the condition or conditions for which he was receiving such inpatient hospital services;

(C) in the case of home health services, such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1395x(m)(7) of this title) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy; or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy; a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician; such services are or were furnished while the individual was under the care of a physician, and, in the case of a certification made by a physician after January 1, 2010, prior to making such certification the physician must document that the physician himself or herself, or a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1395x(aa)(2) of this title) as authorized by State law, or a physician assistant (as defined in section 1395x(aa)(5) of this title) under the supervision of the physician, has had a face-to-face encounter (including through use of telehealth, subject to the requirements in section 1395m(m) of this title, and other than with respect to encounters that are incident to services involved) with the individual within a reasonable timeframe as determined by the Secretary; or

(D) in the case of inpatient hospital services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth, 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;

(3) with respect to inpatient hospital services (other than inpatient psychiatric hospital services) which are furnished over a period of time, a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such services are necessary for such purpose, except that (A) such certification shall be furnished only in such cases, with such frequency, and accompanied by such supporting material, appropriate to the cases involved, as may be provided by regulations, and (B) the first such certification required in accordance with clause (A) shall be furnished no later than the 20th day of such period;

(4) in the case of inpatient psychiatric hospital services, the services are those which the records of the hospital indicate were furnished to the individual during periods when he was receiving (A) intensive treatment services, (B) admission and related services necessary for a diagnostic study, or (C) equivalent services;

(5) with respect to inpatient hospital services furnished such individual after the 20th day of a continuous period of such services, there was not in effect, at the time of admission of such individual to the hospital, a decision under section 1395ccc(d) of this title (based on a finding that utilization review of long-stay cases is not being made in such hospital);

(6) with respect to inpatient hospital services or post-hospital extended care services furnished such individual during a continuous period, a finding has not been made (by the physician members of the committee or group, as described in section 1395x(aa)(3) of this title, including any finding made in the course of a sample or other review of admissions to the institution) pursuant to the system of utilization review that further inpatient hospital services or further post-hospital extended care services, as the case may be, are not medically necessary; except that, if such a finding has been made, payment may be made for such services furnished before the 4th day after the day on which the hospital or skilled nursing facility, as the case may be, received notice of such finding;

(7) in the case of hospice care provided an individual—

(A)(i) in the first 90-day period—

(I) the individual's attending physician (as defined in section 1395x(dd)(3)(B) of this title) which for purposes of this subparagraph does not include a nurse practitioner); and
(II) the medical director (or physician member of the interdisciplinary group described in section 1395x(dd)(2)(B) of this title) of the hospice program providing (or arranging for) the care, each certify in writing at the beginning of the period, that the individual is terminally ill (as defined in section 1395x(dd)(3)(A) of this title) based on the physician's or medical director's clinical judgment regarding the normal course of the individual's illness, and

(ii) in a subsequent 90- or 60-day period, the medical director or physician described in clause (i)(II) recertifies at the beginning of the period that the individual is terminally ill based on such clinical judgment;

(B) a written plan for providing hospice care with respect to such individual has been established (before such care is provided by, or under arrangements made by, that hospice program) and is periodically reviewed by the individual's attending physician and by the medical director (and the interdisciplinary group described in section 1395x(dd)(2)(B) of this title) of the hospice program;

(C) such care is being or was provided pursuant to such plan of care; and

(D) on and after January 1, 2011—

(1) a hospice physician or nurse practitioner has a face-to-face encounter with the individual to determine continued eligibility of the individual for hospice care prior to the 180th-day recertification and each subsequent recertification under subparagraph (A)(ii) and attests that such visit took place (in accordance with procedures established by the Secretary); and

(ii) in the case of hospice care provided an individual for more than 180 days by a hospice program for which the number of such cases for such program comprises more than a percent (specified by the Secretary) of the total number of such cases for all programs under this subchapter, the hospice care provided to such individual is medically reviewed (in accordance with procedures established by the Secretary); and

(8) in the case of inpatient critical access hospital services, a physician certifies that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the critical access hospital.

To the extent provided by regulations, the certification and recertification requirements of paragraph (2) shall be deemed satisfied where, at a later date, a physician, nurse practitioner, clinical nurse specialist, or physician assistant (as the case may be) makes certification of the kind provided in subparagraph (A), (B), (C), or (D) of paragraph (2) (whichever would have applied), but only where such certification is accompanied by such medical and other evidence as may be required by such regulations. With respect to the physician certification required by paragraph (2) for home health services furnished to any individual by a home health agency (other than an agency which is a governmental entity) and with respect to the establishment and review of a plan for such services, the Secretary shall prescribe regulations which shall become effective no later than July 1, 1981, and which prohibit a physician who has a significant financial or contractual relationship with, such home health agency from performing such certification and from establishing or reviewing such plan, except that such prohibition shall not apply with respect to a home health agency which is a sole community home health agency (as determined by the Secretary). For purposes of the preceding sentence, service by a physician as an uncompensated officer or director of a home health agency shall not constitute having a significant ownership interest in, or a significant financial or contractual relationship with, such agency. For purposes of paragraph (2)(C), an individual shall be considered to be "confined to his home" if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered "confined to his home", the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day-care services in the State shall not disqualify an individual from being considered to be "confined to his home". Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or relatively short duration. In applying paragraph (1), the Secretary may specify exceptions to the 1 calendar year period specified in such paragraph.

(b) Amount paid to provider of services

The amount paid to any provider of services (other than a hospice program providing hospice care, other than a critical access hospital providing inpatient critical access hospital services, and other than a home health agency with respect to durable medical equipment) with respect to services for which payment may be made under this part shall, subject to the provisions of sections 1395e, 1395ww, and 1395ff of this title, be—

(1) except as provided in paragraph (3), the lesser of (A) the reasonable cost of such services, as determined under section 1395x(v) of this title and as further limited by section 1395rr(b)(2)(B) of this title, or (B) the customary charges with respect to such services;
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(2) if such services are furnished by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment may be made under this paragraph, free of charge or at nominal charges to the public, the amount determined on the basis of those items (specified in regulations prescribed by the Secretary) included in the determination of such reasonable cost which the Secretary finds will provide fair compensation to such provider for such services; or

(3) if some or all of the hospitals in a State have been reimbursed for services (for which payment may be made under this paragraph) pursuant to a reimbursement system approved as a demonstration project under section 1395ww(b)(3)(B)(ix) of this title, then, subject to section 1395ww(b)(3)(B)(ix)(II) of this title, the Secretary may provide for continuation of reimbursement to such hospitals made in accordance with this paragraph, if the system is operated through a voluntary agreement of hospitals and such hospitals elect to have reimbursement to such hospitals made in accordance with this paragraph or the system is operated through a voluntary agreement of hospitals and such hospitals elect to have reimbursement to such hospitals made in accordance with this paragraph, then, subject to section 1395ww(d)(3)(B)(ix)(III) of this title, the Secretary may provide for continuation of reimbursement to such hospitals under such system until the Secretary determines that—

(A) a third-party payor reimburses such a hospital on a basis other than under such system, or

(B) the aggregate rate of increase from January 1, 1981, to the most recent date for which annual data are available in such hospitals in costs per hospital inpatient admission of individuals entitled to benefits under this part over the duration of such project was equal to or less than such rate of increase for admissions of such individuals with respect to all hospitals in the United States during such period, and if either the State has legislative authority to operate such system and the State elects to have reimbursement to such hospitals made in accordance with this paragraph, or the system is operated through a voluntary agreement of hospitals and such hospitals elect to have reimbursement to such hospitals made in accordance with this paragraph, then, subject to section 1395ww(d)(3)(B)(ix)(III) of this title, the Secretary may provide for continuation of reimbursement to such hospitals under such system until the Secretary determines that—

(A) a third-party payor reimburses such a hospital on a basis other than under such system, or

(B) the aggregate rate of increase from January 1, 1981, to the most recent date for which annual data are available in such hospitals in costs per hospital inpatient admission of individuals entitled to benefits under this part over the duration of such project was equal to or less than such rate of increase for admissions of such individuals with respect to all hospitals in the United States during such period.

In the case of any State which has had such a demonstration project reimbursement system in continuous operation since July 1, 1977, the Secretary shall provide under paragraph (3) for continuation of reimbursement to hospitals in the State under such system until the first day of the 36th month beginning after the date the Secretary determines and notifies the Governor of the State that either of the conditions described in subparagraph (A) or (B) of such paragraph has occurred. If, by the end of such 36-month period, the Secretary determines, based on evidence submitted by the Governor of the State, that neither of the conditions described in subparagraph (A) or (B) of paragraph (3) continues to apply, the Secretary shall continue without interruption payment to hospitals in the State under the State’s system. If, by the end of such 36-month period, the Secretary determines, based on such evidence, that either of the conditions described in subparagraph (A) or (B) of such paragraph continues to apply, the Secretary shall (i) collect any net excess reimbursement to hospitals in the State during such 36-month period (basing such net excess reimbursement on the net difference, if any, in the rate of increase in costs per hospital inpatient admission under the State system compared to the rate of increase in such costs with respect to all hospitals in the United States over the 36-month period, as measured by including the cumulative savings under the State system based on the difference in the rate of increase in costs per hospital inpatient admission under the State system as compared to the rate of increase in such costs with respect to all hospitals in the United States between January 1, 1981, and the date of the Secretary’s initial notice), and (ii) provide a reasonable period, not to exceed 2 years, for transition from the State system to the national payment system. For purposes of applying paragraph (3), there shall be taken into account incentive payments, and payment adjustments under subsection (b)(3)(B)(ix) or (n) of section 1395ww of this title.

(c) No payments to Federal providers of services

Subject to section 1395qq of this title, no payment may be made under this part (except under subsection (d) or subsection (h) of this section) to any Federal provider of services, except a provider of services which the Secretary determines is providing services to the public generally as a community institution or agency; and no such payment may be made to any provider of services for any item or service which such provider is obligated by a law of, or a contract with, the United States to render at public expense.

(d) Payments for emergency hospital services

(1) Payments shall also be made to any hospital for inpatient hospital services furnished in a calendar year, by the hospital or under arrangements (as defined in section 1395x(w) of this title) with it, to an individual entitled to hospital insurance benefits under section 426 of this title even though such hospital does not have an agreement in effect under this subchapter if (A) such services were emergency services, (B) the Secretary would be required to make such payment if the hospital had such an agreement in effect and otherwise met the conditions of payment hereunder, and (C) such hospital has elected to claim payments for all such inpatient emergency services and for the emergency outpatient services referred to in section 1395n(b) of this title furnished during such year. Such payments shall be made only in the amounts provided under subsection (b) of this section and then only if such hospital agrees to comply, with respect to the emergency services provided, with the provisions of section 1395cc(a) of this title.

(2) Payment may be made on the basis of an itemized bill to an individual entitled to hospital insurance benefits under section 426 of this title for services described in paragraph (1) which are emergency services if (A) payment

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2So in original. Probably should be “1395ww(b)(3)(B)(ix)(III)”.

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cannot be made under paragraph (1) solely because the hospital does not elect to claim such payment, and (B) such individual files application (submitted within such time and in such form and manner and by such person, and containing and supported by such information as the Secretary shall by regulations prescribe) for reimbursement.

(3) The amounts payable under the preceding paragraph with respect to services described therein shall, subject to the provisions of section 1395f of this title, be equal to 60 percent of the hospital's reasonable charges for routine services furnished in the accommodations occupied by the individual or in semiprivate accommodations (as defined in section 1395x(v)(4) of this title), whichever is less, plus 80 percent of the hospital's reasonable charges for ancillary services. If separate charges for routine and ancillary services are not made by the hospital, reimbursement may be based on two-thirds of the hospital's reasonable charges for the services received but not to exceed the charges which would have been made if the patient had occupied semiprivate accommodations. For purposes of the preceding provisions of this paragraph, the term "routine services" shall mean the regular room, dietary, and nursing services, minor medical and surgical supplies and the use of equipment and facilities for which a separate charge is not customarily made; the term "ancillary services" shall mean those special services for which charges are customarily made in addition to routine services.

(e) Payment for inpatient hospital services prior to notification of noneligibility

Notwithstanding that an individual is not entitled to have payment made under this part for inpatient hospital services furnished by any hospital, payment shall be made to such hospital (unless it elects not to receive such payment or, if payment has already been made by or on behalf of such individual, fails to refund such payment within the time specified by the Secretary) for services which are furnished to the individual prior to notification to such hospital from the Secretary of his lack of entitlement, if such payments are precluded only by reason of section 1395d of this title and if such hospital complies with the requirements of and regulations under this subchapter with respect to such payments, has acted in good faith and without knowledge of such lack of entitlement, and has acted reasonably in assuming entitlement existed. Payment under the preceding sentence may not be made for services furnished an individual pursuant to any admission after the 6th elapsed day (not including as an elapsed day Saturday, Sunday, or a legal holiday) after the day on which such admission occurred.

(f) Payment for certain inpatient hospital services furnished outside United States

(1) Payment shall be made for inpatient hospital services furnished to an individual entitled to hospital insurance benefits under section 426 of this title by a hospital located outside the United States, or under arrangements (as defined in section 1395x(w) of this title) with it, if—

(A) such individual is a resident of the United States, and

(B) such hospital was closer to, or substantially more accessible from, the residence of such individual than the nearest hospital within the United States which was adequately equipped to deal with, and was available for the treatment of, such individual's illness or injury.

(2) Payment may also be made for emergency inpatient hospital services furnished to an individual entitled to hospital insurance benefits under section 426 of this title by a hospital located outside the United States if—

(A) such individual was physically present—

(i) in a place within the United States; or

(ii) at a place within Canada while traveling without unreasonable delay by the most direct route (as determined by the Secretary) between Alaska and another State;

at the time the emergency which necessitated such inpatient hospital services occurred, and

(B) such hospital was closer to, or substantially more accessible from, such place than the nearest hospital within the United States which was adequately equipped to deal with, and was available for the treatment of, such individual's illness or injury.

(3) Payment shall be made in the amount provided under subsection (b) of this section to any hospital for the inpatient hospital services described in paragraph (1) or (2) furnished to an individual by the hospital or under arrangements (as defined in section 1395x(w) of this title) with it if (A) the Secretary would be required to make such payment if the hospital had an agreement in effect under this subchapter and otherwise met the conditions of payment hereunder, (B) such hospital elects to claim such payment, and (C) such hospital agrees to comply, with respect to such services, with the provisions of section 1395cc(a) of this title.

(4) Payment for the inpatient hospital services described in paragraph (1) or (2) furnished to an individual entitled to hospital insurance benefits under section 426 of this title may be made on the basis of an itemized bill to such individual if (A) payment for such services cannot be made under paragraph (3) solely because the hospital does not elect to claim such payment, and (B) such individual files application (submitted within such time and in such form and manner and by such person, and continuing and supported by such information as the Secretary shall by regulations prescribe) for reimbursement. The amount payable with respect to such services shall, subject to the provisions of section 1395f of this title, be equal to the amount which would be payable under subsection (d)(3) of this section.

(g) Payments to physicians for services rendered in teaching hospitals

For purposes of services for which the reasonable cost thereof is determined under section 1395x(v)(1)(D) of this title (or would be if section 1395ww of this title did not apply), payment under this part shall be made to such fund as may be designated by the organized medical staff of the hospital in which such services were furnished or, if such services were furnished in such hospital by the faculty of a medical school,
to such fund as may be designated by such faculty, but only if—
(1) such hospital has an agreement with the Secretary under section 1395cc of this title, and
(2) the Secretary has received written assurances that (A) such payment will be used by such fund solely for the improvement of care of hospital patients or for educational or charitable purposes and (B) the individuals who were furnished such services or any other persons will not be charged for such services (or, if charged, provision will be made for return of any moneys incorrectly collected).

(h) Payment for specified hospital services provided in Department of Veterans Affairs hospitals; amount of payment

(1) Payments shall also be made to any hospital operated by the Department of Veterans Affairs for inpatient hospital services furnished in a calendar year by the hospital, or under arrangements (as defined in section 1395x(w) of this title) with it, to an individual entitled to hospital benefits under section 426 of this title even though the hospital is a Federal provider of services if (A) the individual was not entitled to have the services furnished to him free of charge by the hospital, (B) the individual was admitted to the hospital in the reasonable belief on the part of the admitting authorities that the individual was a person who was entitled to have the services furnished to him free of charge, (C) the authorities of the hospital, in admitting the individual, and the individual, acted in good faith, and (D) the services were furnished during a period ending with the close of the day on which the authorities operating the hospital first became aware of the fact that the individual was not entitled to have the services furnished to him by the hospital free of charge, or (if later) ending with the first day on which it was medically feasible to remove the individual from the hospital by discharging him therefrom or transferring him to a hospital which has in effect an agreement under this subchapter.

(2) Payment for services described in paragraph (1) shall be in an amount equal to the charge imposed by the Secretary of Veterans Affairs for such services, or (if less) the amount that would be payable for such services under subsection (b) of this section and section 1395ww of this title (as estimated by the Secretary). Any such payment shall be made to the entity to which payment for the services involved would have been payable, if payment for such services had been made by the individual receiving the services involved (or by another private person acting on behalf of such individual).

(i) Payment for hospice care

(1)(A) Subject to the limitation under paragraph (2) and the provisions of section 1395x(a)(4) of this title and except as otherwise provided in this paragraph, the amount paid to a hospice program with respect to hospice care for which payment may be made under this part shall be an amount equal to the costs which are reasonable and related to the cost of providing hospice care or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations (including those authorized under section 1395x(v)(1)(A) of this title), except that no payment may be made for bereavement counseling and no reimbursement may be made for other counseling services (including nutritional and dietary counseling) as separate services.

(B) Notwithstanding subparagraph (A), for hospice care furnished on or after April 1, 1986, the daily rate of payment per day for routine home care shall be $63.17 and the daily rate of payment for other services included in hospice care shall be the daily rate of payment recognized under subparagraph (A) as of July 1, 1985, increased by $10.

(C)(i) With respect to routine home care and other services included in hospice care furnished on or after January 1, 1990, and on or before September 30, 1990, the payment rates for such care and services shall be 120 percent of such rates in effect as of September 30, 1989.

(ii) With respect to routine home care and other services included in hospice care furnished during a subsequent fiscal year (before the first fiscal year in which the payment revisions described in paragraph (6)(D) are implemented), the payment rates for such care and services shall be the payment rates in effect under this subparagraph during the previous fiscal year increased by—

(I) for a fiscal year ending on or before September 30, 1993, the market basket percentage increase (as defined in section 1395ww(b)(3)(B)(iii) of this title) for the fiscal year;

(II) for fiscal year 1994, the market basket percentage increase for the fiscal year minus 2.0 percentage points;

(III) for fiscal year 1995, the market basket percentage increase for the fiscal year minus 1.5 percentage points;

(IV) for fiscal year 1996, the market basket percentage increase for the fiscal year minus 1.5 percentage points;

(V) for fiscal year 1997, the market basket percentage increase for the fiscal year minus 0.5 percentage point;

(VI) for each of fiscal years 1998 through 2002, the market basket percentage increase for the fiscal year involved minus 1.0 percentage points, plus, in the case of fiscal year 2001, 5.0 percentage points; and

(VII) for a subsequent fiscal year (before the first fiscal year in which the payment revisions described in paragraph (6)(D) are implemented), subject to clause (iv), the market basket percentage increase for the fiscal year.

(iii) With respect to routine home care and other services included in hospice care furnished during fiscal years subsequent to the first fiscal year in which payment revisions described in paragraph (6)(D) are implemented, the payment rates for such care and services shall be the payment rates in effect under this clause during the preceding fiscal year increased by, subject to clause (iv), the market basket percentage increase (as defined in section 1395ww(b)(3)(B)(iii) of this title) for the fiscal year.

(iv) After determining the market basket percentage increase under clause (ii)(VII) or (iii), as applicable, with respect to fiscal year 2013 and each subsequent fiscal year, the Secretary shall reduce such percentage—
(I) for 2013 and each subsequent fiscal year, by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title; and

(II) subject to clause (v), for each of fiscal years 2013 through 2019, by 0.3 percentage point.

The application of this clause may result in the market basket percentage increase under clause (i)(VII) or (iii), as applicable, 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.

(v) Clause (iv)(II) shall be applied with respect to any of fiscal years 2014 through 2019 by substituting “0.0 percentage point” for “0.3 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.

(2)(A) The amount of payment made under this part for hospice care provided by (or under arrangements made by) a hospice program for an accounting year may not exceed the “cap amount” for the year (computed under subparagraph (B)) multiplied by the number of medicare beneficiaries in the hospice program in that year (determined under subparagraph (C)).

(B) For purposes of subparagraph (A), the “cap amount” for a year is $6,500, increased or decreased, for accounting years that end after October 1, 1984, by the same percentage as the percentage increase or decrease, respectively, in the medical care expenditure category of the Consumer Price Index for All Urban Consumers (United States city average), published by the Bureau of Labor Statistics, from March 1984 to the fifth month of the accounting year.

(C) For purposes of subparagraph (A), the “number of medicare beneficiaries” in a hospice program in an accounting year is equal to the number of individuals who have made an election under subsection (d) of this section with respect to the hospice program and have been provided hospice care by (or under arrangements made by) the hospice program under this part in the accounting year, such number reduced to reflect the proportion of hospice care that each such individual was provided in a previous or subsequent accounting year or under a plan of care established by another hospice program.

(D) A hospice program shall submit claims for payment for hospice care furnished in an individual’s home under this subsection only on the basis of the geographic location at which the service is furnished, as determined by the Secretary.

(3) Hospice programs providing hospice care for which payment is made under this sub-
(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 hospice program has the opportunity to review the data that is to be made public with respect to the hospice program prior to such data being made public. The Secretary shall report quality measures that relate to hospice care provided by hospice programs on the Internet website of the Centers for Medicare & Medicaid Services.

(6)(A) The Secretary shall collect additional data and information as the Secretary determines appropriate to revise payments for hospice care under this subsection pursuant to subparagraph (D) and for other purposes as determined by the Secretary. The Secretary shall begin to collect such data by not later than January 1, 2011.

(B) The additional data and information to be collected under subparagraph (A) may include data and information on—

(i) charges and payments;

(ii) the number of days of hospice care which are attributable to individuals who are entitled to, or enrolled for, benefits under this part; and

(iii) with respect to each type of service included in hospice care—

(I) the number of days of hospice care attributable to the type of service;

(II) the cost of the type of service; and

(III) the amount of payment for the type of service;

(iv) charitable contributions and other revenue of the hospice program;

(v) the number of hospice visits;

(vi) the type of practitioner providing the visit; and

(vii) the length of the visit and other basic information with respect to the visit.

(C) The Secretary may collect the additional data and information under subparagraph (A) on cost reports, claims, or other mechanisms as the Secretary determines to be appropriate.

(D)(1) Notwithstanding the preceding paragraphs of this subsection, not earlier than October 1, 2013, the Secretary shall, by regulation, implement revisions to the methodology for determining the payment rates for routine home care and other services included in hospice care under this part, as the Secretary determines to be appropriate. Such revisions may be based on an analysis of data and information collected under subparagraph (A). Such revisions may include adjustments to per diem payments that reflect changes in resource intensity in providing such care and services during the course of the entire episode of hospice care.

(ii) Revisions in payment implemented pursuant to clause (i) shall result in the same estimated amount of aggregate expenditures under this subchapter for hospice care furnished in the fiscal year in which such revisions in payment are implemented as would have been made under this subchapter for such care in such fiscal year if such revisions had not been implemented.

(E) The Secretary shall consult with hospice programs and the Medicare Payment Advisory Commission regarding the additional data and information to be collected under subparagraph (A) and the payment revisions under subparagraph (D).

(7) In the case of hospice care provided by a hospice program under arrangements under section 1395x(dd)(5)(D) of this title made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care.

(j) Elimination of lesser-of-cost-or-charges provision

(1) The lesser-of-cost-or-charges provisions (described in paragraph (2)) will not apply in the case of services provided by a class of provider of services if the Secretary determines and certifies to Congress that the failure of such provisions to apply to the services provided by that class of providers will not result in any increase in the amount of payments made for those services under this subchapter. Such change will take effect with respect to services furnished, or cost reporting periods of providers, on or after such date as the Secretary shall provide in the certification. Such change for a class of provider shall be discontinued if the Secretary determines and notifies Congress that such change has resulted in an increase in the amount of payments made under this subchapter for services provided by that class of provider.

(2) The lesser-of-cost-or-charges provisions referred to in paragraph (1) are as follows:

(A) Clause (B) of paragraph (1) and paragraph (2) of subsection (b) of this section.

(B) Section 1395m(a)(1)(B) of this title.

(C) So much of subparagraph (A) of section 1395m(a)(2) of this title as provides for payment other than of the reasonable cost of such services, as determined under section 1395x(v) of this title.

(D) Subclause (II) of clause (i) and clause (ii) of section 1395((a)(2)(B) of this title.

(k) Payments to home health agencies for durable medical equipment

The amount paid to any home health agency with respect to durable medical equipment for which payment may be made under this part shall be the amount described in section 1395m(a)(1) of this title.

(l) Payment for inpatient critical access hospital services

(1) Except as provided in the subsequent paragraphs of this subsection, the amount of payment under this part for inpatient critical access hospital services is equal to 101 percent of the reasonable costs of the critical access hospital in providing such services.

(2) In the case of a distinct part psychiatric or rehabilitation unit of a critical access hospital described in section 1395l–4(c)(2)(E) of this title, the amount of payment for inpatient critical access hospital services of such unit shall be equal to the amount of the payment that would other-
wise be made if such services were inpatient hospital services of a distinct part psychiatric or rehabilitation unit, respectively, described in the matter following clause (v) of section 1395ww(d)(1)(B) of this title.

(3) The following rules shall apply in determining payment and reasonable costs under paragraph (1) for costs described in subparagraph (C) for a critical access hospital that would be a meaningful EHR user (as would be determined under paragraph (3) of section 1395ww(n) of this title) for an EHR reporting period for a cost reporting period beginning during a payment year if such critical access hospital was treated as an eligible hospital under such section:

(i) The Secretary shall compute reasonable costs by expensing such costs in a single payment year and not depreciating such costs over a period of years (and shall include as costs with respect to cost reporting periods beginning during a payment year costs from previous cost reporting periods to the extent they have not been fully depreciated as of the period involved).

(ii) There shall be substituted for the Medicare share that would otherwise be applied under paragraph (1) a percent (not to exceed 100 percent) equal to the sum of—

(A) the Medicare share (as would be specified under paragraph (2)(D) of section 1395ww(n) of this title) for such critical access hospital if such critical access hospital was treated as an eligible hospital under such section; and

(B) 20 percentage points.

(4) The payment under this paragraph with respect to a critical access hospital shall be paid through a prompt interim payment (subject to reconciliation) after submission and review of such information (as specified by the Secretary) necessary to make such payment, including information necessary to apply this paragraph. In no case may payment under this paragraph be made with respect to a cost reporting period beginning during a payment year after 2015 and in no case may a critical access hospital receive payment under this paragraph with respect to more than 4 consecutive payment years.

(C) The costs described in this subparagraph are for costs for the purchase of certified EHR technology to which purchase depreciation (excluding interest) would apply if payment was made under paragraph (1) and not under this paragraph.

(D) For purposes of this paragraph, paragraph (4), and paragraph (5), the terms “certified EHR technology”, “eligible hospital”, “EHR reporting period”, and “payment year” have the meanings given such terms in sections 1395ww(n) of this title.

(A) Subject to subparagraph (C), for cost reporting periods beginning in fiscal year 2015 or a subsequent fiscal year, in the case of a critical access hospital that is not a meaningful EHR user (as would be determined under paragraph (3) of section 1395ww(n) of this title if such critical access hospital was treated as an eligible hospital under such section) for an EHR reporting period with respect to such fiscal year, paragraph (1) shall be applied by substituting the applicable percent under subparagraph (B) for the percent described in such paragraph (1).

(B) The percent described in this subparagraph is—

(i) for fiscal year 2015, 100.66 percent;

(ii) for fiscal year 2016, 100.33 percent; and

(iii) for fiscal year 2017 and each subsequent fiscal year, 100 percent.

(C) The provisions of subclause (II) of section 1395ww(b)(3)(B)(ix) of this title shall apply with respect to subparagraph (A) for a critical access hospital with respect to a cost reporting period beginning in a fiscal year in the same manner as such subclause applies with respect to subclause (I) of such section for a subsection (d) hospital with respect to such fiscal year.

(D) There shall be no administrative or judicial review under section 1395f(n) of this title, section 1395oo of this title, or otherwise, of—

(A) the methodology and standards for determining the amount of payment and reasonable cost under paragraph (3) and payment adjustments under paragraph (4), including selection of periods under section 1395ww(n)(2) of this title for determining, and making estimates or using proxies of, inpatient-bed-days, hospital charges, charity charges, and Medicare share under subparagraph (D) of section 1395ww(n)(2) of this title;

(B) the methodology and standards for determining a meaningful EHR user under section 1395ww(n)(3) of this title as would apply if the hospital was treated as an eligible hospital under section 1395ww(n) of this title, and the hardship exception under paragraph (4)(C);

(C) the specification of EHR reporting periods under section 1395ww(n)(6)(B) of this title as applied under paragraphs (3) and (4); and

(D) the identification of costs for purposes of paragraph (3)(C).


*So in original. Probably should be “1395ww(n)(3)(B)".*


paragraph (B), a physician, or a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician,” for “a physician” after “(C)”.  

Subsec. (a)(2)(B), (6). Pub. L. 101–234 repealed Pub. L. 100–369, §104(d)(2)(A), (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. (a)(7)(A)(i). Pub. L. 101–234, §6005(b), substituted “certify in writing, not later than 2 days after hospice care is initiated (or, if each certify verbally not later than 2 days after hospice care is initiated, not later than 2 days after hospice care is initiated),” in concluding provisions.  


Subsec. (c)(3). Pub. L. 101–234 repealed Pub. L. 100–369, §104(d)(2)(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. (1)(1)(A). Pub. L. 101–239, §6065(a)(1), inserted “and except as otherwise provided in this paragraph” after “section 1395c(a)(4) of this title”.  

Subsec. (1)(1)(C). Pub. L. 101–239, §6065(a)(2), added subpar. (C) and struck out former subpar. (C) which read as follows: “With respect to care and services furnished after such time as is working in collaboration with a physician as an uncompensated officer or director of a home health agency, which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income, payment may be made under this paragraph, free of charge or at nominal charge to the public, 80 percent of the amount which the Secretary finds will provide fair reimbursement to the home health agency.”

1986—Subsec. (1)(1)(B). Pub. L. 99–272, §9123(b)(1), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: “Notwithstanding subparagraph (A), the rate of payment per day for routine home care furnished during fiscal year 1986 shall be $53.17.”  


Pub. L. 98–369, §2336(b), inserted before period at end of third sentence “, except that such prohibition shall not apply with respect to a home health agency which is a sole community home health agency (as determined by the Secretary)”.  

Pub. L. 98–369, §2336(a), inserted sentence at end that for purposes of the preceding sentence, service by a physician as an uncompensated officer or director of a home health agency shall not constitute having a significant ownership interest in, or a significant financial or contractual relationship with, such agency.

Pub. L. 98–369, §2336(a)(4), in concluding provisions, substituted “‘or (D) for ‘(D), or (E)’” for “‘or (D) for ‘(D), or (E)’”.

Subsec. (2)(B) to (E). Pub. L. 98–369, §2335(a)(1), redesignated subpars. (C) to (E) as (B) to (D), respectively, and struck out former subpar. (B) which provided that payment could be made only if a physician certified, in the case of inpatient tuberculosis hospital services, that such services were required to be given on an inpatient basis, or by under the supervision of a physician, for the treatment of an individual for tuberculosis; and that such treatment could reasonably be expected to improve the condition for which such treatment was necessary or render the condition noncommunicable.


Subsec. (a)(5) to (8). Pub. L. 98–369, §2338(a)(3), redesignated paras. (6) to (8) as (5) to (7), respectively, and struck out former par. (5) which had provided that payment would be made only if, in the case of inpatient tuberculosis hospital services, the services were those which the record of the hospital indicate were furnished to the individual during periods when he was receiving treatment which could reasonably be expected to improve his condition or render it noncommunicable.

Subsec. (b). Pub. L. 98–369, §2321(a)(1), inserted in provisions preceding par. (1) “and other than a home health care and the payment rates for other services included in hospice care based on the costs that are reasonable and related to the costs of furnishing such care and services. The Secretary shall report to Congress on October 1 each year on such review and such adjustments and on the adequacy of the rates under this paragraph to ensure participation by an adequate number of hospice programs under this subchapter.”

Subsec. (i)(1)(A). Pub. L. 101–239, §6005(g)(3)(B)(i)(II), added subpar. (I), which read as follows: “With respect to care and services furnished after such time as is working in collaboration with a physician, or a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician,” for “a physician” after “(C)”.  

Subsec. (a)(2)(B). Pub. L. 100–369, §104(d)(2)(A), struck out “‘post-hospital’ after “in the case of” and “, for any of the conditions with respect to which he was receiving inpatient hospital services (or services which would constitute inpatient hospital services if the institution met the requirements of paragraphs (6) and (7) of section 1395c(e) of this title) prior to transfer to the skilled nursing facility or for a condition requiring such extended care services which arose after such transfer and while he was still in the facility for treatment of the condition or conditions for which he was receiving inpatient hospital services” before semicolon at end.


Subsec. (a)(7)(A)(i). Pub. L. 100–369, §104(d)(2)(C), added cl. (ii) which read as follows: “in a subsequent extension period, the medical director or physician described in clause (i)(II) certifies at the beginning of the period that the individual is terminally ill”.

Subsec. (a)(7)(B). Pub. L. 100–369, §104(d)(2)(D), substituted “equal to 100 percent” for “equal to 60 percent” and “plus 100 percent” for “plus 80 percent” and struck out “two-thirds of” after “based on”.

Subsec. (a)(7)(C). Pub. L. 100–369, §4025(a), inserted two sentences at end clarifying “confined to his home” for purposes of par. (2)(C).
health agency with respect to durable medical equipment” after “hospice care”.

Subsec. (b)(2). Pub. L. 98–369, § 238(b)(2)(A), inserted “or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this paragraph),” after “public home health agency” and “30 percent of” before the “amount.”

1981—Subsec. (g). Pub. L. 97–248, § 238(b)(1), added subpar. (A) and redesignated former subpars. (B) and (C) as (B) and (C), respectively.


Subsec. (k)(2). Pub. L. 98–369, § 23(b)(1), inserted “or”, or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this paragraph)” after “public home health agency” and “30 percent of” before the “amount.”

1983—Subsec. (g). Pub. L. 97–248, § 202(b), inserted “(or would be if section 1395sw of this title did not apply)” after “section 1395x(v)(1)(D) of this title”.

Subsec. (h)(2). Pub. L. 98–21, § 602(c), substituted “the amount that would be payable for such services under subsection (b) of this section and section 1395sw of this title” for “the reasonable costs for such services”.


Subsec. (i)(2)(A). Pub. L. 98–90, § 1(1), struck out “located in a region (as defined by the Secretary)” after “as hospice program” and “for the region” after “the cap amount”.

Subsec. (i)(2)(B). Pub. L. 98–90, § 1(2), amended subpar. (B) generally, substituting provisions establishing a hospice reimbursement cap amount of $6,500, indexed by the medical care component of the Consumer Price Index, for provisions which had established a cap of 40% of the estimated regional average medicare expenditure per beneficiary in the regular medicare program during the six months of life for persons dying of cancer.


Subsec. (b). Pub. L. 97–248, § 101(c)(1), substituted “sections 1395e and 1395ew for” “section 1395e” in provisions preceding par. (1), and substituted “until the first day of the seventh month beginning after the date the Secretary determines and notifies the Governor of the State” for “until the Secretary determines” in provisions following par. (3).

Pub. L. 97–248, § 212(c)(2)(A), inserted “(other than a hospice program providing hospice care)” after “tion by such certifying physician made prior to initiation of alcohol detoxification)”.

1980—Subsec. (a). Pub. L. 96–499, § 3930(e), inserted provision at end of subsec. (a) authorizing the Secretary to prescribe regulations to prohibit significantly interested physicians from performing the physician certification required by par. (2) for home health services.

Subsec. (a)(2)(D). Pub. L. 96–499, § 1398(b)(1), substituted “home health services” for “post-hospital home health services” and “physical, occupational, or speech” for “physical or speech and deleted”, for any of the conditions with respect to which he was receiving inpatient hospital services (or services which would constitute inpatient hospital services if the institution met the requirements of paragraphs (6) and (9) of section 1395x(e) of this title) or post-hospital extended care services “after therapy”.

Subsec. (a)(2)(E). Pub. L. 96–499, § 1398(b), inserted “or because of the severity of the dental services”, “substituted” “such services” for “such dental services”.


Subsec. (a)(1). Pub. L. 96–499, § 903(a)(1), inserted “except as provided in paragraph (3)”.


Subsec. (c). Pub. L. 96–499, § 941(b), substituted “subsection (h)” for “subsection (j)”.


1976—Subsec. (c). Pub. L. 94–377 substituted “Subject to section 1395(q) of this title, no payment” for “No payment”.

1975—Subsec. (a)(2)(E). Pub. L. 93–233, § 18(k)(1), substituted “the care, treatment, filling, or replacement of teeth or structures directly supporting teeth, the individual, because of his underlying medical condition and clinical status, requires hospitalization in connection with the provision of such dental services” for “a dental procedure, the individual suffers from impairments of such severity as to require hospitalization”.


1972—Subsec. (a). Pub. L. 92–603, §§ 226(c)(1), 227(b)(1), inserted reference to subsec. (g) of this section and section 1395qnm of this title in provisions preceding par. (1).

Subsec. (a)(1). Pub. L. 92–603, § 231(e), placed a 3-year time limitation on the time within which a written request for payment is filed, with provision for reduction of the limit to 1 year.

Subsec. (a)(2)(C). Pub. L. 92–603, §§ 234(g)(1), 276(a)(1), substituted “because the individual needs or needed on a daily basis skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services, which as a practical matter can only be provided in a skilled nursing facility on an inpatient basis,” for “on an inpatient basis because the individual needs or needed skilled nursing care on a continuing basis”, “skilled nursing facility” for “extended care facility”, and “paragraphs (6) and (9) of section 1395x(e) of this title” for “paragraphs (6) and (8) of section 1395x(e) of this title”.

Subsec. (a)(2)(D). Pub. L. 92–603, § 234(g)(1), substituted reference to par. (9) of section 1395x(e) of this title for reference to par. (8) of section 1395x(e) of this title.


Subsec. (a)(7). Pub. L. 92–603, §§ 238(a), 276(a)(3), inserted “, including any finding made in the course of a
sample or other review of admissions to the institution" after "as described in section 1395k(a)(4) of this title" in the parenthetical provisions covering the finding not made by the committee or group, and substituted "skilled nursing facility" for "extended care facility".

Subsec. (b). Pub. L. 92–603, §233(a), substituted pars. (1) and (2) for provisions describing the amount payable as the reasonable cost determined under section 1395(v) of this title.

Subsec. (f). Pub. L. 92–603, §211(a), designated existing provisions as par. (2), added pars. (1) and (3), and in par. (2) as so redesignated inserted provisions covering individuals physically present at a place within Canada while traveling without unreasonable delay by the most direct route between Alaska and another State.


Subsec. (h). Pub. L. 92–603, §§228(a), 278(b)(4), (17), added subsec. (h) and substituted "skilled nursing facility" for "extended care facility".

Subsec. (i). Pub. L. 92–603, §228(a), added subsec. (i).

1968—Subsec. (a). Pub. L. 90–248, §§126(a)(5), 126(c)(5)(B), struck out references to former subpars. (E) and (F) in last sentence.

Subsec. (a)(2)(A) to (E). Pub. L. 92–248, 128(a)(1), (2), struck out subpar. (A) which provided that there be a physician's certification of medical necessity for admissions to hospitals other than psychiatric or tuberculosis institutions, and redesignated subpars. (B) to (E) as (A) to (D), respectively.

Subsec. (a)(2)(F). Pub. L. 90–248, 128(a)(5)(A), struck out subpar. (F) which provided that there be a physician's certification for services furnished to outpatients.

Subsec. (a)(3)(C) to (6). Pub. L. 90–248, 128(a)(3), (4), added par. (3) and redesignated former pars. (3) to (6) as (4) to (7), respectively.

Subsec. (d). Pub. L. 90–248, §129(c)(6)(A), struck out reference to outpatient hospital diagnostic services from provisions requiring payment for emergency hospital services.

Subsec. (d)(1) to (3). Pub. L. 90–248, §143(c), designated existing provisions as par. (1), inserted "in a calendar year" after "furnished in first sentence of paragraph (1)" and added subpar. (C) to (par. (1), and added pars. (2) and (3).

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, §3108(b), Mar. 23, 2010, 124 Stat. 418, provided that: "The amendments made by this section (amending this section) shall apply to items and services furnished on or after January 1, 2011."

Pub. L. 111–148, title VI, §6404(b), Mar. 23, 2010, 124 Stat. 768, provided that:

"In GENERAL.—The amendments made by subsection (a) [amending this section and sections 1395m and 1395n of this title] shall apply to services furnished on or after January 1, 2010."

"(2) SERVICES FURNISHED BEFORE 2010.—In the case of services furnished before January 1, 2010, a bill or request for payment under section 1814(a)(1), 1842(b)(3)(B), or 1833(a) [probably means section 1814(a)(1) (42 U.S.C. 1395a(a)(1), 1842(b)(3)(B) 1833a (42 U.S.C. 1395a(a)) of act Aug. 14, 1935] shall be filed not later than [sic] December 31, 2010."
or after Jan. 1, 1990, see section 4062(e) of Pub. L. 98–218, set out as a note under section 1395d of this title.

**Effective Date of 1989 Amendments**

Section 4062(e) of Pub. L. 100–203, as amended by Pub. L. 100–203, set out as a note under section 1395f of this title.

**Effective Date of 1987 Amendment**

Section 2321(g) of Pub. L. 98–218, set out as a note under section 1395f of this title.

**Effective Date of 1984 Amendments**

Section 2321(g) of Pub. L. 98–218, set out as a note under section 1395f of this title.

**Effective Date of 1983 Amendments**

Amendment by section 2354(b)(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.

Amendment by section 2354(c)(1)(A) of Pub. L. 98–369 effective as if originally included in Pub. L. 98–498, see section 2354(e)(2) of Pub. L. 98–369, set out as a note under section 1320a–1 of this title.

**Effective Date of 1982 Amendments**

Amendment by section 930(e), (f) of Pub. L. 96–499 effective with respect to services furnished on or after July 1, 1981, see section 930(e)(1) of Pub. L. 96–499, set out as a note under section 1395f of this title.

Amendment by section 931(b) of Pub. L. 96–499 provided that: "The amendments made by this section [amending this section and section 1395f of this title] shall be effective as if they had been originally included in the Deficit Reduction Act of 1981 [Pub. L. 98–369]."

Amendment by section 931(e) of Pub. L. 96–499 provided that: "The amendments made by this section [amending this section and sections 1395x, 1395rr, and 1396d of this title] shall apply to items and services furnished on or after January 1, 1989, to premiums for January 1, 1990, and to blood or blood cells furnished on or after Jan. 1, 1989, see section 101(a) of Pub. L. 100–366, set out as a note under section 1395f of this title.

**Effective Date of 1981 Amendment**

Amendment by section 1212(b) of Pub. L. 97–35 applicable to hospice care provided on or after Nov. 1, 1983, see section 1212(b)(1) of Pub. L. 97–248, as amended, set out as a note under section 1395f of this title.

**Effective Date of 1980 Amendment**

Amendment by section 930(d) of Pub. L. 96–499 provided that: "The amendments made by this section [amending this section and sections 1395x and 1395y of this title] shall apply with respect to services provided on or after July 1, 1981."

**Effective Date of 1978 Amendment**

Amendment by Pub. L. 95–292 effective with respect to services, supplies, and equipment furnished after the third calendar month beginning after June 13, 1978, except that provisions for the implementation of an incentive reimbursement system for dialysis services furnished in facilities and providers to become effective with respect to a facility’s or provider’s first accounting period beginning after the last day of the third month following the date of the enactment of this Act [July 18, 1984]."
yss to become effective on Apr. 1, 1979, see section 6 of Pub. L. 95–292, set out as a note under section 426 of this title.

Effective Date of 1977 Amendment
Section 23(c) of Pub. L. 95–142 provided that: "The amendments made by this section [amending this title] shall apply to inpatient hospital services furnished on and after July 1, 1974."

Effective Date of 1973 Amendment
Section 18(c)(2) of Pub. L. 93–233 provided that: "The amendments made by subsection (k) [amending this section and section 1395y of this title] shall be effective with respect to services furnished on or after June 30, 1973, see section 227(g) of Pub. L. 92–603, set out as a note under section 1395d of this title.

Effective Date of 1972 Amendment
Section 211(d) of Pub. L. 92–603 provided that: "The amendments made by this section [amending this section and sections 1396l, 1396u, 1396x, and 1395y of this title] shall apply to services furnished with respect to admissions occurring after December 31, 1972."

Amendment by section 226(c)(1) 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.

Amendment by section 227(b) 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 201(b) of Pub. L. 92–603 provided that: "The amendment made by subsection (a) [amending this section] and any regulations adopted pursuant to such amendment shall apply with respect to plans of care initiated on or after January 1, 1973, and with respect to admission to skilled nursing facilities and home health plans initiated on or after such date."

Section 233(f) of Pub. L. 92–603 provided that: "The amendments made by subsections (a) and (b) [amending this section and section 1395y of this title] shall apply to services furnished by hospitals, extended care facilities, and home health agencies in accounting periods beginning after December 31, 1972. The amendments made by subsections (c), (d), and (e) [amending sections 706, 709, and 1396b of this title] shall apply with respect to services furnished by hospitals in accounting periods beginning after December 31, 1972. See, also, section 16 of Pub. L. 92–233, set out below."

Amendment by section 234(g)(1) of Pub. L. 92–603 applicable with respect to providers of services for fiscal years beginning after fifth month following October 1972; see section 234(i) of Pub. L. 92–603, set out as a note under section 1395x of this title.

Section 238(b) of Pub. L. 92–603 provided that: "The amendment made by subsection (a) [amending this section and section 1395y of this title] shall apply with respect to services furnished after the second month following the month in which this Act is enacted [October 1972]."

Section 247(c) of Pub. L. 92–603 provided that: "The amendments made by this section [amending this section and section 1396d of this title] shall be effective with respect to services furnished after December 31, 1972."

Section 256(d) of Pub. L. 92–603 provided that: "The amendments made by this section [amending this section and sections 1395x and 1396y of this title] shall apply with respect to admissions occurring after the second month following the month in which this Act is enacted [October 1972]."

Section 256(e) of Pub. L. 92–603 provided that: "The amendments made by this section [amending this section and section 1396d of this title] shall be effective with respect to services furnished after December 31, 1972."

Amendment by section 281(e) of Pub. L. 92–603 applicable in the case of services furnished (or deemed to have been furnished) after October 1970, see section 281(g) of Pub. L. 92–603, set out as a note under section 1395gg of this title.
Pub. L. 110–148, title VI, §607(d), Mar. 23, 2010, 124 Stat. 770, provided that: "The requirements pursuant to the amendments made by subsections (a) [amending this section and section 1395m of this title] and (b) [amending section 1395m of this title] shall apply in the case of physicians making certifications for home health services under title XIX of the Social Security Act [42 U.S.C. 1395 et seq.] in the same manner and to the same extent as such requirements apply in the case of physicians making such certifications under title XVIII of such Act [42 U.S.C. 1395 et seq.]."

**STUDY AND REPORT ON EFFECT OF 2000 AMENDMENT**

Pub. L. 106–554, §1(a)(6) [title V, §507(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–501, provided that:

"(1) IN GENERAL.—The Comptroller General of the United States shall conduct an evaluation of the effect of the amendment [amending this section and section 1395m of this title] on the cost of and access to home health services under the medicare program under title XVIII of the Social Security Act [this subchapter]."

"(2) REPORT.—Not later than 1 year after the date of enactment of this Act [Dec. 21, 2000], the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1)."

**STUDY AND REPORT ON PHYSICIAN CERTIFICATION REQUIREMENT FOR HOSPICE BENEFITS**

Pub. L. 106–554, §1(a)(6) [title III, §322(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–501, provided that:

"(1) STUDY.—The Secretary of Health and Human Services shall conduct a study to examine the appropriateness of the certification regarding terminal illness of an individual under section 1814(a)(7) of the Social Security Act [42 U.S.C. 1395f(a)(7)] that is required in order for such individual to receive hospice benefits under the medicare program under title XVIII of such Act [this subchapter]. In conducting such study, the Secretary shall take into account the effect of the amendment made by subsection (a) [amending this section]."

"(2) 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 to Congress a report on the study conducted under paragraph (1), together with any recommendations for legislation that the Secretary deems appropriate."

**TEMPORARY INCREASE IN PAYMENT FOR HOSPICE CARE**

Pub. L. 106–554, §1(a)(6) [title III, §321(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–361, provided that:

"(1) STUDY.—The Secretary of Health and Human Services shall increase the payment rate in effect for fiscal year 2001, by 0.5 percent, and for fiscal year 2002, by 0.5 percent."

"(b) ADDITIONAL PAYMENT NOT BUILT INTO THE BASE.—The Secretary of Health and Human Services shall not include any additional payment made under this subsection (a) in updating the payment rate, as increased by the applicable market basket percentage increase for the fiscal year involved under section 1814(i)(1)(C)(i) of that Act [42 U.S.C. 1395f(i)(1)(C)(i)]."

**STUDY AND REPORT TO CONGRESS REGARDING MODIFICATION OF PAYMENT RATES FOR HOSPICE CARE**


"(a) STUDY.—The Comptroller General of the United States shall conduct a study to determine the feasibility and advisability of updating the payment rates and the cap amount determined with respect to a fiscal year under section 1814(i) of the Social Security Act [42 U.S.C. 1395f(i)] (regarding terminal illness hospice care provided to medicare beneficiaries for high-cost hospice care provided to medicare beneficiaries). Such study shall examine the cost factors used to determine such rates and such amount and shall evaluate whether such factors should be modified, eliminated, or supplemented with additional cost factors.

"(b) REPORT.—Not later than one year after the date of 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), together with any recommendations for legislation that the Comptroller General determines to be appropriate as a result of such study."

**STUDY OF METHODS TO COMPENSATE HOSPICES FOR HIGH-COST CARE**

Section 6016 of Pub. L. 101–239 directed Secretary of Health and Human Services to conduct a study of high-cost hospice care provided to medicare beneficiaries under the medicare program, evaluate the ability of hospice programs participating in the medicare program to provide such high-cost care to such patients, develop methods to compensate such programs for providing such high-cost care, and submit, not later than Apr. 1, 1991, a report to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate on the study, including in the report any recommendations developed by the Secretary to compensate hospice programs for providing high-cost hospice care to medicare beneficiaries.

**CONTINUATION OF BAD DEBT RECOGNITION FOR HOSPICE SERVICES**

Section 4008(c) of Pub. L. 100–203, as amended by Pub. L. 100–647, title VIII, §8402, Nov. 10, 1987, 102 Stat. 3798; Pub. L. 101–239, title VI, §6023(a), Dec. 19, 1989, 103 Stat. 2167, provided that: 'In making payments to hospitals under title XVIII of the Social Security Act, the Secretary of Health and Human Services shall not make any change in the policy in effect on August 1, 1987, with respect to payment under title XVIII of the Social Security Act to providers of service for reasonable costs relating to unrecovered costs associated with unpaid deductible and coinsurance amounts incurred under such title (including criteria for what constitutes a reasonable collection effort, including criteria for indigency determination procedures, for record keeping, and for determining whether to refer a claim to an external collection agency). The Secretary may not require a hospital to change its bad debt collection policy if a fiscal intermediary, in accordance with the rules in effect as of August 1, 1987, with respect to criteria for indigency determination procedures, record keeping, and determining whether to refer a claim to an external collection agency, has accepted such policy before that date, and the Secretary may not collect from the hospital on the basis of an expectation of a change in the hospital's collection policy.'

Section 6023(b) of Pub. L. 101–239 provided that: 'The amendment made by subsection (a) [amending section 4008(c) of Pub. L. 100–203, set out above] shall take effect as if included in the enactment of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203].'


**PROVIDERS OF SERVICES TO CALCULATE AND REPORT LESSER-OF-COST-OR-CHARGES DETERMINATIONS SEPARATELY WITH RESPECT TO PAYMENTS UNDER PART A AND B OF THIS SUBCHAPTER; ISSUANCE OF REGULATIONS**

Section 2308(a) of Pub. L. 98–369 provided that: 'The Secretary of Health and Human Services shall issue
regulations which require, for purposes of title XVIII of the Social Security Act [this subchapter], that providers of services calculate and report the lesser-of-cost-or-charge determinations separately with respect to payments for services under part A and services under part B of such title (other than clinical diagnostic laboratory tests paid under section 1833(h) [section 1385(h) of this title], and that payments under such title be based upon such separate determinations. Such regulations shall apply to cost reporting periods beginning on or after October 1, 1986."

Determination of Nominal Charges for Applying Nominality Test

Section 2306(b)(1) of Pub. L. 98–369 provided that: "For purposes of applying the nominality test under sections 1814(b)(2) [subsec. (b)(2) of this section] and 1833(a)(2)(B)(ii) [section 1395f(a)(2)(B)(ii) of this title] of the Social Security Act, the Secretary shall, in addition to those rules for establishing nominality which the Secretary determines to be appropriate, provide that charges representing 60 percent or less of costs shall be considered nominal. The charges used in making such determinations shall be the charges actually billed to charge-paying patients who are not entitled to benefits under either part of such title [sections 1395c et seq., 1395] et seq. of this title]. Such determination shall be made separately with respect to payments for services under part A and services under part B of such title (other than clinical diagnostic laboratory tests paid under section 1833(h), or on the basis of inpatient and outpatient services, except that the determinations need not be made separately for home health services if the Secretary finds that such separation is not appropriate."

Study and Report Relating to the Reimbursement Method and Benefit Structure for Hospice Care; Supervision of Report by Comptroller General

Section 122(j), formerly §122(i), of Pub. L. 97–248, re-designated §122(i), by Pub. L. 97–448, title III, §309(a)(6), Jan. 12, 1983, 96 Stat. 2408, provided that: "(1) The Secretary of Health and Human Services shall conduct a study and, prior to January 1, 1986, report to the Congress on whether or not the reimbursement method and benefit structure (including copayments) for hospice care under title XVIII of the Social Security Act [this subchapter] are fair and equitable and promote the most efficient provision of hospice care. Such report shall include the feasibility and advisability of providing for prospective reimbursement for hospice care, an evaluation of the inclusion of payment for outpatient drugs, an evaluation of the need to alter the method of reimbursement for nutritional, dietary, and bereavement counseling as hospice care, and any recommendations for legislative changes in the hospice care reimbursement or benefit structure."

"(2) The Comptroller General shall monitor and evaluate the study and the preparation of the report under paragraph (1)."

Waiver of Limitations To Allow Pre-Existing Hospices To Participate as a Hospice Program

Section 122(k), formerly §122(j), of Pub. L. 97–248, as redesignated and amended by Pub. L. 97–448, title III, §309(a)(6), (7), Jan. 12, 1983, 96 Stat. 2408, provided that: "The Secretary of Health and Human Services shall grant waivers of the limitations imposed by section 1814(a)(2) [subsec. (a)(2) of this section] (relating to the cap amount), section 1861(dd)(1)(G) of such Act [section 1395x(dd)(1)(G) of this title] (relating to the limitations on the frequency and number of respite care days), section 1395x(dd)(2)(A)(ii) of such Act [section 1395x(dd)(2)(A)(ii) of this title] (relating to the aggregate limit on the number of days of inpatient care), as may be necessary to allow any institution which commenced operations as a hospice prior to January 1, 1975, to participate until October 1, 1986, in a viable manner as a hospice program under title XVIII of the Social Security Act [this subchapter]."

Medicare Payment Basis for Services Provided by Agencies and Providers; Effective Date

Section 16 of Pub. L. 93–233 provided that: "In the administration of titles V, XVIII, and XIX of the Social Security Act [subchapters V, XVIII, and XIX of this chapter], the amount payable under such title to any provider of services on account of services provided by such hospital, skilled nursing facility, or home health agency shall be determined (for any period with respect to which the amendments made by section 233 of Public Law 92–663 [this section and sections 706, 709, 1395f, and 1396b of this title]) would, except for the provisions of this section, be applicable in like manner as if the date contained in the first and second sentences of subsection (f) of such section 233 [set out as an Effective Date of 1972 Amendment note above] were December 31, 1973, rather than December 31, 1972."

§ 1395g. Payments to providers of services

(a) Determination of amount

The Secretary shall periodically determine the amount which should be paid under this part to each provider of services with respect to the services furnished by it, and the provider of services shall be paid, at such time or times as the Secretary believes appropriate (but not less often than monthly) and prior to audit or settlement by the Government Accountability Office, from the Federal Hospital Insurance Trust Fund, the amounts so determined, with necessary adjustments on account of previously made overpayments or underpayments; except that no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider for such part for the period with respect to which the amounts are being paid or any prior period.

(b) Conditions

No payment shall be made to a provider of services which is a hospital for or with respect to services furnished by it for any period with respect to which it is deemed, under section 1395x(w)(2) of this title, to have in effect an arrangement with a quality control and peer review organization for the conduct of utilization review activities by such organization unless such hospital has paid to such organization the amount due (as determined pursuant to such section) to such organization for the review activities conducted by it pursuant to such arrangements or such hospital has provided assurances satisfactory to the Secretary that such organization will promptly be paid the amount so due to it from the proceeds of the payment claimed by the hospital. Payment under this subchapter for utilization review activities provided by a quality control and peer review organization pursuant to an arrangement or deemed arrangement with a hospital under section 1395x(w)(2) of this title shall be calculated without any requirement that the reasonable cost of such activities be apportioned among the patients of such hospital, if any, to whom such activities were not applicable.

(c) Payments under assignment or power of attorney

No payment which may be made to a provider of services under this subchapter for any service
furnished to an individual shall be made to any other person under an assignment or power of attorney; but nothing in this subsection shall be construed (1) to prevent the making of such a payment in accordance with an assignment from the provider if such assignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (2) to preclude an agent of the provider of services from receiving any such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services for or in connection with the billing or collection of payments due such provider under this subchapter is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment.

(d) **Accrual of interest on balance of excess or actual collection of any such payment.**

Whenever a final determination is made that the amount of payment made under this part to a provider of services was in excess of or less than the amount of payment that is due, and payment of such excess or deficit is not made (or effected by offset) within 30 days of the date of the determination, interest shall accrue on the balance of such excess or deficit not paid or offset (to the extent that the balance is owed by or owing to the provider) at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payments.

(e) **Periodic interim payments**

(1) The Secretary shall provide payment under this part for inpatient hospital services furnished by a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title, and including a distinct psychiatric or rehabilitation unit of such a hospital) and a subsection (d) Puerto Rico hospital (as defined in section 1395ww(d)(9)(A) of this title) on a periodic interim payment basis (rather than on the basis of bills actually submitted) in the following cases:

(A) Upon the request of a hospital which is paid through an agency or organization with an agreement with the Secretary under section 1395h of this title, if the agency or organization meets such requirements for three consecutive calendar months.

(B) In the case of a hospital that—

(i) has a disproportionate share adjustment percentage (as established in clause (iv) of such section) of at least 5.1 percent (as computed for purposes of establishing the average standardized amounts for discharges occurring during fiscal year 1987), and

(ii) requests payment on such basis, but only if the hospital was being paid for inpatient hospital services on such a periodic interim payment basis as of June 30, 1987, and continues to meet the requirements (in effect as of October 1, 1986) applicable to payment on such a basis.

(C) In the case of a hospital that—

(i) is located in a rural area, (ii) has 100 or fewer beds, and (iii) requests payment on such basis, but only if the hospital was being paid for inpatient hospital services on such a periodic interim payment basis as of June 30, 1987, and continues to meet the requirements (in effect as of October 1, 1986) applicable to payment on such a basis.

(2) The Secretary shall provide (or continue to provide) for payment on a periodic interim payment basis (under the standards established under section 1395ww(d)(1)(B) of title 42, Code of Federal Regulations, as in effect on October 1, 1986) in the cases described in subparagraphs (A) through (D) with respect to—

(A) inpatient hospital services of a hospital that is not a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title);

(B) a hospital which is receiving payment under a State hospital reimbursement system under section 1395f(b)(3) or 1395ww(c) of this title, if payment on a periodic interim payment basis is an integral part of such reimbursement system;

(C) extended care services;

(D) hospice care; and

(E) inpatient critical access hospital services;

if the provider of such services elects to receive, and qualifies for, such payments.

(3) In the case of a subsection (d) hospital or a subsection (d) Puerto Rico hospital (as defined for purposes of section 1395ww of this title) which has significant cash flow problems resulting from operations of its intermediary or from unusual circumstances of the hospital’s operation, the Secretary may make available appropriate accelerated payments.

(4) A hospital created by the merger or consolidation of two or more hospitals or hospital campuses shall be eligible to receive periodic interim payment on the basis described in paragraph (1)(B) if—

(A) at least one of the hospitals or campuses received periodic interim payment on such basis prior to the merger or consolidation; and

(B) the merging or consolidating hospitals or campuses would each meet the requirement of paragraph (1)(B)(i) if such hospitals or campuses were treated as independent hospitals for purposes of this subchapter.

AMENDMENTS
Subsec. (e)(2)(E), Pub. L. 108–173, § 465(c)(1)(B)(D), added subpar. (E). 1997—Subsec. (e)(2)(C) to (E), Pub. L. 105–33 inserted “and” at end of subpar. (C), redesignated subpar. (E) as (D), and struck out former subpar. (D) which read as follows: “home health services; and”.
1980—Subsec. (c). Pub. L. 96–473 substituted “for or in connection with” for “for on in connection with”.
1975—Pub. L. 94–182 designated existing provisions as subsec. (a) and added subsec. (b).

EFFECTIVE DATE OF 2003 AMENDMENT
Pub. L. 108–173, title IV, § 405(c)(2), Dec. 8, 2003, 117 Stat. 2387, provided that: “With respect to periodic interim payments to critical access hospitals for inpatient critical access hospital services under section 1815(e)(2)(E) of the Social Security Act [subsec. (e)(2)(E) of this section], as added by paragraph (1), the Secretary of Health and Human Services shall develop alternative methods for the timing of such payments.”

TRANSITION
Section 9311(a)(3) of Pub. L. 99–559 provided that: “Upon the request of a hospital which—
“(A) as of June 30, 1987, is receiving payments under part A of title XVIII of such Act [this part] for inpatient hospital services on a periodic interim payment basis,
“(B) requests continuation of payment on such basis, and
“(C) is paid through an agency or organization with an agreement under section 1816 of such Act [section 1395f of this title],
the Secretary of Health and Human Services shall continue payment on such a basis until not earlier than the end of the first period of three consecutive calendar months (beginning no earlier than April 1987) during all of which the agency or organization has met the requirements of section 1816(e)(2)(C) of such Act (relating to prompt payment of claims).”

DELAY IN PERIODIC INTERIM PAYMENTS
Section 120 of Pub. L. 97–248 provided that: “Notwithstanding section 1815(a) of the Social Security Act [subsec. (a) of this section], in the case of a hospital which is paid periodic interim payments under such section, the Secretary of Health and Human Services shall provide that—
“(1) with respect to the last 21 days for which such payments would otherwise be made during fiscal year 1983, such payments shall be deferred until fiscal year 1984; and
“(2) with respect to the last 21 days for which such payments would otherwise be made during fiscal year 1984, such payments shall be deferred until fiscal year 1985.”

§ 1395h. Provisions relating to the administration of part A

(a) In general
The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1395kk–1 of this title.


(c) Prompt payment of claims
(2)(A) Each contract under section 1395kk–1 of this title that provides for making payments under this part shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to not less than 95 percent of all claims submitted under this subchapter—
(i) which are clean claims, and
(ii) for which payment is not made on a periodic interim payment basis,
within the applicable number of calendar days after the date on which the claim is received.
(B) In this paragraph:
(i) The term “clean claim” means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this subchapter.
(ii) The term “applicable number of calendar days” means—
   (I) with respect to claims received in the 12-month period beginning October 1, 1986, 30 calendar days,
   (II) with respect to claims received in the 12-month period beginning October 1, 1987, 26 calendar days,
   (III) with respect to claims received in the 12-month period beginning October 1, 1988, 25 calendar days,
   (IV) with respect to claims received in the 12-month period beginning October 1, 1989, and claims received in any succeeding 12-month period ending on or before September 30, 1993, 24 calendar days, and
   (V) with respect to claims received in the 12-month period beginning October 1, 1993, and claims received in any succeeding 12-month period, 30 calendar days.
(C) If payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in clause (ii) of subparagraph (B)) after a clean claim (as defined in clause (i) of such subparagraph) is received from a hospital, critical access hospital, skilled nursing facility, home health agency, hospice program, comprehensive outpatient rehabilitation facility, or rehabilitation agency that is not receiving payments on a periodic interim payment basis with respect to such services, interest shall be paid at the rate used for purposes of section 3902(a) of title 31 (relating to interest penalty for failure to make prompt payments) for the period beginning on the day after the required payment date and ending on the date on which payment is made.

(3) Each contract under section 1395kk–1 of this title that provides for making payments under this part shall provide that no payment shall be issued, mailed, or otherwise transmitted with respect to any claim submitted under this subchapter within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph, the term “applicable number of calendar days” means—
(i) with respect to claims submitted electronically as prescribed by the Secretary, 13 days, and
(ii) with respect to claims submitted otherwise, 28 days.


(j) Denial of claim; notification and reconsideration

A contract with a medicare administrative contractor under section 1395kk–1 of this title with respect to the administration of this part shall require that, with respect to a claim for home health services, extended care services, or post-hospital extended care services submitted by a provider to such medicare administrative contractor that is denied, such medicare administrative contractor—

(1) furnish the provider and the individual with respect to whom the claim is made with a written explanation of the denial and of the statutory or regulatory basis for the denial; and

(2) in the case of a request for reconsideration of a denial, promptly notify such individual and the provider of the disposition of such reconsideration.

(k) Annual reporting requirement on erroneous payment recovery

A contract with a medicare administrative contractor under section 1395kk–1 of this title with respect to the administration of part A shall require that such medicare administrative contractor submit an annual report to the Secretary describing the steps taken to recover payments made for items or services for which payment has been or could be made under a primary plan (as defined in section 1385(y)(2)(A) of this title).


AMENDMENTS


2003—Pub. L. 108–173, § 911(b)(1), substituted “Provisions relating to the administration of part A” for “Use of public or private agencies or organizations to facilitate payment to providers of services” in section catchline.

Subsec. (a). Pub. L. 108–173, § 911(b)(2), amended subsec. (a) generally. Prior to amendment, subsec. (a) authorized Secretary to enter into agreements with agen-
cies or organizations to determine and pay amounts under this part.


Subsec. (c)(3)(A). Pub. L. 108–173, § 911(b)(4)(B), substituted “contract under section 1395kk–1 of this title that provides for making payments under this part” for “agreement under this section”.

Subsecs. (d) to (t). Pub. L. 108–173, § 911(b)(5), struck out subsecs. (d) to (t), which related to nomination of agency or organization, designation of agency or organization to perform provider services, standards, criteria, and procedures for evaluation of agency or organization’s performance, termination of agreement, bonding requirement for officers and employees, and liability of certifying and disbursing officers.

Subsec. (j). Pub. L. 108–173, § 911(b)(6), in introductory provisions, substituted “A contract with a Medicare administrative contractor under section 1395kk–1 of this title with respect to the administration of this part” for “An agreement with an agency or organization under this section” and “such Medicare administrative contractor” for “such agency or organization” in two places.

Subsec. (k). Pub. L. 108–173, § 911(b)(6), substituted “A contract with a Medicare administrative contractor under section 1395kk–1 of this title with respect to the administration of this part” for “An agreement with an agency or organization under this section” and “such Medicare administrative contractor” for “such agency or organization”.

Subsec. (l). Pub. L. 108–173, § 911(b)(7), struck out subsec. (l), which prohibited any activity pursuant to an agreement under this section that is carried out pursuant to a contract under the Medicare Integrity Program.

Subsec. (c)(2)(C). Pub. L. 105–33 substituted “‘rural hospital’” for “‘rural hospital’” in the fiscal year 1989, 66 percent of reconsiderations) and 90 percent of reconsiderations within 90 days and the extent to which its determinations are reversed on appeal.”, and added par. (2).

1989—Subsec. (c)(1). Pub. L. 101–239, § 2320(d)(1), inserted at end “The Secretary may not require, as a condition of entering into or renewing an agreement under this section or under section 1395hh of this title, that a fiscal intermediary match data obtained other than in its activities under this part with data used in the administration of this part for purposes of identifying situations in which the provisions of section 1395y(b) of this title may apply.”


Subsec. (k). Pub. L. 101–234 repealed Pub. L. 100–360, § 203(f), 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.


1987—Subsec. (c)(1). Pub. L. 100–203, § 403(a)(1), inserted at end “The Secretary shall cause to have published in the Federal Register, by not later than September 1 before each fiscal year, data, standards, and methodology to be used to establish budgets for fiscal intermediaries under this section for that fiscal year, and shall cause to be published in the Federal Register for public comment, at least 90 days before such data, standards, and methodology are published, the data, standards, and methodology proposed to be used.”

Subsec. (c)(2)(C). Pub. L. 100–203, § 4065(d)(1), substituted “‘hospice program, comprehensive outpatient rehabilitation facility, or rehabilitation agency’” for “or hospice program”.

Subsec. (c)(3). Pub. L. 100–203, § 4031(a)(1), added par. (3).

Subsec. (f). Pub. L. 100–203, § 4023(b), inserted at end “Such standards and criteria shall include with respect to claims for services furnished under this part by any provider of services other than a hospital whether such agency or organization is able to process 75 percent of reconsiderations within 60 days (except in the case of the fiscal year 1989, 66 percent of reconsiderations) and 90 percent of reconsiderations within 90 days and the extent to which its determinations are reversed on appeal.”, and added par. (2).

1986—Subsec. (f)(1)(A). Pub. L. 103–432, § 151(b)(2)(A), inserted at end “Such standards and criteria shall be published in the Federal Register, and opportunity shall be provided for public comment prior to implementation. Such standards and criteria shall include with respect to claims for services furnished under this part by any provider of services other than a hospital whether such agency or organization is able to process 75 percent of reconsiderations within 60 days (except in the case of the fiscal year 1989, 66 percent of reconsiderations) and 90 percent of reconsiderations within 90 days and the extent to which its determinations are reversed on appeal.”, and added par. (2).
and inserted provision that the standards and criteria be published in the Federal Register and an opportunity be provided for public comment prior to implementation.


1980—Subsec. (e)(2). Pub. L. 96–499, § 930(c), inserted "subject to the provisions of paragraph (4)"


1977—Subsec. (a). Pub. L. 95–142, §14a(a)(1), inserted provisions relating to applicability to providers assigned to the agency or organization under subsec. (e) of this section.

Subsec. (b). Pub. L. 95–142, §14a(a)(2), substituted provisions setting forth criteria for agreements by the Secretary or renewal of such agreements with agencies or organizations, for agreements by the Secretary with agencies or organizations.

Subsecs. (e), (f). Pub. L. 95–142, §14a(a)(4), (5), added subsecs. (e) and (f). Former subsec. (e) and (f) redesignated (g) and (h), respectively.

Subsec. (g). Pub. L. 95–142, §14a(a)(3), (4), redesignated former subsec. (e) as (g) and inserted provisions relating to applicability of standards, etc., developed under subsec. (f) of this section. Former subsec. (g) redesignated (i).

Subsecs. (h), (i). Pub. L. 95–142, §14a(a)(4), redesignated former subsecs. (f) and (g) as (h) and (i), respectively.


Effectiveness Date of 2006 Amendment
Pub. L. 109–171, title V, §5202(b), Feb. 8, 2006, 120 Stat. 47, provided that: "The amendments made by this section [amending this section and section 1395u of this title] shall apply to claims submitted on or after January 1, 2006."

Effectiveness Date of 2003 Amendment
Amendment by section 911(b) of Pub. L. 106–173 effective Dec. 22, 2003, except as provided otherwise provided, with transition rules authorizing Secretary of Health and Human Services to continue to enter into agreements under this section prior to such date, and provisions authorizing continuation of Medicare Integrity Program functions during the period that begins on Dec. 8, 2003, and ends on Oct. 1, 2011, see section 911(d) of Pub. L. 108–173, set out as an Effective Date; Transition Rule note under section 1395k–1 of this title.

Effectiveness Date of 1997 Amendment
Amendment by Pub. L. 105–33 applicable to services furnished on or after Oct. 1, 1997.

Effectiveness Date of 1994 Amendment
Section 151(b)(4) of Pub. L. 103–332 provided that: "The amendments made by paragraphs (1) and (2) [amending this section and section 1395u of this title] shall apply to contracts with fiscal intermediaries and carriers under title XVIII of the Social Security Act [this subchapter] for contract years beginning with 1995."

Effectiveness Date of 1993 Amendment
Section 13508(c) of Pub. L. 103–66 provided that: "The amendments made by this section [amending this section and section 1395u of this title] shall apply to claims received on or after October 1, 1993."

Effectiveness Date of 1989 Amendments
Section 6202(d)(3) of Pub. L. 101–239 provided that: "The amendments made by this subsection [amending this section and section 1395u of this title] shall apply to agreements and contracts entered into on or before September 30, 1989."

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.

Effectiveness Date of 1988 Amendment
Amendment by section 203(f) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100–360, set out as a note under section 1320c–3 of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(e)(1)(B) 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. 100–360, see section 411(a) of Pub. L. 100–360, set out as a note to OBRA; Effective Date note under section 106 of Title I, General Provisions.

Effectiveness Date of 1987 Amendment
Section 4031(a)(3)(A) of Pub. L. 100–203 provided that: "The amendments made by paragraphs (1) and (2) [amending this section and section 1395u of this title] shall apply to claims received on or after July 1, 1988."

Section 4032(c)(1) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, §411(e)(1)(C), July 1, 1988, 102 Stat. 775, provided that: "(A) The amendment made by subsection (a) [amending this section] shall apply with respect to claims received on or after January 1, 1988."

"(B) The amendment made by subsection (b) [amending this section] shall apply with respect to reconsiderations requested on or after October 1, 1988."

Section 4036(a) of Pub. L. 100–203 provided that: "The amendments made by this section [amending this section and sections 1395u and 1395hh of this title] shall take effect on the date of the enactment of this Act [Dec. 22, 1987] and shall apply to budgets for fiscal years beginning with fiscal year 1989."

Section 4038(d)(2) of Pub. L. 100–203 provided that: "(A) The amendment made by paragraph (1) [amending this section] shall apply to claims received on or after the date of enactment of this Act [Dec. 22, 1987]."

"(B) The Secretary of Health and Human Services shall provide for such timely amendments to agreements under section 1816 [this section], and regulations, to such extent as may be necessary to implement the amendment made by paragraph (1)."

Effectiveness Date of 1986 Amendment
Section 9311(d) of Pub. L. 99–509 provided that: "(1) Except as provided in paragraph (2), the amendments made by subsections (b) and (c) [amending this section and section 1395u of this title] shall apply to claims received on or after November 1, 1986.

"(2) Sections 1816(c)(2)(C) [sic] and 1842(c)(2)(C) of the Social Security Act [subsec. (c)(2)(C) of this section and section 1395u(c)(2)(C) of this title], as added by such amendments, shall apply to claims received on or after April 1, 1987."

"(3) The Secretary of Health and Human Services shall provide for such timely amendments to agreements under section 1816 of the Social Security Act [this section] and contracts under section 1842 of such Act [section 1395u of this title], and regulations, to such extent as may be necessary to implement the provisions of this Act on a timely basis."

Amendment by section 9352(a)(2) of Pub. L. 99–509 to be implemented by Secretary of Health and Human Services not later than 6 months after Oct. 21, 1986, see section 9352(c)(1) of Pub. L. 99–509, set out as a note under section 1320c–2 of this title.

Effectiveness Date of 1984 Amendment
Section 2325(d)(3) of Pub. L. 98–369 provided that: "The amendments made by this subsection [amending this section and section 1395u of this title] shall apply to agreements and contracts entered into on or before September 30, 1984."

Effectiveness 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 Amendment**


**Effective Date of 1977 Amendment**

Section 14(c), (d) of Pub. L. 95–142 provided that:

‘‘(c) The amendment made by paragraphs (2) and (3) of subsection (a) [amending this section] to the extent that they apply to cost reports of providers of services for accounting periods ending on or after June 30, 1973, see section 1395g of this title.

‘‘(d) Except as provided in subsection (c), the amendment made by subsection (a)(2) [amending this section] shall apply to agreements entered into or renewed on or after the date of enactment of this Act [Oct. 26, 1977].’’

**Effective Date of 1972 Amendment**

Amendment by Pub. L. 92–692 applicable with respect to cost reports of providers of services for accounting periods ending on or after June 30, 1973, see section 243(c) of Pub. L. 92–693, set out as an Effective Date note under section 1395oo of this title.

**Advisory Committee on Medicare Home Health Claims**

Section 427 of Pub. L. 100–203, which provided that the Administrator of the Health Care Financing Administration was to establish an advisory committee to be known as the Advisory Committee on Medicare Home Health Claims to study the reasons for the increase in the number of claims for home health services during 1986 and 1987, the ramifications of such increase, and the need to reform the process involved in such denials, was repealed by Pub. L. 101–234, title III, § 301(a), Dec. 15, 1989, 103 Stat. 1985.

**Amendments to Agreements and Contracts Necessary to Implement Section 4031(a) of Pub. L. 100–203**

Section 4031(a)(3)(B) of Pub. L. 100–203 provided that: ‘‘The Secretary of Health and Human Services shall provide for such timely amendments to agreements under section 1816 of the Social Security Act [this section] and contracts under section 1842 of the Social Security Act [section 1395u of this title], and regulations, to such extent as may be necessary to implement the provisions of this subsection [amending this section and section 1395a of this title] on a timely basis.’’

**Prohibition of Policies Other Than as Provided by Section 4031 of Pub. L. 100–203 Intended to Slow Down Medicare Payments; Budget Considerations**

Section 4031(b), (c) of Pub. L. 100–203 provided that, notwithstanding any other provision of law, the Secretary of Health and Human Services was not authorized to issue, after Dec. 22, 1987, and before Oct. 1, 1990, any final regulation, instruction, or other policy change which was primarily intended to have the effect of slowing down claims processing, or delaying payment of claims, under this subchapter, and that section 4031 of Pub. L. 100–203, amending this section and section 1395a of this title and enacting provisions set out as notes under this section, was a necessary (but secondary) result of a significant policy change.

**Amendments to Agreements and Contracts Necessary to Implement Section 4032(a), (b) of Pub. L. 100–203**

Section 4032(c)(2) provided that: ‘‘The Secretary of Health and Human Services shall provide for such timely amendments to agreements under section 1816 [this section] and contracts under section 1842 of the Social Security Act [section 1395u of this title], and regulations, to such extent as may be necessary to implement the amendments made by subsections (a) and (b) [amending this section] on a timely basis.’’

**Replacement of Agency, Organization, or Carrier Processing Medicare Claims; Number of Agreements and Contracts Authorized for Fiscal Years 1985 Through 1993**

Section 2326(a) of Pub. L. 98–369, as amended by Pub. L. 98–437, § 369(a)(2), Nov. 8, 1984, 98 Stat. 2325; Pub. L. 99–509, title IX, § 9232(b), Oct. 21, 1986, 100 Stat. 2016; Pub. L. 101–239, title VI, § 6215(a), Dec. 19, 1989, 103 Stat. 2352; Pub. L. 103–422, title I, § 115(a), Oct. 31, 1994, 108 Stat. 4433, provided that: ‘‘During each fiscal year (beginning with fiscal year 1985 and ending with fiscal year 1993), the Secretary of Health and Human Services may enter into not more than two agreements under section 1816 of the Social Security Act [this section], and not more than two contracts under section 1842 of such Act [section 1395u of this title], on the basis of competitive bidding, without regard to the nominating process under section 1816(a) of such Act or cost reimbursement provisions under sections 1816(c) or 1842(c) of such Act during the term of the agreement. Such procedure may be used only for the purpose of replacing an agency or organization or carrier which over a 2-year period of time has been in the lowest 20th percentile of agencies and organizations or carriers having agreements or contracts under the respective section, as measured by the Secretary’s cost and performance criteria. In addition, beginning with fiscal year 1990 and any subsequent fiscal year the Secretary may enter into such additional agreements and contracts without regard to such cost reimbursement provisions if the fiscal intermediary or carrier involved and the Secretary agree to waive such provisions, but the Secretary may not take any action that has the effect of requiring that the intermediary or carrier agree to waive such provisions, including requiring such a waiver as a condition for entering into or renewing such an agreement or contract. Any agency or organization or carrier selected on the basis of competitive bidding must perform all of the duties listed in section 1816(a) of such Act, or the duties listed in paragraphs (1) through (4) of section 1812(a) of such Act, as the case may be, and must be a health insuring organization (as determined by the Secretary).’’

Section 1395b of Pub. L. 103–422 provided that: ‘‘The amendment made by subsection (a) [amending section 2326(a) of Pub. L. 98–369, set out above] shall apply beginning with fiscal year 1994.’’

Section 623(b) of Pub. L. 101–239 provided that: ‘‘The amendments made by subsection (a) [amending section 2326(a) of Pub. L. 98–369, set out above] shall apply beginning with fiscal year 1990.’’

**Audit and Medical Claims Review**

Pub. L. 97–248, title I, § 118, Sept. 3, 1982, 96 Stat. 335, as amended by Pub. L. 99–272, title IX, § 9216(a), Apr. 7, 1986, 100 Stat. 190, provided that, in addition to any funds otherwise provided for payments to intermediaries and carriers under agreements entered into under this section and section 1395u of this title, there were transferred from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Fund an additional $45,000,000 for each of fiscal years 1983, 1984, and 1985, and $105,000,000 for each of fiscal years 1986, 1987, and 1988 for payments to such intermediaries and carriers under such agreements to be used exclusively for purposes of carrying out provider cost audits, of reviewing medical necessity, and of recovering third-party liability payments.

**Developmental Date for Standards, Criteria, and Procedures Pursuant to Subsec. (f) of This Section**

Section 14(b) of Pub. L. 95–142 directed the Secretary of Health, Education, and Welfare to develop the stand-
§ 1395i. Federal Hospital Insurance Trust Fund

(a) Creation; deposits; transfers from Treasury

There is hereby created on the books of the Treasury of the United States a trust fund to be known as the “Federal Hospital Insurance Trust Fund” (hereinafter in this section referred to as the “Trust Fund”). The Trust Fund shall consist of such gifts and bequests as may be made as provided in section 401(i)(1) of this title, and such amounts as may be deposited in, or appropriated to, such fund as provided in this part. There are hereby appropriated to the Trust Fund, such amounts as may be deposited in, or appropriated to, such fund as provided in this part.

(b) Board of Trustees; composition; meetings; duties

With respect to the Trust Fund, there is hereby created a body to be known as the Board of Trustees of the Trust Fund (hereinafter in this section referred to as the “Board of Trustees”) to—

(1) Hold the Trust Fund;

(2) Report to the Congress not later than the first day of April of each year on the operation and status of the Trust Fund during the preceding fiscal year and on its expected operation and status during the current fiscal year and the next 2 fiscal years; Each report provided under paragraph (2) beginning with the report in 2005 shall include the information specified in section 801(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.\(^1\)

(3) Report immediately to the Congress whenever the Board is of the opinion that the amount of the Trust Fund is unduly small; and

(4) Review the general policies followed in managing the Trust Fund, and recommend changes in such policies, including necessary changes in the provisions of law which govern the way in which the Trust Fund is to be managed.

The amounts appropriated by the preceding section shall be transferred from time to time from the general fund in the Treasury to the Trust Fund, such amounts to be determined on the basis of estimates by the Secretary of the Treasury by applying the applicable rate of tax under section 3111(b) of the Internal Revenue Code of 1986 with respect to self-employment income reported to the Secretary of the Treasury or his delegate pursuant to subtitle F of such Code after December 31, 1965, as determined by the Secretary of the Treasury by applying the applicable rates of tax under such sections to such wages, which wages shall be certified by the Commissioner of Social Security on the basis of records of wages established and maintained by the Commissioner of Social Security in accordance with such reports; and

(2) the taxes imposed by section 3101(b) of the Internal Revenue Code of 1986 with respect to wages reported to the Secretary of the Treasury or his delegate pursuant to subtitle F of such Code after December 31, 1965, as determined by the Secretary of the Treasury by applying the applicable rates of tax under such sections to such wages, which wages shall be certified by the Commissioner of Social Security on the basis of records of wages established and maintained by the Commissioner of Social Security in accordance with such reports; and

(3) Report to the Congress not later than the first day of April of each year on the operation and status of the Trust Fund during the preceding fiscal year and on its expected operation and status during the current fiscal year and the next 2 fiscal years; Each report provided under paragraph (2) beginning with the report in 2005 shall include the information specified in section 801(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.\(^1\)

(4) Review the general policies followed in managing the Trust Fund, and recommend changes in such policies, including necessary changes in the provisions of law which govern the way in which the Trust Fund is to be managed.

The report provided for in paragraph (2) shall include a statement of the assets of, and the disbursements made from, the Trust Fund during the preceding fiscal year, an estimate of the expected income to, and disbursements to be made from, the Trust Fund during the current fiscal year and each of the next 2 fiscal years, and a statement of the actuarial status of the Trust Fund. Such report shall also include an actuarial opinion by the Chief Actuary of the Centers for Medicare & Medicaid Services certifying that the techniques and methodologies used are generally accepted within the actuarial profession and that the assumptions and cost estimates used are reasonable. Such report shall be printed as a House document of the session of the Congress to which the report is made. A person serving on the Board of Trustees shall not be considered to be a fiduciary and shall not be personally liable for actions taken in such capacity with respect to the Trust Fund.

\(^1\) So in original. See 2003 Amendment note below.
(c) Investment of Trust Fund by Managing Trustee

It shall be the duty of the Managing Trustee to invest such portion of the Trust Fund as is not, in his judgment, required to meet current withdrawals. Such investments may be made only in interest-bearing obligations of the United States or in obligations guaranteed as to both principal and interest by the United States. For such purpose such obligations may be acquired (1) on original issue at the issue price, or (2) by purchase of outstanding obligations at the market price. The purposes for which obligations of the United States may be issued under chapter 31 of title 31 are hereby extended to authorize the issuance at par of public-debt obligations for purchase by the Trust Fund. Such obligations issued for purchase by the Trust Fund shall have maturities fixed with due regard for the needs of the Trust Fund and shall bear interest at a rate equal to the average market yield (computed by the Managing Trustee on the basis of market quotations as of the end of the calendar month next preceding the date of such issue) on all marketable interest-bearing obligations of the United States then forming a part of the public debt which are not due or callable until after the expiration of 4 years from the end of such calendar month; except that where such average market yield is not a multiple of one-eighth of 1 per centum, the rate of interest on such obligations shall be the multiple of one-eighth of 1 per centum nearest such market yield. The Managing Trustee may purchase other interest-bearing obligations of the United States or obligations guaranteed as to both principal and interest by the United States, on original issue or at the market price, only where he determines that the purchase of such other obligations is in the public interest.

(d) Authority of Managing Trustee to sell obligations

Any obligations acquired by the Trust Fund (except public-debt obligations issued exclusively to the Trust Fund) may be sold by the Managing Trustee at the market price, and such public-debt obligations may be redeemed at par plus accrued interest.

(e) Interest on and proceeds from sale or redemption of obligations

The interest on, and the proceeds from the sale or redemption of, any obligations held in the Trust Fund shall be credited to and form a part of the Trust Fund.

(f) Payment of estimated taxes

(1) The Managing Trustee is directed to pay from time to time from the Trust Fund into the Treasury the amount estimated by him as taxes imposed under section 3121(h) which are subject to refund under section 6413(c) of the Internal Revenue Code of 1986 with respect to wages paid after December 31, 1965. Such taxes shall be determined on the basis of the records of wages established and maintained by the Commissioner of Social Security in accordance with the wages reported to the Secretary of the Treasury or his delegate pursuant to subtitle F of the Internal Revenue Code of 1986, and the Commissioner of Social Security shall furnish the Managing Trustee such information as may be required by the Managing Trustee for such purpose.

The payments by the Managing Trustee shall be covered into the Treasury as repayments to the account for refunding internal revenue collections.

(2) Repayments made under paragraph (1) shall not be available for expenditures but shall be carried to the surplus fund of the Treasury. If it subsequently appears that the estimates under such paragraph in any particular period were too high or too low, appropriate adjustments shall be made by the Managing Trustee in future payments.

(g) Transfers from other Funds

There shall be transferred periodically (but not less often than once each fiscal year) to the Trust Fund from the Federal Old-Age and Survivors Insurance Trust Fund and from the Federal Disability Insurance Trust Fund amounts equivalent to the amounts not previously so transferred which the Secretary of Health and Human Services shall have certified as overpayments (other than amounts so certified to the Railroad Retirement Board pursuant to section 1395gg(b) of this title. There shall be transferred periodically (but not less often than once each fiscal year) to the Trust Fund from the Railroad Retirement Account amounts equivalent to the amounts not previously so transferred which the Secretary of Health and Human Services shall have certified as overpayments to the Railroad Retirement Board pursuant to section 1395gg(b) of this title.

(h) Payments from Trust Fund amounts certified by Secretary

The Managing Trustee shall also pay from time to time from the Trust Fund such amounts as the Secretary of Health and Human Services certifies are necessary to make the payments provided for by this part, and the payments with respect to administrative expenses in accordance with section 401(g)(1) of this title.

(i) Payment of travel expenses for travel within United States; reconsideration interviews and proceedings before administrative law judges

There are authorized to be made available for expenditure out of the Trust Fund such amounts as are required to pay travel expenses, either on an actual cost or commuted basis, to parties, their representatives, and all reasonably necessary witnesses for travel within the United States (as defined in section 410(i) of this title) to attend reconsideration interviews and proceedings before administrative law judges with respect to any determination under this subchapter. The amount available under the preceding sentence for payment for air travel by any person shall not exceed the coach fare for air travel between the points involved unless the use of first-class accommodations is required (as determined under regulations of the Secretary) because of such person’s health condition or the unavailability of alternative accommodations; and the amount available for other travel by any person shall not exceed the cost of travel (between the points involved) by the most economical and expeditious means of transportation appropriate to such person’s health con-
diction, as specified in such regulations. The amount available for payment under this subsection for travel by a representative to attend an administrative proceeding before an administrative law judge or other adjudicator shall not exceed the maximum amount allowable under this subsection for such travel originating within the geographic area of the office having jurisdiction over such proceeding.

(j) Loans from other Funds; interest; repayment; report to Congress

(1) If at any time prior to January 1988 the Managing Trustee determines that borrowing authorized under this subsection is appropriate in order to meet the need for financing the benefit payments from the Federal Hospital Insurance Trust Fund, the Managing Trustee may, subject to paragraph (5), borrow such amounts as he determines to be appropriate from either the Federal Old-Age and Survivors Insurance Trust Fund or the Federal Disability Insurance Trust Fund for transfer to and deposit in the Federal Hospital Insurance Trust Fund.

(2) In any case where a loan has been made to the Federal Hospital Insurance Trust Fund under paragraph (1), there shall be transferred on the last day of each month after such loan is made, from such Trust Fund to the lending Trust Fund, the total interest accrued to such day with respect to the unrepaid balance of such loan at a rate equal to the rate which the lending Trust Fund would earn on the amount involved if the loan were an investment under subsection (c) of this section (even if such an investment would earn interest at a rate different than the rate earned by investments redeemed by the lending fund in order to make the loan).

(3)(A) If in any month after a loan has been made to the Federal Hospital Insurance Trust Fund under paragraph (1), the Managing Trustee determines that the assets of such Trust Fund are sufficient to permit repayment of all or part of any loans made to such Fund under paragraph (1), he shall make such repayments as he determines to be appropriate.

(B)(i) If on the last day of any year after a loan has been made under paragraph (1) by the Federal Old-Age and Survivors Insurance Trust Fund or the Federal Disability Insurance Trust Fund, the Managing Trustee determines that the Hospital Insurance Trust Fund ratio exceeds 15 percent, he shall transfer from such Trust Fund to the lending Trust Fund an amount that—

(I) together with any amounts transferred to another trust fund under this paragraph for such year, will reduce the Hospital Insurance Trust Fund ratio to 15 percent; and

(II) does not exceed the outstanding balance of such loan.

(ii) Amounts required to be transferred under clause (i) shall be transferred on the last day of the first month of the year succeeding the year in which the determination described in clause (i) is made.

(iii) For purposes of this subparagraph, the term “Hospital Insurance Trust Fund ratio” means, with respect to any calendar year, the ratio of—

(I) the balance in the Federal Hospital Insurance Trust Fund, as of the last day of such calendar year; to

(II) the amount estimated by the Secretary to be the total amount to be paid from the Federal Hospital Insurance Trust Fund during the calendar year following such calendar year (other than payments of interest on, and repayments of, loans from the Federal Old-Age and Survivors Insurance Trust Fund and the Federal Disability Insurance Trust Fund under paragraph (1)), and reducing the amount of any transfer to the Railroad Retirement Account by the amount of any transfers into such Trust Fund from the Railroad Retirement Account.

(C)(i) The full amount of all loans made under paragraph (1) (whether made before or after January 1, 1983) shall be repaid at the earliest feasible date and in any event no later than December 31, 1989.

(ii) For the period after December 31, 1987 and before January 1, 1990, the Managing Trustee shall transfer each month from the Federal Hospital Insurance Trust Fund to any Trust Fund that is owed any amount by the Federal Hospital Insurance Trust Fund on a loan made under paragraph (1), an amount not less than an amount equal to (I) the amount owed to such Trust Fund by the Federal Hospital Insurance Trust Fund at the beginning of such month (plus the interest accrued on the outstanding balance of such loan during such month), divided by (II) the number of months elapsing after the preceding month and before January 1990. The Managing Trustee may, during this period, transfer larger amounts than prescribed by the preceding sentence.

(4) The Board of Trustees shall make a timely report to the Congress of any amounts transferred (including interest payments) under this subsection.

(5)(A) No amounts may be loaned by the Federal Old-Age and Survivors Insurance Trust Fund or the Federal Disability Insurance Trust Fund under paragraph (1) during any month if the OASDI trust fund ratio for such month is less than 10 percent.

(B) For purposes of this paragraph, the term “OASDI trust fund ratio” means, with respect to any month, the ratio of—

(i) the combined balance in the Federal Old-Age and Survivors Insurance Trust Fund and the Federal Disability Insurance Trust Fund, reduced by the outstanding amount of any loan (including interest thereon) theretofore made to either such Trust Fund from the Federal Hospital Insurance Trust Fund under section 401(l) of this title, as of the last day of the second month preceding such month, to

(ii) the amount obtained by multiplying by twelve the total amount which (as estimated by the Secretary) will be paid from the Federal Old-Age and Survivors Insurance Trust Fund and the Federal Disability Insurance Trust Fund during the month for which such ratio is to be determined for all purposes authorized by section 401 of this title (other than payments of interest on, or repayments of, loans from the Federal Hospital Insurance Trust Fund under section 401(l) of this title).
but excluding any transfer payments between such trust funds and reducing the amount of any transfers to the Railroad Retirement Account by the amount of any transfers into either such trust fund from that Account.

(k) Health Care Fraud and Abuse Control Account

(1) Establishment

There is hereby established in the Trust Fund an expenditure account to be known as the “Health Care Fraud and Abuse Control Account” (in this subsection referred to as the “Account”).

(2) Appropriated amounts to Trust Fund

(A) In general

There are hereby appropriated to the Trust Fund—

(i) such gifts and bequests as may be made as provided in subparagraph (B);

(ii) such amounts as may be deposited in the Trust Fund as provided in sections 242(b) and 242(c) of the Health Insurance Portability and Accountability Act of 1996, and subchapter XI of this chapter; and

(iii) such amounts as are transferred to the Trust Fund under subparagraph (C).

(B) Authorization to accept gifts

The Trust Fund is authorized to accept on behalf of the United States money gifts and bequests made unconditionally to the Trust Fund, for the benefit of the Account or any activity financed through the Account.

(C) Transfer of amounts

The Managing Trustee shall transfer to the Trust Fund, under rules similar to the rules in section 9601 of the Internal Revenue Code of 1986, an amount equal to the sum of the following:

(i) Criminal fines recovered in cases involving a Federal health care offense (as defined in section 24(a) of title 18);

(ii) Civil monetary penalties and assessments imposed in health care cases, including amounts recovered under this subchapter and subchapters XI and XIX of this chapter, and chapter 38 of title 31 (except as otherwise provided by law);

(iii) Amounts resulting from the forfeiture of property by reason of a Federal health care offense;

(iv) Penalties and damages obtained and otherwise creditable to miscellaneous receipts of the general fund of the Treasury obtained under sections 3729 through 3733 of title 31 (known as the False Claims Act), in cases involving claims related to the provision of health care items and services (other than funds awarded to a relator, for restitution or otherwise authorized by law).

(D) Application

Nothing in subparagraph (C)(iii) shall be construed to limit the availability of recoveries and forfeitures obtained under title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.) for the purpose of providing equitable or remedial relief for employee welfare benefit plans, and for participants and beneficiaries under such plans, as authorized under such title.

(3) Appropriated amounts to Account for fraud and abuse control program, etc.

(A) Departments of Health and Human Services and Justice

(i) In general

There are hereby appropriated to the Account from the Trust Fund such sums as the Secretary and the Attorney General certify are necessary to carry out the purposes described in subparagraph (C), to be available without further appropriation until expended, in an amount not to exceed—

(I) for fiscal year 1997, $104,000,000;

(II) for each of the fiscal years 1998 through 2003, the limit for the preceding fiscal year, increased by 15 percent;

(III) for each of fiscal years 2004, 2005, and 2006, the limit for fiscal year 2003; and

(IV) for each fiscal year after fiscal year 2006, the limit under this clause for the preceding fiscal year, increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) over the previous year.

(ii) Medicare and medicaid activities

For each fiscal year, of the amount appropriated in clause (i), the following amounts shall be available only for the purposes of the activities of the Office of the Inspector General of the Department of Health and Human Services with respect to the programs under this subchapter and subchapter XIX of this chapter—

(I) for fiscal year 1997, not less than $60,000,000 and not more than $70,000,000;

(II) for fiscal year 1998, not less than $80,000,000 and not more than $90,000,000;

(III) for fiscal year 1999, not less than $90,000,000 and not more than $100,000,000;

(IV) for fiscal year 2000, not less than $110,000,000 and not more than $120,000,000;

(V) for fiscal year 2001, not less than $120,000,000 and not more than $130,000,000;

(VI) for fiscal year 2002, not less than $140,000,000 and not more than $150,000,000;

(VII) for each of fiscal years 2003, 2004, 2005, and 2006, not less than $150,000,000 and not more than $160,000,000;

(VIII) for fiscal year 2007, not less than $160,000,000, increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) over the previous year; and

(IX) for each fiscal year after fiscal year 2007, not less than the amount required under this clause for the preceding fiscal year, increased by the percentage increase in the consumer price index for all urban consumers (all items;
United States city average) over the previous year.

(B) Federal Bureau of Investigation

There are hereby appropriated from the general fund of the United States Treasury and hereby appropriated to the Account for transfer to the Federal Bureau of Investigation to carry out the purposes described in subparagraph (C), to be available without further appropriation until expended—

(i) for fiscal year 1997, $47,000,000;
(ii) for fiscal year 1998, $56,000,000;
(iii) for fiscal year 1999, $66,000,000;
(iv) for fiscal year 2000, $76,000,000;
(v) for fiscal year 2001, $88,000,000;
(vi) for fiscal year 2002, $101,000,000;
(vii) for each of fiscal years 2003, 2004, 2005, and 2006, $114,000,000; and
(viii) for each fiscal year after fiscal year 2006, the amount to be appropriated under this subparagraph for the preceding fiscal year, increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) over the previous year.

(C) Use of funds

The purposes described in this subparagraph are to cover the costs (including equipment, salaries and benefits, and travel and training) of the administration and operation of the health care fraud and abuse control program established under section 1320a-7c(a) of this title, including the costs of—

(i) prosecuting health care matters (through criminal, civil, and administrative proceedings);
(ii) investigations;
(iii) financial and performance audits of health care programs and operations;
(iv) inspections and other evaluations; and
(v) provider and consumer education regarding compliance with the provisions of subchapter XI of this chapter.

(4) Appropriated amounts to Account for Medicare Integrity Program

(A) In general

There are hereby appropriated to the Account from the Trust Fund for each fiscal year such amounts as are necessary for activities described in subparagraph (B), (C), and (D) and to carry out the Medicare Integrity Program under section 1395ddd of this title, subject to subparagraphs (B), (C), and (D) and to be available without further appropriation until expended.

(B) Amounts specified

Subject to subparagraph (C), the amount appropriated under subparagraph (A) for a fiscal year is as follows:

(i) For fiscal year 1997, such amount shall be not less than $430,000,000 and not more than $440,000,000.
(ii) For fiscal year 1998, such amount shall be not less than $490,000,000 and not more than $500,000,000.
(iii) For fiscal year 1999, such amount shall be not less than $550,000,000 and not more than $560,000,000.

(iv) For fiscal year 2000, such amount shall be not less than $620,000,000 and not more than $630,000,000.
(v) For fiscal year 2001, such amount shall be not less than $670,000,000 and not more than $680,000,000.
(vi) For fiscal year 2002, such amount shall be not less than $690,000,000 and not more than $700,000,000.
(vii) For each fiscal year after fiscal year 2002, such amount shall be not less than $710,000,000 and not more than $720,000,000.

(C) Adjustments

The amount appropriated under subparagraph (A) for a fiscal year is increased as follows:

(i) For fiscal year 2006, $100,000,000.
(ii) For each fiscal year after 2010, by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) over the previous year.

(D) Expansion of the Medicare-Medicaid Data Match Program

The amount appropriated under subparagraph (A) for a fiscal year is further increased as follows for purposes of carrying out section 1395ddd(b)(6) of this title for the respective fiscal year:

(i) $12,000,000 for fiscal year 2006.
(ii) $24,000,000 for fiscal year 2007.
(iii) $36,000,000 for fiscal year 2008.
(iv) $48,000,000 for fiscal year 2009.
(v) $60,000,000 for fiscal year 2010 and each fiscal year thereafter.

(5) Annual report

Not later than January 1, the Secretary and the Attorney General shall submit jointly a report to Congress which identifies—

(A) the amounts appropriated to the Trust Fund for the previous fiscal year under paragraph (2)(A) and the source of such amounts; and
(B) the amounts appropriated from the Trust Fund for such year under paragraph (3) and the justification for the expenditure of such amounts.

(6) GAO report

Not later than June 1, 1998, and January 1 of 2000, 2002, and 2004, the Comptroller General of the United States shall submit a report to Congress which—

(A) identifies—

(i) the amounts appropriated to the Trust Fund for the previous two fiscal years under paragraph (2)(A) and the source of such amounts; and
(ii) the amounts appropriated from the Trust Fund for such fiscal years under paragraph (3) and the justification for the expenditure of such amounts;

(B) identifies any expenditures from the Trust Fund with respect to activities not involving the program under this subchapter;

(C) identifies any savings to the Trust Fund, and any other savings, resulting from expenditures from the Trust Fund; and

(D) analyzes such other aspects of the operation of the Trust Fund as the Comptroller...
General of the United States considers appropriate.

(7) Additional funding

In addition to the funds otherwise appropriated to the Account from the Trust Fund under paragraphs (3) and (4) and for purposes described in paragraphs (3)(C) and (4)(A), there are hereby appropriated an additional $10,000,000 to such Account from such Trust Fund for each of fiscal years 2011 through 2020. The funds appropriated under this paragraph shall be allocated in the same proportion as the total funding appropriated with respect to paragraphs (3)(A) and (4)(A) was allocated with respect to fiscal year 2010, and shall be available without further appropriation until expended.

(8) Additional funding

(A) in general

In addition to the funds otherwise appropriated to the Account from the Trust Fund under paragraphs (3)(C) and (4)(A) and for purposes described in paragraphs (3)(C) and (4)(A), there are hereby appropriated to such Account from such Trust Fund the following additional amounts:

(i) For fiscal year 2011, $95,000,000.

(ii) For fiscal year 2012, $55,000,000.

(iii) For each of fiscal years 2013 and 2014, $30,000,000.

(iv) For each of fiscal years 2015 and 2016, $20,000,000.

(B) Allocation

The funds appropriated under this paragraph shall be allocated in the same proportion as the total funding appropriated with respect to paragraphs (3)(A) and (4)(A) was allocated with respect to fiscal year 2010, and shall be available without further appropriation until expended.

References in Text

The Internal Revenue Code of 1986, referred to in subsec. (a)(1), (2), (f)(1), and (k)(2)(C), is classified generally to Title 26, Internal Revenue Code. Subtitle F of such Code appears at section 6001 et seq. of Title 26. Section 801(a) of the Medicare Prescription Drug Improvement, and Modernization Act of 2003, referred to in subsec. (b)(2), is section 801(a) of Pub. L. 108–173, which is set out as a note under this section.

Sections 242(b) and 249(b) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (k)(2)(A)(i), are sections 242(b) and 249(b) of Pub. L. 104–191, which are set out as notes under this section.


Amendments


Subsec. (k)(3)(A)(i)(V). Pub. L. 111–148, § 6402(i)(2)(A)(ii), struck out subcl. (V) which read as follows: "for each fiscal year after fiscal year 2010, the limit under this clause for fiscal year 2010."


Subsec. (k)(3)(A)(ii)(X). Pub. L. 111–148, § 6402(i)(2)(B)(iii), struck out subcl. (X) which read as follows: "for each fiscal year after fiscal year 2010, not less than the amount required under this clause for fiscal year 2010."
year after fiscal year 2003" and semicolon for period at
end, and added subcls. (IV) and (V).

Subsec. (k)(3)(A)(ix)(VI) to (X). Pub. L. 109–432, § 303(b), in intradoc-

tory provisions inserted "until expended" after "with- out further appropriation", in cl. (vi) struck out "and at end, in cl. (vii) substituted "for each of fiscal years 2003, 2004, 2005, and 2006" for "for each fiscal year after fiscal year 2002" and semicolon for period at end, and added subcls. (VII) to (X).

Subsec. (k)(3)(B). Pub. L. 109–432, § 303(b), in introduc-
tory provisions inserted "until expended" after "with- out further appropriation", in cl. (vi) struck out "and at end, in cl. (vii) substituted "for each of fiscal years 2003, 2004, 2005, and 2006" for "for each fiscal year after fiscal year 2002" and semicolon for period at end, and added cls. (viii) and (ix).

tituted "subparagraphs (B), (C), and (D)" for "subpara- graph (B)".

Subsec. (k)(4)(B). Pub. L. 109–171, § 5204(1), sub-
tituted "subparagraph (c), the amount" for "The amount" in introductory provisions.

Subsec. (k)(4)(C). Pub. L. 109–171, § 5204(1), added sub-
par. (C).


tence of introductory provisions, substituted "Centers for Medicare & Medicaid Services" for "Health Care Financing Administration", and, in second sen-
tence of concluding provisions, substituted "Chief Ac-
tuary of the Centers for Medicare & Medicaid Services" for "Chief Actuarial Officer of the Health Care Financ-
ing Administration".

Subsec. (b)(2). Pub. L. 108–173, § 801(d)(1), inserted at end "Each report provided under paragraph (2) begin-
ing with the report in 2005 shall include the informa-
tion specified in section 801(a) of the Medicare Prescrip-

tituted semicolon for comma at end.

tituted "the programs under this subchapter and sub-
chapter XIX of this chapter" for "the Medicare and medicaid programs" in introductory provisions.

Subsec. (k)(4)(B). Pub. L. 108–173, § 796(a)(8), sub-
tituted "program under this subchapter" for "Medi-
care program under this subchapter".


1997—Subsec. (k)(6). Pub. L. 105–33 inserted "June 1, 1998, and" after "Not later than" in introductory provi-
sions.


1994—Subsec. (a). Pub. L. 103–296, § 108(c)(1)(A), sub-
tituted "Commissioner of Social Security" for "Secre-
try of Health and Human Services" wherever app-
lying.

Subsec. (b). Pub. L. 103–296, § 108(c)(1)(B), inserted "the Commissioner of Social Security," after "com-
posed of" in introductory provisions.

Subsec. (f)(1). Pub. L. 102–296, § 108(c)(1)(C), sub-
tituted "Commissioner of Social Security" for "Sec-
retary of Health and Human Services" in two places.

1990—Subsec. (i). Pub. L. 101–938 inserted at end "The amount available for payment under this subsection for travel by a representative to attend an administrative proceeding before an administrative law judge or other adjudicator shall not be the maximum amount al-
lowable under this subsection for such travel originat-
ing within the geographic area of the office having ju-
risdiction over such proceeding.

1989—Subsec. (b). Pub. L. 101–234 repealed Pub. L. 100–360, § 212(c)(3), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (b). Pub. L. 100–647 inserted after first sentence "A member of the Board of Trustees serving as a member of the public and nominated and con-
firmed to fill a vacancy occurring during a term shall be nominated and confirmed only for the remainder of such term. An individual nominated and confirmed as a member of the public may serve only for the expiration of such member's term until the earlier of the time at which the member's successor takes of-
fice or the time at which a report of the Board is first pro-
vided under paragraph (2) after the expiration of the member's term."

Pub. L. 100–360 inserted after sixth sentence "Such re-
port shall also identify (and treat separately) those out-
lays from the Trust Fund which are also outlays from the Medicare Catastrophic Coverage Account cre-
ated under section 1395–2 of this title and those out-
lays for which there are amounts transferred into the Federal Hospital Insurance Catastrophic Coverage Re-
serve Fund."


Subsec. (b). Pub. L. 99–272 struck out provision at end of penultimate sentence that certification shall not refer to economic assumptions underlying Trustee's re-
port.


1984—Subsec. (a). Pub. L. 98–369, § 2376(a), in prov-
sions following par. (2) substituted "from time to time" for "monthly on the first day of each calendar month", changed "paid to or deposited into the Treasury" for "to be paid to or deposited into the Treasury during such month", and struck out provision that all amounts transferred to the Trust Fund under the preceding sentence had to be invested by the Managing Trustee in the same man-
ner and to the same extent as the other assets of the Trust Fund, and the Trust Fund had to pay interest to the general fund on the amount so transferred on the first day of any month at a rate calculated on a daily basis, and applied against the difference between the amount so transferred on such first day and the amount which would have been transferred to the Trust Fund up to that day under the procedures in effect on January 1, 1983 equal to the rate earned by the invest-
ments of the Trust Fund in the same month under sub-
sec. (c).

Subsec. (a)(1), (2). Pub. L. 98–369, § 2563(j)(2)(F)(ii), sub-

Subsec. (c). Pub. L. 98–369, § 2563(j)(2)(F)(ii), sub-
tituted "under chapter 31 of title 31" for "under the Second Liberty Bond Act, as amended".

Subsec. (f)(1), (g), (h). Pub. L. 98–369, § 2563(j)(2)(F)(ii), sub-

sions following par. (2) substituted "from time to time" for "monthly on the first day of each calendar month" for "from time to time", substituted "to be paid to or deposited into the Treasury during such month" for "paid to or deposited into the Treasury", and inserted provision that all amounts transferred to the Trust Fund under existing provisions shall be invested by the Managing Trustee in the same manner and to the same extent as the other assets of the Trust Fund, and the Trust Fund shall pay interest to the general fund on the amount so trans-
ferred on the first day of any month at a rate (cal-
culated on a daily basis, and applied against the dif-
fERENCE between the amount so transferred on such first day and the amount which would have been transferred to the Trust Fund up to that day under the procedures in effect on Jan. 1, 1983) equal to the rate earned by the investments of the Trust Fund in the same month under subsection (c).

Subsec. (b). Pub. L. 98–21, § 341(b)(1), substituted in prov-
sions preceding par. (1) "Secretary of Health and Human Services, all ex officio, and of two members of the public (both of whom may not be in the same political party), who shall be nominated by the President for a term of four years and subject to confirmation by
the Senate” for “Secretary of Health, Education, and Welfare, all ex officio”.

Pub. L. 98–21, §154(b), inserted at end provision that the report referred to in par. (2) shall also include an actuarial opinion by the Chief Actuarial Officer of the Health Care Financing Administration certifying that the techniques and methodologies used are generally accepted within the actuarial profession and that the assumptions and cost estimates used are reasonable and provided further that the certification shall not refer to economic assumptions underlying the Trustee’s report.

Pub. L. 98–21, §341(b)(2), inserted at end provision that a person serving on the Board of Trustees shall not be considered to be a fiduciary and shall not be personally liable for actions taken in such capacity with respect to the Trust Fund.


Subsec. (j)(2). Pub. L. 98–21, §142(b)(2)(A), substituted “on the last day of each month after such loan is made” for “from time to time”, substituted “the total interest accrued to such day” for “interest”, and inserted “even if such an investment would earn interest at a rate different than the rate earned by investments redeemed by the lending fund in order to make the loan”.

Subsec. (j)(3)(A). Pub. L. 98–21, §142(b)(3), designated existing provisions as subpar. (A) and added subpars. (B) and (C).


1972—Subsec. (a). Pub. L. 92–603 inserted “such gifts and bequests as may be made as provided in section 401(i)(1) of this title, and” after “consists of” and before “such gifts and bequests” in provisions preceding par. (1).


**Effective Date of 1999 Amendment**


Amendment by section 2354(b)(2) 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 1330a-1 of this title.

Amendment by section 2663(b)(2)(F)(i) 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 2664(b) of Pub. L. 98–369, set out as a note under section 401 of this title.

**Effective Date of 1983 Amendment**

Amendment by section 141(b) of Pub. L. 98–21 effective on first day of month following April 1983, see section 141(c) of Pub. L. 98–21, set out as a note under section 401 of this title.

Section 142(b)(2)(B) of Pub. L. 98–21 provided that: “The amendment made by this paragraph [amending this section] shall apply with respect to months beginning more than 30 days after the date of enactment of this Act [Apr. 20, 1983].”

Amendment by sections 154(b) and 341(b) of Pub. L. 98–21 effective Apr. 20, 1983, see sections 154(e) and 341(d) of Pub. L. 98–21, set out as notes under section 401 of this title.

**Effective Date of 1981 Amendment**


**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 Apr. 1, 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 second month following the end of the first calendar month in which the provisions of law involved became 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 1972 Amendment**

Amendment by Pub. L. 92–603 applicable with respect to gifts and bequests received after Oct. 30, 1972, see section 132(c) of Pub. L. 92–603, set out as a note under section 401 of this title.

**Restoration of Medicare Trust Funds**


“(1) CLERICAL ERROR.—The term ‘clerical error’ means a failure that occurs on or after April 15, 2001, to have transferred the correct amount from the general fund of the Treasury to a Trust Fund.

“(2) TRUST FUND.—The term ‘Trust Fund’ means the Federal Hospital Insurance Trust Fund established under section 1841 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. 1395g).

“(b) CORRECTION OF TRUST FUND HOLDINGS.—

“(1) IN GENERAL.—The Secretary of the Treasury shall take the actions described in paragraph (2) with respect to the Trust Fund with the goal being that, after such actions are taken, the holdings of the Trust Fund will replicate, to the extent practicable in the judgment of the Secretary of the Treasury, in

...
consultation with the Secretary [of Health and Human Services], the holdings that would have been held by the Trust Fund if the clerical error involved had not occurred.

"(2) OBLIGATIONS ISSUED AND REDEEMED.—The Secretary of the Treasury shall—

(A) issue to the Trust Fund obligations under chapter 31 of title 31, United States Code, that bear issue dates, interest rates, and maturity dates that are the same as those for the obligations that—

(i) would have been issued to the Trust Fund if the clerical error involved had not occurred; or

(ii) were issued to the Trust Fund and were redeemed by reason of the clerical error involved; and

(B) redeem from the Trust Fund obligations that would have been redeemed from the Trust Fund if the clerical error involved had not occurred.

"(c) APPROPRIATION.—There is appropriated to the Trust Fund, out of any money in the Treasury not otherwise appropriated, an amount determined by the Secretary of the Treasury, in consultation with the Secretary, to be equal to the interest income lost by the Trust Fund through the date on which the appropriation is being made as a result of the clerical error involved.

"CONGRESSIONAL NOTICE.—In the case of a clerical error that occurs after April 15, 2001, the Secretary of the Treasury, before taking action to correct the error under this section, shall notify the appropriate committees of Congress concerning such error and the actions to be taken under this section in response to such error.

"(e) DEADLINE.—With respect to the clerical error that occurred on April 15, 2001, not later than 120 days after the date of the enactment of this Act [Dec. 8, 2003].

(1) The Secretary of the Treasury shall take the actions under subsection (b)(1); and

(2) the appropriation under subsection (c) shall be made.

INCLUSION IN ANNUAL REPORT OF MEDICARE TRUSTERS OF INFORMATION ON STATUS OF MEDICARE TRUST FUND


"(a) DETERMINATIONS OF EXCESS GENERAL REVENUE MEDICARE FUNDING.—

(1) IN GENERAL.—The Board of Trustees of each medicare trust fund shall include in the annual reports submitted under subsection (b)(2) of sections 1817 and 1841 of the Social Security Act [42 U.S.C. 1395m and 1395t]—

(A) the information described in subsection (b); and

(B) a determination as to whether there is projected to be excess general revenue medicare funding (as defined in subsection (c)) for the fiscal year in which the report is submitted or for any of the succeeding 6 fiscal years.

(2) MEDICARE FUNDING WARNING.—For purposes of section 1105(h) of title 31, United States Code, and this subtitle [subtitle A (§§ 801–804) of title VIII of Pub. L. 108–173, amending this section, section 1395t of this title, and section 1105 of Title 31, Money and Finance, and enacting provisions set out as a note under section 1105 of Title 31], an affirmative determination under paragraph (1)(B) in 2 consecutive annual reports shall be treated as a medicare funding warning in the year in which the second such report is made.

(3) 7-FISCAL-YEAR REPORTING PERIOD.—For purposes of this subtitle, the term '7-fiscal-year reporting period' means, with respect to a year in which an annual report described in paragraph (1) is made, the period of 7 consecutive fiscal years beginning with the fiscal year in which the report is submitted.

"(b) INFORMATION.—The information described in this subsection for an annual report in a year is as follows:

"(1) PROJECTIONS OF GROWTH OF GENERAL REVENUE SPENDING.—A statement of the general revenue medicare funding as a percentage of the total medicare outlays for each of the following:

(A) Each fiscal year within the 7-fiscal-year reporting period.

(B) Previous fiscal years and as of 10, 50, and 75 years after such year.

"(2) COMPARISON WITH OTHER GROWTH TRENDS.—A comparison of the trend of such percentages with the annual growth rate in the following:

(A) The gross domestic product.

(B) Private health costs.

(C) National health expenditures.

(D) Other appropriate measures.

"(3) PART D SPENDING.—Expenditures, including trends in expenditures, under part D of title XVIII of the Social Security Act [part D of this subchapter], as added by section 101.

"(4) COMBINED MEDICARE TRUST FUND ANALYSIS.—A financial analysis of the combined medicare trust funds if general revenue medicare funding were limited to the percentage specified in subsection (c)(1)(B) of total medicare outlays.

"(c) DEFINITIONS.—For purposes of this section:

(1) EXCESS GENERAL REVENUE MEDICARE FUNDING.—The term 'excess general revenue medicare funding' means, with respect to a fiscal year, that—

(A) general revenue medicare funding (as defined in paragraph (2)), expressed as a percentage of total medicare outlays (as defined in paragraph (4)) for the fiscal year; exceeds

(B) 45 percent.

(2) GENERAL REVENUE MEDICARE FUNDING.—The term 'general revenue medicare funding' means for a year—

(A) the total medicare outlays (as defined in paragraph (4)) for the year; minus

(B) the dedicated medicare financing sources (as defined in paragraph (3)) for the year.

(3) DEDICATED MEDICARE FINANCING SOURCES.—The term 'dedicated medicare financing sources' means the following:

(A) HOSPITAL INSURANCE TAX.—Amounts appropriated to the Hospital Insurance Trust Fund under the third sentence of section 1817(a) of the Social Security Act [42 U.S.C. 1395v] or pursuant to section 1935(c) of such Act [section 1396u–5(c) of this title].

(B) TAXATION OF CERTAIN OASDI BENEFITS.—Amounts appropriated to the Hospital Insurance Trust Fund under section 212(e)(1)(B) of the Social Security Amendments of 1963 (Public Law 88–21) [set out as a note under section 401 of this title], as inserted by section 1321(c) of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66).

(C) STATE TRANSFERS.—The State share of amounts paid to the Federal Government by a State under section 1443 of the Social Security Act [42 U.S.C. 1395u] or pursuant to section 1935(c) of such Act [section 1396u–5(c) of this title].

(D) PREMIUMS.—The following premiums:


(ii) PART B.—Premiums paid by non-Federal sources under section 1399 of such Act [42 U.S.C. 1395g], including any adjustments in premiums under such section.

(iii) PART D.—Monthly beneficiary premiums paid under part D of title XVIII of such Act [part D of this subchapter], as added by section 101, and MA monthly prescription drug beneficiary premiums paid under part C of such title [part C of this subchapter] insofar as they are attributable to basic prescription drug coverage. Premiums under clauses (ii) and (iii) shall be determined without regard to any reduction in such premiums attributable to a beneficiary rebate under sec-
§ 1395i–1. Authorization of appropriations

There are authorized to be appropriated to the Federal Hospital Insurance Trust Fund (established by section 1395i of this title) from time to time such sums as the Secretary deems necessary for any fiscal year, on account of—

(1) payments made or to be made during such fiscal year from such Trust Fund under this part with respect to individuals who are qualified railroad retirement beneficiaries (as defined in section 426(c) of this title) and who are not, and upon filing application for monthly insurance benefits under section 402 of this title would not be, entitled to such benefits if service as an employee (as defined in the Railroad Retirement Act of 1937 [45 U.S.C. 223 et seq.]) after December 31, 1936, had been included in the term “employment” as defined in this chapter;

(2) the additional administrative expenses resulting or expected to result therefrom, and

(3) any loss of interest to such Trust Fund resulting from the payment of such amounts,
in order to place such Trust Fund in the same position at the end of such fiscal year in which it would have been if the individuals described in paragraph (1) had not been entitled to benefits under this part.


REFERENCES IN TEXT


For complete classification of these Acts to the Code, see Tables.

CODIFICATION

Section was enacted as part of the Social Security Amendments of 1965 and also as part of the Health Insurance for the Aged Act, and not as part of the Social Security Act which comprises this chapter.

EFFECTIVE DATE

Section 111(e) of Pub. L. 89-97 provided that:

“(1) The amendments made by the preceding provisions of this section (enacting this section and section 228s-2 of Title 45, Railroads, and amending section 1395kk of this title and sections 1401, 3101, 3201, 3201, and 3221 of Title 26, Internal Revenue Code, and section 228s of Title 45) shall apply to the calendar year 1966 or to any subsequent calendar year, but only if the requirement in paragraph (2) has been met with respect to such calendar year.

“(2) The requirement referred to in paragraph (1) shall be deemed to have been met with respect to any calendar year if, as of the October 1 immediately preceding such calendar year, the Railroad Retirement Tax Act [section 3101 et seq. of Title 26] provides that the maximum amount of monthly compensation taxable under such Act during all months of such calendar year will be an amount equal to one-twelfth of the maximum wages which the Federal Insurance Contributions Act [section 3201 et seq. of Title 26] provides may be counted for such calendar year.”


EFFECTIVE DATE OF REPEAL

Repeal effective Jan. 1, 1990, see section 102(d)(1) of Pub. L. 101–234, set out as a note under section 59B of Title 26, Internal Revenue Code.

ADJUSTMENTS FOR INTEREST LOST DUE TO DELAY OF TRANSFERS TO RESERVE FUND DURING 1989

Section 112(b) of Pub. L. 100–360, which directed Secretary of the Treasury, in July of 1990, to calculate interest lost to Federal Hospital Insurance Catastrophic Coverage Reserve Fund due to lag between outlays (attributable to amendments made by Pub. L. 100–360) from Federal Hospital Insurance Trust Fund during 1989 and transfers made to such Reserve Fund to cover such outlays, and provided that appropriations under subsection (a)(2) of this section include amount so calculated, was repealed by Pub. L. 101–234, title I, §102(a), Dec. 13, 1989, 103 Stat. 1980.

§ 1395i-2. Hospital insurance benefits for uninsured elderly individuals not otherwise eligible

(a) Individuals eligible to enroll

Every individual who—

(1) has attained the age of 65,

(2) is enrolled under part B of this subchapter,

(3) is a resident of the United States, and is either (A) a citizen or (B) an alien lawfully admitted for permanent residence who has resided in the United States continuously during the 5 years immediately preceding the month in which he applies for enrollment under this section, and

(4) is not otherwise entitled to benefits under this part,

shall be eligible to enroll in the insurance program established by this part. Except as otherwise provided, any reference to an individual entitled to benefits under this part includes an individual entitled to benefits under this part pursuant to an enrollment under this section or section 1395i-2a of this title.

(b) Time, manner, and form of enrollment

An individual may enroll under this section only in such manner and form as may be prescribed in regulations, and only during an enrollment period prescribed in or under this section.

(c) Period of enrollment; scope of coverage

The provisions of section 1395p of this title (except subsection (f) thereof), section 1395q of this title, subsection (b) of section 1395r of this title, and subsections (f) and (h) of section 1395s of this title shall apply to persons authorized to enroll under this section except that—

(1) individuals who meet the conditions of subsection (a)(1), (3), and (4) of this section on or before the last day of the seventh month after October 1972 may enroll under this part and (if not already so enrolled) may also enroll under part B of this subchapter during an initial general enrollment period which shall begin on the first day of the second month which begins after October 30, 1972, and shall end on the last day of the tenth month after October 1972;

(2) in the case of an individual who first meets the conditions of eligibility under this section on or after the first day of the eighth month after October 1972, the initial enrollment period shall begin on the first day of the third month before the month in which he first becomes eligible and shall end 7 months later;

(3) in the case of an individual who enrolls pursuant to paragraph (1) of this subsection, entitlement to benefits shall begin on—

(A) the first day of the second month after the month in which he enrolls,

(B) July 1, 1973, or

(C) the first day of the first month in which he meets the requirements of subsection (a) of this section, whichever is the latest;

(4) an individual’s entitlement under this section shall terminate with the month before
the first month in which he becomes eligible for hospital insurance benefits under section 426 of this title or section 426a of this title; and upon such termination, such individual shall be deemed, solely for purposes of hospital insurance entitlement, to have filed in such first month the application required to establish such entitlement;

(5) termination of coverage for supplementary medical insurance shall result in simultaneous termination of hospital insurance benefits for uninsured individuals who are not otherwise entitled to benefits under this chapter;

(6) any percent increase effected under section 1395r(b) of this title in an individual’s monthly premium may not exceed 10 percent and shall only apply to premiums paid during a period equal to twice the number of months in the full 12-month periods described in that section and shall be subject to reduction in accordance with subsection (d)(6) of this section;

(7) an individual who meets the conditions of subsection (a) of this section may enroll under this part during a special enrollment period that includes any month during any part of which the individual is enrolled under section 1395mm of this title with an eligible organization and ending with the last day of the 8th consecutive month in which the individual is at no time so enrolled;

(8) in the case of an individual who enrolls during a special enrollment period under paragraph (7)—

(A) in any month of the special enrollment period in which the individual is at any time enrolled under section 1395mm of this title with an eligible organization or in the first month following such a month, the coverage period shall begin on the first day of the month in which the individual so enrolls (or, at the option of the individual, on the first day of any of the following three months), or

(B) in any other month of the special enrollment period, the coverage period shall begin on the first day of the month following the month in which the individual so enrolls; and

(9) in applying the provisions of section 1395r(b) of this title, there shall not be taken into account months for which the individual can demonstrate that the individual was enrolled under section 1395mm of this title with an eligible organization.

**d) Monthly premiums**

(1) The Secretary shall, during September of each year (beginning with 1988), estimate the monthly actuarial rate for months in the succeeding year. Such actuarial rate shall be one-twelfth of the amount which the Secretary estimates (on an average, per capita basis) is equal to 100 percent of the benefits and administrative costs which will be payable from the Federal Hospital Insurance Trust Fund for services performed and related administrative costs incurred in the succeeding year with respect to individuals age 65 and over who will be entitled to benefits under this part during that year.

(2) The Secretary shall, during September of each year\(^1\) determine and promulgate the dollar amount which shall be applicable for premiums for months occurring in the following year. Subject to paragraphs (4) and (5), the amount of an individual’s monthly premium under this section shall be equal to the monthly actuarial rate determined under paragraph (1) for that following year. Any amount determined under the preceding sentence which is not a multiple of $1 shall be rounded to the nearest multiple of $1 (or, if it is a multiple of 50 cents but not a multiple of $1, to the next higher multiple of $1).

(3) Whenever the Secretary promulgates the dollar amount which shall be applicable as the monthly premium under this section, he shall, at the time such promulgation is announced, issue a public statement setting forth the actuarial assumptions and bases employed by him in arriving at the amount of an adequate actuarial rate for individuals 65 and older as provided in paragraph (1).

(4)(A) In the case of an individual described in subparagraph (B), the monthly premium for a month shall be reduced by the applicable reduction percent specified in the following table:

<table>
<thead>
<tr>
<th>The applicable reduction percent is:</th>
<th>For a month in:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994</td>
<td>25 percent</td>
</tr>
<tr>
<td>1995</td>
<td>30 percent</td>
</tr>
<tr>
<td>1996</td>
<td>35 percent</td>
</tr>
<tr>
<td>1997</td>
<td>40 percent</td>
</tr>
<tr>
<td>1998 or subsequent year</td>
<td>45 percent</td>
</tr>
</tbody>
</table>

(B) An individual described in this subparagraph with respect to a month is an individual who establishes to the satisfaction of the Secretary that, as of the last day of the previous month, the individual—

(i) had at least 30 quarters of coverage under subchapter II of this chapter;

(ii) was married (and had been married for the previous 1-year period) to an individual who had at least 30 quarters of coverage under such subchapter;

(iii) had been married to an individual for a period of at least 1 year (at the time of such individual’s death) if at such time the individual had at least 30 quarters of coverage under such subchapter; or

(iv) is divorced from an individual and had been married to the individual for a period of at least 10 years (at the time of the divorce) if at such time the individual had at least 30 quarters of coverage under such subchapter.

(5)(A) The amount of the monthly premium shall be zero in the case of an individual who is a person described in subparagraph (B) for a month if—

(i) the individual’s premium under this section for the month is not (and will not be) paid for, in whole or in part, by a State (under subchapter XIX of this chapter or otherwise), a political subdivision of a State, or an agency in the instrumentality of one or more States or political subdivisions thereof; and

(ii) in each of 84 months before such month, the individual was enrolled in this part under

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\(^1\) So in original. Probably should be followed by a comma.
this section and the payment of the individual’s premium under this section for the month was not paid for, in whole or in part, by a State (under subchapter XIX of this chapter or otherwise), a political subdivision of a State, or an agency or instrumentality of one or more States or political subdivisions thereof.

(B) A person described in this subparagraph for a month is a person who establishes to the satisfaction of the Secretary that, as of the last day of the previous month—

(i) the person was receiving cash benefits under a qualified State or local government retirement system (as defined in subparagraph (C)) on the basis of the person’s employment in one or more positions covered under any such system, and (II) the person would have at least 40 quarters of coverage under subchapter II of this chapter if remuneration for medicare qualified government employment (as defined in paragraph (1) of section 410(p) of this title, but determined without regard to paragraph (3) of such section) paid to such person were treated as wages paid to such person and credited for purposes of determining quarters of coverage under section 413 of this title;

(ii) the person married (and had been married for the previous 1-year period) to an individual who is described in clause (i), or (II) the person met the requirement of clause (i)(II) and was married (and had been married for the previous 1-year period) to an individual described in clause (i)(I);

(iii) the person had been married to an individual for a period of at least 1 year (at the time of such individual’s death) if (I) the individual was described in clause (i) at the time of the individual’s death, or (II) the person met the requirement of clause (i)(II) and the individual was described in clause (i)(I) at the time of the individual’s death; or

(iv) the person is divorced from an individual and was married to the individual for a period of at least 10 years (at the time of the divorce) if (I) the individual was described in clause (i) at the time of the divorce, or (II) the person met the requirement of clause (i)(II) and the individual was described in clause (i)(I) at the time of the divorce.

(C) For purposes of subparagraph (B)(i)(I), the term “qualified State or local government retirement system” means a retirement system that—

(i) is established or maintained by a State or political subdivision thereof, or an agency or instrumentality of one or more States or political subdivisions thereof;

(ii) covers positions of some or all employees of such a State, subdivision, agency, or instrumentality; and

(iii) does not adjust cash retirement benefits based on eligibility for a reduction in premium under this paragraph.

(6)(A) In the case where a State, a political subdivision of a State, or an agency or instrumentality of a State or political subdivision thereof determines to pay, for the life of each individual, the monthly premiums due under paragraph (1) on behalf of each of the individuals in a qualified State or local government retiree group who meets the conditions of subsection (a) of this section, the amount of any increase otherwise applicable under section 1395r(b) of this title (as applied and modified by subsection (c)(6) of this section) with respect to the monthly premium for benefits under this part for an individual who is a member of such group shall be reduced by the total amount of taxes paid under section 3101(b) of the Internal Revenue Code of 1986 by such individual and under section 3111(b) of such Code by the employers of such individual on behalf of such individual with respect to employment (as defined in section 3121(b) of such Code).

(B) For purposes of this paragraph, the term “qualified State or local government retiree group” means all of the individuals who retire prior to a specified date that is before January 1, 2002, from employment in one or more occupations or other broad classes of employees of—

(i) the State;

(ii) a political subdivision of the State; or

(iii) an agency or instrumentality of the State or political subdivision of the State.

(e) Contract or other arrangement for payment of monthly premiums

Payment of the monthly premiums on behalf of any individual who meets the conditions of subsection (a) of this section may be made by any public or private agency or organization under a contract or other arrangement entered into between it and the Secretary if the Secretary determines that payment of such premiums under such contract or arrangement is administratively feasible.

(f) Deposit of amounts into Treasury

Amounts paid to the Secretary for coverage under this section shall be deposited in the Treasury to the credit of the Federal Hospital Insurance Trust Fund.

(g) Buy-in under this part for qualified medicare beneficiaries

(1) The Secretary shall, at the request of a State made after 1989, enter into a modification of an agreement entered into with the State pursuant to section 1395v(a) of this title under which the agreement provides for enrollment in the program established by this part of qualified medicare beneficiaries (as defined in section 1396d(p)(1) of this title).

(2)(A) Except as provided in subparagraph (B), the provisions of subsections (c), (d), (e), and (f) of section 1395v of this title shall apply to qualified medicare beneficiaries enrolled, pursuant to such agreement, in the program established by this part in the same manner and to the same extent as they apply to qualified medicare beneficiaries enrolled, pursuant to such agreement, in part B of this subchapter.

(B) For purposes of this subsection, section 1395v(d)(1) of this title shall be applied by substituting “section 1395i–2 of this title” for “section 1395r of this title” and “subsection (c)” (with reference to subsection (b) of section 1395r of this title)” for “subsection (b)”.

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REFERENCES IN TEXT

Part B of this chapter, referred to in subsec. (a)(1), (c)(3), and (g)(2)(A), is classified to section 1395i et seq. of this title.

The Internal Revenue Code of 1986, referred to in subsec. (d)(5)(A), is classified generally to Title 26, Internal Revenue Code.

Amendments

2003—Subsec. (a). Pub. L. 108–173, §101(e)(5), inserted at end of concluding provisions "Except as otherwise provided, any reference to an individual entitled to benefits under this part includes an individual entitled to benefits under this part pursuant to an enrollment under this section or section 1395i–2a of this title."


1997—Subsec. (d)(1). Pub. L. 105–33, §4453(a)(2), redesignated subsection (a) of section 1395r of this title as subsection (c) of section 1395r.

Subsec. (d)(2). Pub. L. 105–8, §411(b)(4), inserted "a multiple of $1" after "midway between multiples of $1".


Subsec. (d). Pub. L. 100–360, §103, amended subsec. (d) generally. Prior to amendment, subsec. (d) read as follows:

"(1) The monthly premium of each individual for each month in his coverage period before July 1974 shall be $33.

"(2) The Secretary shall, during the next to last calendar quarter of each year determine and promulgate the dollar amount (whether or not such dollar amount was applicable for premiums for any prior month) which shall be applicable for premiums for months occurring in the following calendar year. Such amount shall be equal to $33, multiplied by the ratio of (A) the inpatient hospital deductible, as promulgated under section 1395e(b)(2) of this title, to (B) such deductible promulgated for 1973. Any amount determined under the preceding sentence which is not a multiple of $1 shall be rounded to the nearest multiple of $1, or, if a multiple of 50 cents but not a multiple of $1, to the next higher multiple of $1."

Subsec. (d)(1). Pub. L. 100–485 substituted "during that year" for "during that entire year".

1987—Subsec. (c)(5) to (7). Pub. L. 100–203, §4009(h)(9), as added by Pub. L. 100–360, §411(b)(8)(D), redesignated pars. (5) to (7) as (4) to (6), respectively, and struck out former par. (4) which read as follows: "termination of coverage under this section by the filing of notice that the individual no longer wishes to participate in the hospital insurance program shall take effect at the close of the month following the month in which such notice is filed;"


1984—Subsec. (c). Pub. L. 98–369, §235(b)(3), substituted "October 1972" for "the month in which this Act is enacted;"

Subsec. (d)(2). Pub. L. 98–369, §235(b)(4), substituted "if midway between multiples of $1" for "if midway between multiples of $1;"

1983—Subsec. (c). Pub. L. 98–21, §606(a)(3)(D), substituted "paragraphs (b) to (5), respectively, and struck out as added by Pub. L. 100–360, §411(b)(8)(D), redesignated as added by Pub. L. 100–360, §411(b)(8)(D), substituted "October 1972" for "the month in which this Act is enacted;"

Subsec. (d)(2). Pub. L. 98–21, §606(b), substituted during the next to last calendar quarter of each calendar year for "during the last calendar quarter of each year, beginning in 1973, "the following calendar year" for "the 12-month period commencing July 1 of the next year", and "for that following calendar year" for "for such next year".

Effective Date of 2000 Amendment

Pub. L. 106–554, §1(a)(6) [title III, §331(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–502, provided that: "The amendments made by section (a) [amending this section] shall apply to premiums for months beginning with January 1, 2002."

Effective Date of 1997 Amendment

Section 4453(b) of Pub. L. 105–33 provided that: "The amendments made by subsection (a) [amending this section] shall apply to premiums for months beginning with January 1998, and months before such month may be taken into account for purposes of meeting the requirement of section 1818(d)(5)(B)(iii) of the Social Security Act [subsection (b)(5)(B)(iii) of this section], as added by subsection (a)."

Effective Date of 1993 Amendment

Section 1395b of Pub. L. 103–66 provided that: "The amendments made by this section (amending this section) shall apply to monthly premiums under section 1818 of the Social Security Act [this section] for months beginning with January 1, 1994."

Effective Date of 1990 Amendment

Section 4008(g)(2) of Pub. L. 101–508 provided that: "The amendments made by paragraph (1) [amending this section] shall take effect on February 1, 1991."

Effective Date of 1989 Amendment

Amendment by section 6012(a)(1) of Pub. L. 101–239 effective Dec. 19, 1989, but not applicable so as to provide coverage under this part for any month before July 1990, see section 6012(b) of Pub. L. 101–239, set out as an Effective Date note under section 1395i–2a of this title.

Section 6013(c) of Pub. L. 101–239 provided that: "The amendments made by this section (amending this section and section 1395v of this title) shall become effective January 1, 1990."
**Effective Date of 1988 Amendments**

Amendment by Pub. L. 100–485 effective as if originally included in 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 103 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 1395f of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(b)(8)(D) of Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–253, effective as if included in the enactment of that provision in Pub. L. 100–253, 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 1986 Amendment**

Section 924(b)(3) of Pub. L. 99–272 provided that: "(1) any amendment made by subsection (a)(3) [amending this section] shall apply to premiums paid for months beginning with July 1986. (2) In applying that amendment, months (before, during, or after April 1986) in which an individual was required to pay a premium increased under the section that was so amended shall be taken into account in determining the month in which the premium will no longer be subject to an increase under that section as so amended."

**Effective Date of 1984 Amendment**


Amendment by section 2354(b)(3), (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 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; Transitional Rule**

Amendment by 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 individual "respective program", may enroll (if not otherwise enrolled) in the respective program during the period beginning on the first day of the first month beginning at least 20 days after the date of the enactment of this Act (Sept. 3, 1982) and ending on December 31, 1982.

"(b)(1) The coverage period under the respective program of an individual who enrolls under subsection (a) shall begin— "(A) on the first day of the month following the month in which the individual enrolls, or "(B) on October 1, 1981, if the individual files a request for this subparagraph to apply and pays the monthly premiums for the months so covered. "(2) The coverage period under the respective program of an individual described in subsection (a) who enrolled in the respective program before the enrollment period described in that subsection shall be retroactively extended to October 1, 1981, if the individual files a request before January 1, 1983, for such retroactive extension and pays the monthly premiums for the months so covered.

"(c)(1) For purposes of section 1839(d) of the Social Security Act (section 1395w(d) of this title) with respect to the monthly premium for months after September 1981, if an individual described in subsection (a) has enrolled in the insurance program under part B of title XVIII of the Social Security Act (part B of this subchapter) at any time before the end of the enrollment period described in subsection (a), any month (before the end of that enrollment period) in which he was not enrolled in that program shall not be treated as a month in which he could have been enrolled in the program.

"(2) Paragraph (1) shall not apply to an individual— "(A) if the individual has enrolled in the insurance program before March 10, 1981, unless the enrollment was terminated solely because the individual lost eligibility to be so enrolled, or "(B) unless the individual applies for the benefit of such paragraph before January 1, 1983.

"(d)(1) The Secretary of Health and Human Services, beginning as soon as possible but not later than 30 days after the date of the enactment of this Act [Sept. 3, 1982], shall provide for the dissemination of information— "(A) to unions and other associations representing or assisting seamen, "(B) to offices enrolling individuals under the respective programs, and "(C) to such other entities and in such a manner as will effectively inform individuals eligible for benefits under this section, concerning the special benefits provided under this section.

"(2) An individual may establish that the individual was entitled at a date to medical, surgical, and dental treatment and hospitalization under section 322(a) of the Public Health Service Act [section 249(a) of this title] (as in effect before October 1, 1981) by providing— "(A) documentation relating to the status under which the individual was provided care in (or under arrangements with) a Public Health Service facility on that date, "(B) the individual's seamen's papers covering that date, or "(C) such other reasonable documentation as the Secretary may require."
(B)(i) continues to have the disabling physical or mental impairment on the basis of which the individual was found to be under a disability or to be a disabled qualified railroad retirement beneficiary, or (ii) is blind (within the meaning of section 418(i)(1) of this title), but
(C) whose entitlement under section 426(b) of this title ends due solely to the individual having earnings that exceed the substantial gainful activity amount (as defined in section 423(d)(4) of this title); and
(3) is not otherwise entitled to benefits under this part.
shall be eligible to enroll in the insurance program established by this part.
(b) Enrollment
(1) An individual may enroll under this section only in such manner and form as may be prescribed in regulations, and only during an enrollment period prescribed in or under this section.
(2) The individual’s initial enrollment period shall begin with the month in which the individual receives notice that the individual’s entitlement to benefits under section 426(b) of this title will end due solely to the individual having earnings that exceed the substantial gainful activity amount (as defined in section 423(d)(4) of this title) and shall end 7 months later.
(3) There shall be a general enrollment period during the period beginning on January 1 and ending on March 31 of each year (beginning with 1990).
(c) Coverage period
(1) The period (in this subsection referred to as a “coverage period”) during which an individual is entitled to benefits under the insurance program under this part shall begin on whichever of the following is the latest:
(A) In the case of an individual who enrolls under subsection (b)(2) of this section before the month in which the individual first satisfies subsection (a) of this section, the first day of such month.
(B) In the case of an individual who enrolls under subsection (b)(2) of this section in the month in which the individual first satisfies subsection (a) of this section, the first day of the month following the month in which the individual so enrolls.
(C) In the case of an individual who enrolls under subsection (b)(2) of this section in the month following the month in which the individual first satisfies subsection (a) of this section, the first day of the second month following the month in which the individual so enrolls.
(D) In the case of an individual who enrolls under subsection (b)(2) of this section during the period beginning on January 1 and ending on March 31 of each year (beginning with 1990), in the month before the month in which such individual so enrolls.
(2) An individual’s coverage period under this section shall continue until the individual’s enrollment is terminated as follows:
(A) As of the month following the month in which the Secretary provides notice to the individual that the individual no longer meets the condition described in subsection (a)(2)(B) of this section.
(B) As of the month following the month in which the individual files notice that the individual no longer wishes to participate in the insurance program established by this part.
(C) As of the month before the first month in which the individual becomes eligible for hospital insurance benefits under section 426(a) or 426-1 of this title.
(D) As of a date, determined under regulations of the Secretary, for nonpayment of premiums.
The regulations under subparagraph (D) may provide a grace period of not longer than 90 days, which may be extended to not to exceed 180 days in any case where the Secretary determines that there was good cause for failure to pay the overdue premiums within such 90-day period. Termination of coverage under this section shall result in simultaneous termination of any coverage affected under any other part of this subchapter.
(3) The provisions of subsections (b) and (i) of section 1395p of this title apply to enrollment and nonenrollment under this section in the same manner as they apply to enrollment and nonenrollment and special enrollment periods under section 1395i–2 of this title.
(d) Payment of premiums
(1)(A) Premiums for enrollment under this section shall be paid to the Secretary at such times, and in such manner, as the Secretary shall by regulations prescribe, and shall be deposited in the Treasury to the credit of the Federal Hospital Insurance Trust Fund.
(B)(i) Subject to clause (ii), such premiums shall be payable for the period commencing with the first month of an individual’s coverage period and ending with the month in which the individual dies or, if earlier, in which the individual’s coverage period terminates.
(ii) Such premiums shall not be payable for any month in which the individual is eligible for benefits under this part pursuant to section 426(b) of this title.
(2) The provisions of subsections (d) through (f) of section 1395i–2 of this title (relating to premiums) shall apply to individuals enrolled under this section in the same manner as they apply to individuals enrolled under that section.
Amendments
Subsec. (d)(1)(C). Pub. L. 101–508, §4008(m)(3)(C)(i), struck out subpar. (C) which read as follows: “For purposes of applying section 1395p(g) of this title and sec-
§ 1395i-3. Requirements for, and assuring quality of care in, skilled nursing facilities

(a) "Skilled nursing facility" defined

In this subchapter, the term "skilled nursing facility" means an institution (or a distinct part of an institution) which—

(1) is primarily engaged in providing to residents—

(A) skilled nursing care and related services for residents who require medical or nursing care, or

(B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons, and is not primarily for the care and treatment of mental diseases;

(2) has in effect a transfer agreement (meeting the requirements of section 1395x(l) of this title) with one or more hospitals having agreements in effect under section 1395cc of this title; and

(3) meets the requirements for a skilled nursing facility described in subsections (b), (c), and (d) of this section.

(b) Requirements relating to provision of services

(1) Quality of life

(A) In general

A skilled nursing facility must care for its residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident.

(B) Quality assessment and assurance

A skilled nursing facility must maintain a quality assessment and assurance committee, consisting of the director of nursing services, a physician designated by the facility, and at least 3 other members of the facility’s staff, which (i) meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary and (ii) develops and implements appropriate plans of action to correct identified quality deficiencies. A State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this subparagraph.

(2) Scope of services and activities under plan of care

A skilled nursing facility must provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care which—

(A) describes the medical, nursing, and psychosocial needs of the resident and how such needs will be met;

(B) is initially prepared, with the participation to the extent practicable of the resident or the resident’s family or legal representative, by a team which includes the resident’s attending physician and a registered professional nurse with responsibility for the resident; and

(C) is periodically reviewed and revised by such team after each assessment under paragraph (3).

(3) Residents’ assessment

(A) Requirement

A skilled nursing facility must conduct a comprehensive, accurate, standardized, reproducible assessment of each resident’s functional capacity, which assessment—

(i) describes the resident’s capability to perform daily life functions and significant impairments in functional capacity;

(ii) is based on a uniform minimum data set specified by the Secretary under subsection (f)(6)(A) of this section;

(iii) uses an instrument which is specified by the State under subsection (e)(5) of this section; and

(iv) includes the identification of medical problems.

(B) Certification

(i) In general

Each such assessment must be conducted or coordinated (with the appropriate participation of health professionals) by a registered professional nurse who signs and certifies the completion of the assessment. Each individual who completes a portion of such an assessment shall sign and certify as to the accuracy of that portion of the assessment.

(ii) Penalty for falsification

(I) An individual who willfully and knowingly certifies under clause (i) a material and false statement in a resident assessment is subject to a civil money penalty of not more than $1,000 with respect to each assessment.

(II) An individual who willfully and knowingly causes another individual to certify under clause (i) a material and false statement in a resident assessment is subject to a civil money penalty of not more than $5,000 with respect to each assessment.

(III) The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(iii) Use of independent assessors

If a State determines, under a survey under subsection (g) of this section or otherwise, that there has been a knowing and willful certification of false assessments under this paragraph, the State...
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(4) Provision of services and activities

for the provision of—

(A) nursing services and specialized rehabilitative services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident;

(B) medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident;

(C) dietary services that assure that the meals meet the daily nutritional and special dietary needs of each resident;

(D) pharmaceutical services (including procedures that assure the accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals) to meet the needs of each resident;

(E) nutritional services that assure the daily nutritional and special dietary needs of each resident;

(f) an on-going program, directed by a qualified professional, of activities designed to meet the interests and the physical, mental, and psychosocial well-being of each resident;

(g) routine and emergency dental services to meet the needs of each resident; and

(h) treatment and services required by mentally ill and mentally retarded residents not otherwise provided or arranged for (or required to be provided or arranged for) by the State.

The services provided or arranged by the facility must meet professional standards of quality. Nothing in clause (vi) shall be construed as requiring a facility to provide or arrange for dental services described in that clause without additional charge.

(B) Qualified persons providing services

Services described in clauses (i), (ii), (iii), (iv), and (vi) of subparagraph (A) must be provided by qualified persons in accordance with each resident’s written plan of care.

(C) Required nursing care

(i) In general

Except as provided in clause (ii), a skilled nursing facility must provide 24-hour licensed nursing service which is sufficient to meet nursing needs of its residents and must use the services of a registered professional nurse at least 8 consecutive hours a day, 7 days a week.

(ii) Exception

To the extent that clause (i) may be deemed to require that a skilled nursing facility engage the services of a registered professional nurse for more than 40 hours a week, the Secretary is authorized to waive such requirement if the Secretary finds that—

(I) the facility is located in a rural area and the supply of skilled nursing facility services in such area is not sufficient to meet the needs of individuals residing therein;

(II) the facility has one full-time registered professional nurse who is regularly on duty at such facility 40 hours a week;

(III) the facility either has only patients whose physicians have indicated (through physicians’ orders or admission notes) that each such patient does not require the services of a registered nurse or a physician for a 48-hour period, or has made arrangements for a registered professional nurse or a physician to spend such time at such facility as may be indicated as necessary by the physician to provide necessary skilled nursing services on days when the regular full-time registered professional nurse is not on duty;

(IV) the Secretary provides notice of the waiver to the State long-term care ombudsman (established under section 307(a)(12) of the Older Americans Act of

1 See References in Text note below.
(5) Required training of nurse aides

(A) In general

(i) Except as provided in clause (ii), a skilled nursing facility must not use on a full-time basis any individual as a nurse aide in the facility on or after January 1, 1990 for more than 4 months unless the individual—
   (I) has completed a training and competency evaluation program, or a competency evaluation program, approved by the State under subsection (e)(1)(A) of this section, and
   (II) is competent to provide nursing or nursing-related services.

(ii) A skilled nursing facility must not use on a temporary, per diem, leased, or on any basis other than as a permanent employee any individual as a nurse aide in the facility on or after January 1, 1991, unless the individual meets the requirements described in clause (i).

(B) Offering competency evaluation programs for current employees

A skilled nursing facility must provide, for individuals used as a nurse aide by the facility as of January 1, 1990, for a competency evaluation program approved by the State under subsection (e)(1) of this section and such preparation as may be necessary for the individual to complete such a program by October 1, 1990.

(C) Competency

The skilled nursing facility must not permit an individual, other than in a training and competency evaluation program approved by the State, to serve as a nurse aide or provide services of a type for which the individual has not demonstrated competency and must not use such an individual as a nurse aide unless the facility has inquired of any State registry established under subsection (e)(2)(A) of this section that the facility believes will include information concerning the individual.

(D) Re-training required

For purposes of subparagraph (A), if, since an individual’s most recent completion of a training and competency evaluation program, there has been a continuous period of 24 consecutive months during none of which the individual performed nursing or nursing-related services for monetary compensation, such individual shall complete a new training and competency evaluation program or a new competency evaluation program.

(E) Regular in-service education

The skilled nursing facility must provide such regular performance review and regular in-service education as assures that individuals used as nurse aides are competent to perform services as nurse aides, including training for individuals providing nursing and nursing-related services to residents with cognitive impairments.

(F) “Nurse aide” defined

In this paragraph, the term “nurse aide” means any individual providing nursing or nursing-related services to residents in a skilled nursing facility, but does not include an individual—

(i) who is a licensed health professional (as defined in subparagraph (G)) or a registered dietitian, or

(ii) who volunteers to provide such services without monetary compensation.

Such term includes an individual who provides such services through an agency or under a contract with the facility.

(G) “Licensed health professional” defined

In this paragraph, the term “licensed health professional” means a physician, physician assistant, nurse practitioner, physical, speech, or occupational therapist, registered professional nurse, licensed practical nurse, licensed or certified social worker, registered respiratory therapist, or certified respiratory therapy technician.

(6) Physician supervision and clinical records

A skilled nursing facility must—

(A) require that the medical care of every resident be provided under the supervision of a physician;

(B) provide for having a physician available to furnish necessary medical care in case of emergency; and

(C) maintain clinical records on all residents, which records include the plans of care (described in paragraph (2)) and the residents’ assessments (described in paragraph (3)).

(7) Required social services

In the case of a skilled nursing facility with more than 120 beds, the facility must have at least one social worker (with at least a bachelor’s degree in social work or similar professional qualifications) employed full-time to provide or assure the provision of social services.

(8) Information on nurse staffing

(A) In general

A skilled nursing facility shall post daily for each shift the current number of licensed and unlicensed nursing staff directly responsible for resident care in the facility. The information shall be displayed in a uniform manner (as specified by the Secretary) and in a clearly visible place.

(B) Publication of data

A skilled nursing facility shall, upon request, make available to the public the nursing staff data described in subparagraph (A).

2So in original. Probably should be “as nurse aides”.

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(c) Requirements relating to residents’ rights

(1) General rights

(A) Specified rights

A skilled nursing facility must protect and promote the rights of each resident, including each of the following rights:

(i) **Free choice**

The right to choose a personal attending physician, to be fully informed in advance about care and treatment, to be fully informed in advance of any changes in care or treatment that may affect the resident’s well-being, and (except with respect to a resident adjudged incompetent) to participate in planning care and treatment or changes in care and treatment.

(ii) **Free from restraints**

The right to be free from physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident’s medical symptoms. Restraints may only be imposed—

(I) to ensure the physical safety of the resident or other residents, and

(II) only upon the written order of a physician that specifies the duration and circumstances under which the restraints are to be used (except in emergency circumstances specified by the Secretary until such an order could reasonably be obtained).

(iii) **Privacy**

The right to privacy with regard to accommodations, medical treatment, written and telephonic communications, visits, and meetings of family and of resident groups.

(iv) **Confidentiality**

The right to confidentiality of personal and clinical records and to access to current clinical records of the resident upon request by the resident or the resident’s legal representative, within 24 hours (excluding hours occurring during a weekend or holiday) after making such a request.

(v) **Accommodation of needs**

The right—

(I) to reside and receive services with reasonable accommodation of individual needs and preferences, except where the health or safety of the individual or other residents would be endangered, and

(II) to receive notice before the room or roommate of the resident in the facility is changed.

(vi) **Grievances**

The right to voice grievances with respect to treatment or care that is (or fails to be) furnished, without discrimination or reprisal for voicing the grievances and the right to prompt efforts by the facility to resolve grievances the resident may have, including those with respect to the behavior of other residents.

(vii) **Participation in resident and family groups**

The right of the resident to organize and participate in resident groups in the facility and the right of the resident’s family to meet in the facility with the families of other residents in the facility.

(viii) **Participation in other activities**

The right of the resident to participate in social, religious, and community activities that do not interfere with the rights of other residents in the facility.

(ix) **Examination of survey results**

The right to examine, upon reasonable request, the results of the most recent survey of the facility conducted by the Secretary or a State with respect to the facility and any plan of correction in effect with respect to the facility.

(x) **Refusal of certain transfers**

The right to refuse a transfer to another room within the facility, if a purpose of the transfer is to relocate the resident from a portion of the facility that is a skilled nursing facility (for purposes of this subchapter) to a portion of the facility that is not such a skilled nursing facility.

(xi) **Other rights**

Any other right established by the Secretary.

Clause (iii) shall not be construed as requiring the provision of a private room. A resident’s exercise of a right to refuse transfer under clause (x) shall not affect the resident’s eligibility or entitlement to benefits under this subchapter or to medical assistance under subchapter XIX of this chapter.

(B) **Notice of rights and services**

A skilled nursing facility must—

(i) inform each resident, orally and in writing at the time of admission to the facility, of the resident’s legal rights during the stay at the facility;

(ii) make available to each resident, upon reasonable request, a written statement of such rights (which statement is updated upon changes in such rights) including the notice (if any) of the State developed under section 1396r(e)(6) of this title; and

(iii) inform each other resident, in writing before or at the time of admission and periodically during the resident’s stay, of services available in the facility and of related charges for such services, including any charges for services not covered under this subchapter or by the facility’s basic per diem charge.

The written description of legal rights under this subparagraph shall include a description of the protection of personal funds under paragraph (6) and a statement that a resident may file a complaint with a State survey and certification agency respecting resident abuse and neglect and misappropriation of resident property in the facility.
(C) Rights of incompetent residents

In the case of a resident adjudged incompetent under the laws of a State, the rights of the resident under this subchapter shall devolve upon, and, to the extent judged necessary by a court of competent jurisdiction, be exercised by, the person appointed under State law to act on the resident’s behalf.

(D) Use of psychopharmacologic drugs

Psychopharmacologic drugs may be administered only on the orders of a physician and only as part of a plan (included in the written plan of care described in paragraph (2)) designed to eliminate or modify the symptoms for which the drugs are prescribed and only if, at least annually, an independent, external consultant reviews the appropriateness of the drug plan of each resident receiving such drugs. In determining whether such a consultant is qualified to conduct reviews under the preceding sentence, the Secretary shall take into account the needs of nursing facilities under this subchapter to have access to the services of such a consultant on a timely basis.

(E) Information respecting advance directives

A skilled nursing facility must comply with the requirements of section 1395cc(f) of this title (relating to maintaining written policies and procedures respecting advance directives).

(2) Transfer and discharge rights

(A) In general

A skilled nursing facility must permit each resident to remain in the facility and must not transfer or discharge the resident from the facility unless—

(i) the transfer or discharge is necessary to meet the resident’s welfare and the resident’s welfare cannot be met in the facility;

(ii) the transfer or discharge is appropriate because the resident’s health has improved sufficiently so the resident no longer needs the services provided by the facility;

(iii) the safety of individuals in the facility is endangered;

(iv) the health of individuals in the facility would otherwise be endangered;

(v) the resident has failed, after reasonable and appropriate notice, to pay (or to have paid under this subchapter or subchapter XIX of this chapter on the resident’s behalf) for a stay at the facility; or

(vi) the facility ceases to operate.

In each of the cases described in clauses (i) through (v), the basis for the transfer or discharge must be documented in the resident’s clinical record. In the cases described in clauses (i) and (ii), the documentation must be made by the resident’s physician, and in the cases described in clauses (iii) and (iv) the documentation must be made by a physician.

(B) Pre-transfer and pre-discharge notice

(i) In general

Before effecting a transfer or discharge of a resident, a skilled nursing facility must—

(I) notify the resident (and, if known, a family member of the resident or legal representative) of the transfer or discharge and the reasons therefor;

(II) record the reasons in the resident’s clinical record (including any documentation required under subparagraph (A)), and

(III) include in the notice the items described in clause (iii).

(ii) Timing of notice

The notice under clause (i)(I) must be made at least 30 days in advance of the resident’s transfer or discharge except—

(I) in a case described in clause (iii) or (iv) of subparagraph (A);

(II) in a case described in clause (ii) of subparagraph (A), where the resident’s health improves sufficiently to allow a more immediate transfer or discharge;

(III) in a case described in clause (i) of subparagraph (A), where a more immediate transfer or discharge is necessitated by the resident’s urgent medical needs; or

(IV) in a case where a resident has not resided in the facility for 30 days.

In the case of such exceptions, notice must be given as many days before the date of the transfer or discharge as is practicable.

(iii) Items included in notice

Each notice under clause (i) must include—

(I) for transfers or discharges effected on or after October 1, 1990, notice of the resident’s right to appeal the transfer or discharge under the State process established under subsection (e)(3) of this section; and

(II) the name, mailing address, and telephone number of the State long-term care ombudsman (established under title III or VII of the Older Americans Act of 1965 [42 U.S.C. 3021 et seq., 3058 et seq.] in accordance with section 712 of the Act [42 U.S.C. 3058g(j)]).

(C) Orientation

A skilled nursing facility must provide sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.

(3) Access and visitation rights

A skilled nursing facility must—

(A) permit immediate access to any resident by any representative of the Secretary, by any representative of the State, by an ombudsman described in paragraph (2)(B)(iii)(II), or by the resident’s individual ombudsman;

(B) permit immediate access to a resident, subject to the resident’s right to deny or withdraw consent at any time, by immediate family or other relatives of the resident;
(C) permit immediate access to a resident, subject to reasonable restrictions and the resident’s right to deny or withdraw consent at any time, by others who are visiting with the consent of the resident;

(D) permit reasonable access to a resident by any entity or individual that provides health, social, legal, or other services to the resident, subject to the resident’s right to deny or withdraw consent at any time; and

(E) permit representatives of the State ombudsman (described in paragraph (2)(B)(iii)(III)), with the permission of the resident (or the resident’s legal representative) and consistent with State law, to examine a resident’s clinical records.

(4) Equal access to quality care

A skilled nursing facility must establish and maintain identical policies and practices regarding transfer, discharge, and covered services under this subchapter for all individuals regardless of source of payment.

(5) Admissions policy

(A) Admissions

With respect to admissions practices, a skilled nursing facility must—

(i) not require individuals applying to reside or residing in the facility to waive their rights to benefits under this subchapter or under a State plan under subchapter XIX of this chapter, (II) not require oral or written assurance that such individuals are not eligible for, or will not apply for, benefits under this subchapter or such a State plan, and (III) prominently display in the facility and provide to such individuals written information about how to apply for, benefits under this subchapter or such a State plan, and afford the resident (or a legal representative of the resident) reasonable access to such record.

(B) Construction

(i) No preemption of stricter standards

Subparagraph (A) shall not be construed as preventing States or political subdivisions therein from prohibiting, under State or local law, the discrimination against individuals who are entitled to medical assistance under this subchapter with respect to admissions practices of skilled nursing facilities.

(ii) Contracts with legal representatives

Subparagraph (A)(ii) shall not be construed as preventing a facility from requiring an individual, who has legal access to a resident’s income or resources available to pay for care in the facility, to sign a contract (without incurring personal financial liability) to provide payment from the resident’s income or resources for such care.

(6) Protection of resident funds

(A) In general

The skilled nursing facility—

(i) may not require residents to deposit their personal funds with the facility, and

(ii) upon the written authorization of the resident, must hold, safeguard, and account for such personal funds under a system established and maintained by the facility in accordance with this paragraph.

(B) Management of personal funds

Upon written authorization of a resident under subparagraph (A)(ii), the facility must manage and account for the personal funds of the resident deposited with the facility as follows:

(i) Deposit

The facility must deposit any amount of personal funds in excess of $100 with respect to a resident in an interest bearing account (or accounts) that is separate from any of the facility’s operating accounts and credits all interest earned on such separate account to such account. With respect to any other personal funds, the facility must maintain such funds in a non-interest bearing account or petty cash fund.

(ii) Accounting and records

The facility must assure a full and complete separate accounting of each such resident’s personal funds, maintain a written record of all financial transactions involving the personal funds of a resident deposited with the facility, and afford the resident (or a legal representative of the resident) reasonable access to such record.

(iii) Conveyance upon death

Upon the death of a resident with such an account, the facility must convey promptly the resident’s personal funds (and a final accounting of such funds) to the individual administering the resident’s estate.

(C) Assurance of financial security

The facility must purchase a surety bond, or otherwise provide assurance satisfactory to the Secretary, to assure the security of all personal funds of residents deposited with the facility.

(D) Limitation on charges to personal funds

The facility may not impose a charge against the personal funds of a resident for any item or service for which payment is made under this subchapter or subchapter XIX of this chapter.

(d) Requirements relating to administration and other matters

(1) Administration

(A) In general

A skilled nursing facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident (consistent with requirements established under subsection (f)(5) of this section).

3So in original. Probably should be “credit”.
(B) Required notices

If a change occurs in—

(i) the persons with an ownership or control interest (as defined in section 1320a–3(a)(3) of this title) in the facility,
(ii) the persons who are officers, directors, agents, or managing employees (as defined in section 1320a–5(b) of this title) of the facility,
(iii) the corporation, association, or other company responsible for the management of the facility, or
(iv) the individual who is the administrator or director of nursing of the facility,

the skilled nursing facility must provide notice to the State agency responsible for the licensing of the facility, at the time of the change, of the change and of the identity of each new person, company, or individual described in the respective clause.

(C) Skilled nursing facility administrator

The administrator of a skilled nursing facility must meet standards established by the Secretary under subsection (f)(4) of this section.

(2) Licensing and Life Safety Code

(A) Licensing

A skilled nursing facility must be licensed under applicable State and local law.

(B) Life Safety Code

A skilled nursing facility must meet such provisions of such edition (as specified by the Secretary in regulation) of the Life Safety Code of the National Fire Protection Association as are applicable to nursing homes; except that—

(i) the Secretary may waive, for such periods as he deems appropriate, specific provisions of such Code which if rigidly applied would result in unreasonable hardship upon a facility, but only if such waiver would not adversely affect the health and safety of residents or personnel, and
(ii) the provisions of such Code shall not apply in any State if the Secretary finds that in such State there is in effect a fire and safety code, imposed by State law, which adequately protects residents of and personnel in skilled nursing facilities.

(3) Sanitary and infection control and physical environment

A skilled nursing facility must—

(A) establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment in which residents reside and to help prevent the development and transmission of disease and infection, and
(B) be designed, constructed, equipped, and maintained in a manner to protect the health and safety of residents, personnel, and the general public.

(4) Miscellaneous

(A) Compliance with Federal, State, and local laws and professional standards

A skilled nursing facility must operate and provide services in compliance with all applicable Federal, State, and local laws and regulations (including the requirements of section 1320a–3 of this title) and with accepted professional standards and principles which apply to professionals providing services in such a facility.

(B) Other

A skilled nursing facility must meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary.

(e) State requirements relating to skilled nursing facility requirements

The requirements, referred to in section 1395aa(d) of this title, with respect to a State are as follows:

(1) Specification and review of nurse aide training and competency evaluation programs and of nurse aide competency evaluation programs

The State must—

(A) by not later than January 1, 1989, specify those training and competency evaluation programs, and those competency evaluation programs, that the State approves for purposes of subsection (b)(5) of this section and that meet the requirements established under subsection (f)(2) of this section, and
(B) by not later than January 1, 1990, provide for the review and reapproval of such programs, at a frequency and using a methodology consistent with the requirements established under subsection (f)(2)(A)(iii) of this section.

The failure of the Secretary to establish requirements under subsection (f)(2) of this section shall not relieve any State of its responsibility under this paragraph.

(2) Nurse aide registry

(A) In general

By not later than January 1, 1989, the State shall establish and maintain a registry of all individuals who have satisfactorily completed a nurse aide training and competency evaluation program, or a nurse aide competency evaluation program, approved under paragraph (1) in the State, or any individual described in subsection (f)(2)(B)(ii) of this section or in subparagraph (B), (C), or (D) of section 6901(b)(4) of the Omnibus Budget Reconciliation Act of 1989.

(B) Information in registry

The registry under subparagraph (A) shall provide (in accordance with regulations of the Secretary) for the inclusion of specific documented findings by a State under subsection (g)(1)(C) of this section of resident neglect or abuse or misappropriation of resident property involving an individual listed in the registry, as well as any brief statement of the individual disputing the findings, but shall not include any allegations of resident abuse or neglect or misappropriation of resident property that are not specifically documented by the State under
such subsection. The State shall make available to the public information in the registry. In the case of inquiries to the registry concerning an individual listed in the registry, any information disclosed concerning such an individual shall also include disclosure of any such statement in the registry relating to the finding or a clear and accurate summary of such a statement.

(C) Prohibition against charges

A State may not impose any charges on a nurse aide relating to the registry established and maintained under subparagraph (A).

(3) State appeals process for transfers and discharges

The State, for transfers and discharges from skilled nursing facilities effected on or after October 1, 1989, must provide for a fair mechanism for hearing appeals on transfers and discharges of residents of such facilities. Such mechanism must meet the guidelines established by the Secretary under subsection (f)(3) of this section; but the failure of the Secretary to establish such guidelines shall not relieve any State of its responsibility to provide for such a fair mechanism.

(4) Skilled nursing facility administrator standards

By not later than January 1, 1990, the State must have implemented and enforced the skilled nursing facility administrator standards developed under subsection (f)(4) of this section respecting the qualification of administrators of skilled nursing facilities.

(5) Specification of resident assessment instrument

Effective July 1, 1990, the State shall specify the instrument to be used by nursing facilities in the State in complying with the requirement of subsection (b)(3)(A)(iii) of this section. Such instrument shall be—

(A) one of the instruments designated under subsection (f)(6)(B) of this section, or

(B) an instrument which the Secretary has approved as being consistent with the minimum data set of core elements, common definitions, and utilization guidelines specified by the Secretary under subsection (f)(6)(A) of this section.

(f) Responsibilities of Secretary relating to skilled nursing facility requirements

(1) General responsibility

It is the duty and responsibility of the Secretary to assure that requirements which govern the provision of care in skilled nursing facilities under this subchapter, and the enforcement of such requirements, are adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys.

(2) Requirements for nurse aide training and competency evaluation programs and for nurse aide competency evaluation programs

(A) In general

For purposes of subsections (b)(5) and (e)(1)(A) of this section, the Secretary shall establish, by not later than September 1, 1988—

(i) requirements for the approval of nurse aide training and competency evaluation programs, including requirements relating to (I) the areas to be covered in such a program (including at least basic nursing skills, personal care skills, recognition of mental health and social service needs, care of cognitively impaired residents, basic restorative services, and residents’ rights) and content of the curriculum (including, in the case of initial training and, if the Secretary determines appropriate, in the case of ongoing training, dementia management training, and patient abuse prevention training), (II) minimum hours of initial and ongoing training and retraining (including not less than 75 hours in the case of initial training), (III) qualifications of instructors, and (IV) procedures for determination of competency;

(ii) requirements for the approval of nurse aide competency evaluation programs, including requirement relating to the areas to be covered in such a program, including at least basic nursing skills, personal care skills, recognition of mental health and social service needs, care of cognitively impaired residents, basic restorative services, residents’ rights, and procedures for determination of competency;

(iii) requirements respecting the minimum frequency and methodology to be used by a State in reviewing such programs’ compliance with the requirements for such programs; and

(iv) requirements, under both such programs, that—

(I) provide procedures for determining competency that permit a nurse aide, at the nurse aide’s option, to establish competency through procedures or methods other than the passing of a written examination and to have the competency evaluation conducted at the nursing facility at which the aide is (or will be) employed (unless the facility is described in subparagraph (B)(iii)(I)),

(II) prohibit the imposition on a nurse aide who is employed by (or who has received an offer of employment from) a facility on the date on which the aide begins either such program of any charges (including any charges for textbooks and other required course materials and any charges for the competency evaluation) for either such program, and

(III) in the case of a nurse aide not described in clause (II) who is employed by (or who has received an offer of employment from) a facility not later than 12 months after completing either such program, the State shall provide for the reimbursement of costs incurred in completing such program on a prorata basis

4So in original. A closing parenthesis probably should appear before the comma.

5So in original. Probably should be “pro rata”.


(B) Approval of certain programs

Such requirements—

(i) may permit approval of programs offered by or in facilities (subject to clause (iii)), as well as outside facilities (including employee (e) organizations), and of programs in effect on December 22, 1987;

(ii) shall permit a State to find that an individual who has completed (before July 1, 1989) a nurse aide training and competency evaluation program shall be deemed to have completed such a program approved under subsection (b)(5) of this section if the State determines that, at the time the program was offered, the program met the requirements for approval under such paragraph; and

(iii) subject to subparagraphs (C) and (D), shall prohibit approval of such a program—

(I) offered by or in a skilled nursing facility which, within the previous 2 years—

(a) has operated under a waiver under subsection (b)(4)(C)(ii)(II) of this section;

(b) has been subject to an extended (or partial extended) survey under subsection (g)(2)(B)(i) of this section or section 1396(r)(2)(B)(i) of this title, unless the survey shows that the facility is in compliance with the requirements of subsections (b), (c), and (d) of this section; or

(c) has been assessed a civil money penalty described in subsection (h)(2)(B)(ii) of this section or section 1396(r)(2)(A)(i) of this title of not less than $5,000, or has been subject to a remedy described in clause (i) or (iii) of subsection (h)(4) of this section, subsection (h)(2)(B) of this section, subsection (h)(2)(A) of this section, or section 1396(r)(2)(A)(i) of this title, or in clause (i), (iii), or (iv) of section 1396(r)(2)(A) of this title, or

(II) offered by or in a skilled nursing facility unless the State makes the determination, upon an individual’s completion of the program, that the individual is competent to provide nursing and nursing-related services in skilled nursing facilities.

A State may not delegate (through subcontract or otherwise) its responsibility under clause (iii)(II) to the skilled nursing facility.

(C) Waiver authorized

Clause (ii)(I) of subparagraph (B) shall not apply to a program offered in (but not by) a nursing facility (or skilled nursing facility for purposes of this subchapter) in a State if the State—

(i) determines that there is no other such program offered within a reasonable distance of the facility,

(ii) assures, through an oversight effort, that an adequate environment exists for operating the program in the facility, and

(iii) provides notice of such determination and assurances to the State long-term care ombudsman.

(D) Waiver of disapproval of nurse-aide training programs

Upon application of a nursing facility, the Secretary may waive the application of subparagraph (B)(iii)(I)(c) if the imposition of the civil monetary penalty was not related to the quality of care provided to residents of the facility. Nothing in this subparagraph shall be construed as eliminating any requirement upon a facility to pay a civil monetary penalty described in the preceding sentence.

(3) Federal guidelines for State appeals process for transfers and discharges

For purposes of subsections (c)(2)(B)(iii)(I) and (e)(3) of this section, by not later than October 1, 1988, the Secretary shall establish guidelines for minimum standards which State appeals processes under subsection (e)(3) of this section must meet to provide a fair mechanism for hearing appeals on transfers and discharges of residents from skilled nursing facilities.

(4) Secretarial standards for qualification of administrators

For purposes of subsections (d)(1)(C) and (e)(4) of this section, the Secretary shall develop, by not later than March 1, 1989, standards to be applied in assuring the qualifications of administrators of skilled nursing facilities.

(5) Criteria for administration

The Secretary shall establish criteria for assessing a skilled nursing facility’s compliance with the requirement of subsection (d)(1) of this section with respect to—

(A) its governing body and management,

(B) agreements with hospitals regarding transfers of residents to and from the hospitals and to and from other skilled nursing facilities,

(C) disaster preparedness,

(D) direction of medical care by a physician,

(E) laboratory and radiological services,

(F) clinical records, and

(G) resident and advocate participation.

(6) Specification of resident assessment data set and instruments

The Secretary shall—

(A) not later than January 1, 1989, specify a minimum data set of core elements and common definitions for use by nursing facilities in conducting the assessments required under subsection (b)(3) of this section, and establish guidelines for utilization of the data set; and

(B) by not later than April 1, 1990, designate one or more instruments which are consistent with the specification made under subparagraph (A) and which a State may specify under subsection (e)(5)(A) of this section for use by nursing facilities in complying with the requirements of subsection (b)(3)(A)(iii) of this section.
(7) List of items and services furnished in skilled nursing facilities not chargeable to the personal funds of a resident

(A) Regulations required

Pursuant to the requirement of section 21(b) of the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977, the Secretary shall issue regulations, on or before the first day of the seventh month to begin after December 22, 1987, that define those costs which may be charged to the personal funds of residents in skilled nursing facilities who are individuals receiving benefits under this part and those costs which are to be included in the reasonable cost (or other payment amount) under this subchapter for extended care services.

(B) Rule if failure to publish regulations

If the Secretary does not issue the regulations under subparagraph (A) on or before the date required in such subparagraph, in the case of a resident of a skilled nursing facility who is eligible to receive benefits under this part, the costs which may not be charged to the personal funds of such resident (and for which payment is considered to be made under this subchapter) shall include, at a minimum, the costs for routine personal hygiene items and services furnished by the facility.

(8) Special focus facility program

(A) In general

The Secretary shall conduct a special focus facility program for enforcement of requirements for skilled nursing facilities that the Secretary has identified as having substantially failed to meet applicable requirements of this chapter.

(B) Periodic surveys

Under such program the Secretary shall conduct surveys of each facility in the program not less than once every 6 months.

(g) Survey and certification process

(1) State and Federal responsibility

(A) In general

Pursuant to an agreement under section 1395aa of this title, each State shall be responsible for certifying, in accordance with surveys conducted under paragraph (2), the compliance of skilled nursing facilities (other than facilities of the State) with the requirements of subsections (b), (c), and (d) of this section. The Secretary shall be responsible for certifying, in accordance with surveys conducted under paragraph (2), the compliance of State skilled nursing facilities with the requirements of such subsections.

(B) Educational program

Each State shall conduct periodic educational programs for the staff and residents (and their representatives) of skilled nursing facilities in order to present current regulations, procedures, and policies under this section.

(C) Investigation of allegations of resident neglect and abuse and misappropriation of resident property

The State shall provide, through the agency responsible for surveys and certification of nursing facilities under this subsection, for a process for the receipt and timely review and investigation of allegations of neglect and abuse and misappropriation of resident property by a nurse aide of a resident in a nursing facility or by another individual used by the facility in providing services to such a resident. The State shall, after providing the individual involved with a written notice of the allegations (including a statement of the availability of a hearing for the individual to rebut the allegations) and the opportunity for a hearing on the record, make a written finding as to the accuracy of the allegations. If the State finds that a nurse aide has neglected or abused a resident or misappropriated resident property in a facility, the State shall notify the nurse aide and the registry of such finding. If the State finds that any other individual used by the facility has neglected or abused a resident or misappropriated resident property in a facility, the State shall notify the appropriate licensure authority. A State shall not make a finding that an individual has neglected a resident if the individual demonstrates that such neglect was caused by factors beyond the control of the individual.

(D) Removal of name from nurse aide registry

(i) In general

In the case of a finding of neglect under subparagraph (C), the State shall establish a procedure to permit a nurse aide to petition the State to have his or her name removed from the registry upon a determination by the State that—

(I) the employment and personal history of the nurse aide does not reflect a pattern of abusive behavior or neglect; and

(II) the neglect involved in the original finding was a singular occurrence.

(ii) Timing of determination

In no case shall a determination on a petition submitted under clause (i) be made prior to the expiration of the 1-year period beginning on the date on which the name of the petitioner was added to the registry under subparagraph (C).

(E) Construction

The failure of the Secretary to issue regulations to carry out this subsection shall not relieve a State of its responsibility under this subsection.

(2) Surveys

(A) Standard survey

(i) In general

Each skilled nursing facility shall be subject to a standard survey, to be conducted without any prior notice to the facility. Any individual who notifies (or
(ii) Timing

The extended survey shall be conducted immediately after the standard survey (or, if not practicable, not later than 2 weeks after the date of completion of the standard survey).

(iii) Contents

In such an extended survey, the survey team shall review and identify the policies and procedures which produced such substandard quality of care and shall determine whether the facility has complied with all the requirements described in subsections (b), (c), and (d) of this section. Such review shall include an expansion of the size of the sample of residents’ assessments reviewed and a review of the staffing, in-service training, and, if appropriate, of contracts with consultants.

(iv) Construction

Nothing in this paragraph shall be construed as requiring an extended or partial extended survey as a prerequisite to imposing a sanction against a facility under subsection (h) of this section on the basis of findings in a standard survey.

(C) Survey protocol

Standard and extended surveys shall be conducted—

(i) based upon a protocol which the Secretary has developed, tested, and validated by not later than January 1, 1990, and

(ii) by individuals, of a survey team, who meet such minimum qualifications as the Secretary establishes by not later than such date.

The failure of the Secretary to develop, test, or validate such protocols or to establish such minimum qualifications shall not relieve any State of its responsibility (or the Secretary of the Secretary’s responsibility) to conduct surveys under this subsection.

(D) Consistency of surveys

Each State and the Secretary shall implement programs to measure and reduce inconsistency in the application of survey results among surveyors.

(E) Survey teams

(i) In general

Surveys under this subsection shall be conducted by a multidisciplinary team of professionals (including a registered professional nurse).

(ii) Prohibition of conflicts of interest

A State may not use as a member of a survey team under this subsection an individual who is serving (or has served within the previous 2 years) as a member of the staff of, or as a consultant to, the facility surveyed respecting compliance with the requirements of subsections (b), (c), and (d) of this section, or who has a personal or familial financial interest in the facility being surveyed.

(iii) Training

The Secretary shall provide for the comprehensive training of State and Federal
surveys in the conduct of standard and extended surveys under this subsection, including the auditing of resident assessments and plans of care. No individual shall serve as a member of a survey team unless the individual has successfully completed a training and testing program in survey and certification techniques that has been approved by the Secretary.

(3) Validation surveys

(A) In general

The Secretary shall conduct onsite surveys of a representative sample of skilled nursing facilities in each State, within 2 months of the date of surveys conducted under paragraph (2) by the State, in a sufficient number to allow inferences about the adequacies of each State’s surveys conducted under paragraph (2). In conducting such surveys, the Secretary shall use the same survey protocols as the State is required to use under paragraph (2). If the State has determined that an individual skilled nursing facility meets the requirements of subsections (b), (c), and (d) of this section, but the Secretary determines that the facility does not meet such requirements, the Secretary’s determination as to the facility’s noncompliance with such requirements is binding and supersedes that of the State survey.

(B) Scope

With respect to each State, the Secretary shall conduct surveys under subparagraph (A) each year with respect to at least 5 percent of the number of skilled nursing facilities surveyed by the State in the year, but in no case less than 5 skilled nursing facilities in the State.

(C) Remedies for substandard performance

If the Secretary finds, on the basis of such surveys, that a State has failed to perform surveys as required under paragraph (2) or that a State’s survey and certification performance otherwise is not adequate, the Secretary shall provide for an appropriate remedy, which may include the training of survey teams in the State.

(D) Special surveys of compliance

Where the Secretary has reason to question the compliance of a skilled nursing facility with any of the requirements of subsections (b), (c), and (d) of this section, the Secretary may conduct a survey of the facility and, on the basis of that survey, make independent and binding determinations concerning the extent to which the skilled nursing facility meets such requirements.

(4) Investigation of complaints and monitoring compliance

Each State shall maintain procedures and adequate staff to—

(A) investigate complaints of violations of requirements by skilled nursing facilities, and

(B) monitor, on-site, on a regular, as needed basis, a skilled nursing facility’s compliance with the requirements of subsections (b), (c), and (d) of this section, if—

(i) the facility has been found not to be in compliance with such requirements and is in the process of correcting deficiencies to achieve such compliance;

(ii) the facility was previously found not to be in compliance with such requirements, has corrected deficiencies to achieve such compliance, and verification of continued compliance is indicated; or

(iii) the State has reason to question the compliance of the facility with such requirements.

A State may maintain and utilize a specialized team (including an attorney, an auditor, and appropriate health care professionals) for the purpose of identifying, surveying, gathering and preserving evidence, and carrying out appropriate enforcement actions against substandard skilled nursing facilities.

(5) Disclosure of results of inspections and activities

(A) Public information

Each State, and the Secretary, shall make available to the public—

(i) information respecting all surveys and certifications made respecting skilled nursing facilities, including statements of deficiencies, within 14 calendar days after such information is made available to those facilities, and approved plans of correction,

(ii) copies of cost reports of such facilities filed under this subchapter or subchapter XIX of this chapter,

(iii) copies of statements of ownership under section 1320a–3 of this title, and

(iv) information disclosed under section 1320a–5 of this title.

(B) Notice to ombudsman

Each State shall notify the State long-term care ombudsman (established under title III or VII of the Older Americans Act of 1965 [42 U.S.C. 3021 et seq., 3058 et seq.] in accordance with section 712 of the Act [42 U.S.C. 3058g]) of the State’s findings of noncompliance with any of the requirements of subsections (b), (c), and (d) of this section, or of any adverse action taken against a skilled nursing facility under paragraph (1), (2), or (4) of subsection (h) of this section, with respect to a skilled nursing facility in the State.

(C) Notice to physicians and skilled nursing facility administrator licensing board

If a State finds that a skilled nursing facility has provided substandard quality of care, the State shall notify—

(i) the attending physician of each resident with respect to which such finding is made, and

(ii) the State board responsible for the licensing of the skilled nursing facility administrator at the facility.

(D) Access to fraud control units

Each State shall provide its State medical aid fraud and abuse control unit (established under section 1396b(q) of this title) with access to all information of the State agency
responsible for surveys and certifications under this subsection.

(E) Submission of survey and certification information to the Secretary

In order to improve the timeliness of information made available to the public under subparagraph (A) and provided on the Nursing Home Compare Medicare website under subsection (i), each State shall submit information respecting any survey or certification made respecting a skilled nursing facility (including any enforcement actions taken by the State) to the Secretary not later than the date on which the State sends such information to the facility. The Secretary shall use the information submitted under the preceding sentence to update the information provided on the Nursing Home Compare Medicare website as expeditiously as practicable but not less frequently than quarterly.

(h) Enforcement process

(1) In general

If a State finds, on the basis of a standard, extended, or partial extended survey under subsection (g)(2) of this section or otherwise, that a skilled nursing facility no longer meets a requirement of subsection (b), (c), or (d) of this section, and further finds that the facility’s deficiencies—

(A) immediately jeopardize the health or safety of its residents, the State shall recommend to the Secretary that the Secretary take such action as described in paragraph (2)(A)(i); or

(B) do not immediately jeopardize the health or safety of its residents, the State may recommend to the Secretary that the Secretary take such action as described in paragraph (2)(A)(ii).

If a State finds that a skilled nursing facility meets the requirements of subsections (b), (c), and (d) of this section, but, as of a previous period, did not meet such requirements, the State may recommend a civil money penalty under paragraph (2)(B)(ii) for the days in which it finds that the facility was not in compliance with such requirements.

(2) Secretarial authority

(A) In general

With respect to any skilled nursing facility in a State, if the Secretary finds, or pursuant to a recommendation of the State under paragraph (1) finds, that a skilled nursing facility no longer meets a requirement of subsection (b), (c), (d), or (e) of this section, and further finds that the facility’s deficiencies—

(i) immediately jeopardize the health or safety of its residents, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in subparagraph (B)(vi), or terminate the facility’s participation under this subchapter and may provide, in addition, for one or more of the other remedies described in subparagraph (B); or

(ii) do not immediately jeopardize the health or safety of its residents, the Secretary may impose any of the remedies described in subparagraph (B).

Nothing in this subparagraph shall be construed as restricting the remedies available to the Secretary to remedy a skilled nursing facility’s deficiencies. If the Secretary finds, or pursuant to the recommendation of the State under paragraph (1) finds, that a skilled nursing facility meets such requirements but, as of a previous period, did not meet such requirements, the Secretary may provide for a civil money penalty under subparagraph (B)(ii) for the days on which he finds that the facility was not in compliance with such requirements.

(B) Specified remedies

The Secretary may take the following actions with respect to a finding that a facility has not met an applicable requirement:

(i) Denial of payment

The Secretary may deny any further payments under this subchapter with respect to all individuals entitled to benefits under this subchapter in the facility or with respect to such individuals admitted to the facility after the effective date of the finding.

(ii) Authority with respect to civil money penalties

(I) In general

Subject to subclause (II), if the Secretary had imposed on the facility in the preceding calendar year under such subclause with respect to a repeat deficiency.

(II) Reduction of civil money penalties

Subject to subclause (III), in the case where a facility self-reports and promptly corrects a deficiency for which a penalty was imposed under this clause not later than 10 calendar days after the date of such imposition, the Secretary may reduce the amount of the penalty imposed by not more than 50 percent.

(III) Prohibitions on reduction for certain deficiencies

(aa) Repeat deficiencies

The Secretary may not reduce the amount of a penalty under subclause (II) if the Secretary had reduced a penalty imposed on the facility in the preceding year under such subclause with respect to a repeat deficiency.

(bb) Certain other deficiencies

The Secretary may not reduce the amount of a penalty under subclause (II) if the penalty is imposed on the facility for a deficiency that is found to
result in a pattern of harm or widespread harm, immediately jeopardizes the health or safety of a resident or residents of the facility, or results in the death of a resident of the facility.

(IV) Collection of civil money penalties

In the case of a civil money penalty imposed under this clause, the Secretary shall issue regulations that—

(aa) subject to item (cc), not later than 30 days after the imposition of the penalty, provide for the facility to have the opportunity to participate in an independent informal dispute resolution process which generates a written record prior to the collection of such penalty;

(bb) in the case where the penalty is imposed for each day of noncompliance, provide that a penalty may not be imposed for any day during the period beginning on the initial day of the imposition of the penalty and ending on the day on which the informal dispute resolution process under item (aa) is completed;

(cc) may provide for the collection of such civil money penalty and the placement of such amounts collected in an escrow account under the direction of the Secretary on the earlier of the date on which the informal dispute resolution process under item (aa) is completed or the date that is 90 days after the date of the imposition of the penalty;

(dd) may provide that such amounts collected are kept in such account pending the resolution of any subsequent appeals;

(ee) in the case where the facility successfully appeals the penalty, may provide for the return of such amounts collected (plus interest) to the facility; and

(ff) in the case where all such appeals are unsuccessful, may provide that some portion of such amounts collected may be used to support activities that benefit residents, including assistance to support and protect residents of a facility that closes voluntarily or involuntarily or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility), projects that support resident and family councils and other consumer involvement in assuring quality care in facilities, and facility improvement initiatives approved by the Secretary (including joint training of facility staff and surveyors, technical assistance for facilities implementing quality assurance programs, the appointment of temporary management firms, and other activities approved by the Secretary).

(iii) Appointment of temporary management

In consultation with the State, the Secretary may appoint temporary management to oversee the operation of the facility and to assure the health and safety of the facility’s residents, where there is a need for temporary management while—

(I) there is an orderly closure of the facility, or

(II) improvements are made in order to bring the facility into compliance with all the requirements of subsections (b), (c), and (d) of this section.

The temporary management under this clause shall not be terminated under subclause (II) until the Secretary has determined that the facility has the management capability to ensure continued compliance with all the requirements of subsections (b), (c), and (d) of this section.

The Secretary shall specify criteria, as to when and how each of such remedies is to be applied, the amounts of any fines, and the severity of each of these remedies, to be used in the imposition of such remedies. Such criteria shall be designed so as to minimize the time between the identification of violations and final imposition of the remedies and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies. In addition, the Secretary may provide for other specified remedies, such as directed plans of correction.

(C) Continuation of payments pending remediation

The Secretary may continue payments, over a period of not longer than 6 months after the effective date of the findings, under this subchapter with respect to a skilled nursing facility not in compliance with a requirement of subsection (b), (c), or (d) of this section, if—

(i) the State survey agency finds that it is more appropriate to take alternative action to assure compliance of the facility with the requirements than to terminate the certification of the facility;

(ii) the State has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action, and

(iii) the facility agrees to repay to the Federal Government payments received under this subparagraph if the corrective action is not taken in accordance with the approved plan and timetable.

The Secretary shall establish guidelines for approval of corrective actions requested by States under this subparagraph.

(D) Assuring prompt compliance

If a skilled nursing facility has not complied with any of the requirements of subsections (b), (c), and (d) of this section, within 3 months after the date the facility is found to be out of compliance with such requirements, the Secretary shall impose the remedy described in subparagraph (B)(i) for
all individuals who are admitted to the facility after such date.

(E) Repeated noncompliance

In the case of a skilled nursing facility which, on 3 consecutive standard surveys conducted under subsection (g)(2) of this section, has been found to have provided substandard quality of care, the Secretary shall (regardless of what other remedies are provided)—

(i) impose the remedy described in subparagraph (B)(i), and
(ii) monitor the facility under subsection (g)(4)(B) of this section,

until the facility has demonstrated, to the satisfaction of the Secretary, that it is in compliance with the requirements of subsections (b), (c), and (d) of this section, and that it will remain in compliance with such requirements.

(3) Effective period of denial of payment

A finding to deny payment under this subsection shall terminate when the Secretary finds that the facility is in substantial compliance with all the requirements of subsections (b), (c), and (d) of this section.

(4) Immediate termination of participation for facility where Secretary finds noncompliance and immediate jeopardy

If the Secretary finds that a skilled nursing facility has not met a requirement of subsection (b), (c), or (d) of this section, and finds that the failure immediately jeopardizes the health or safety of its residents, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in paragraph (2)(B)(iii), or the Secretary, subject to section 1320a–7(j)(h) of this title, shall terminate the facility’s participation under this subchapter. If the facility’s participation under this subchapter is terminated, the State shall provide for the safe and orderly transfer of the residents eligible under this subchapter consistent with the requirements of subsection (c)(2) and section 1320a–7(j)(h) of this title.

(5) Construction

The remedies provided under this subsection are in addition to those otherwise available under State or Federal law and shall not be construed as limiting such other remedies, including any remedy available to an individual at common law. The remedies described in clauses (i), (ii)(IV), and (iii) of paragraph (2)(B) may be imposed during the pendency of any hearing.

(6) Sharing of information

Notwithstanding any other provision of law, all information concerning skilled nursing facilities required by this section to be filed with the Secretary or a State agency shall be made available by such facilities to Federal or State employees for purposes consistent with the effective administration of programs established under this subchapter and subchapter XIX of this chapter, including investigations by State medicaid fraud control units.

(i) Nursing Home Compare website

(1) Inclusion of additional information

(A) In general

The Secretary shall ensure that the Department of Health and Human Services includes, as part of the information provided for comparison of nursing homes on the official Internet website of the Federal Government for Medicare beneficiaries (commonly referred to as the “Nursing Home Compare” Medicare website) (or a successor website), the following information in a manner that is prominent, updated on a timely basis, easily accessible, readily understandable to consumers of long-term care services, and searchable:

(i) Staffing data for each facility (including resident census data and data on the hours of care provided per resident per day) based on data submitted under section 1320a–7(g) of this title, including information on staffing turnover and tenure, in a format that is clearly understandable to consumers of long-term care services and allows such consumers to compare differences in staffing between facilities and State and national averages for the facilities. Such format shall include—

(I) concise explanations of how to interpret the data (such as a plain English explanation of data reflecting “nursing home staff hours per resident day”);

(II) differences in types of staff (such as training associated with different categories of staff);

(III) the relationship between nurse staffing levels and quality of care; and

(IV) an explanation that appropriate staffing levels vary based on patient case mix.

(ii) Links to State Internet websites with information regarding State survey and certification programs, links to Form 2567 State inspection reports (or a successor form) on such websites, information to guide consumers in how to interpret and understand such reports, and the facility plan of correction or other response to such report. Any such links shall be posted on a timely basis.

(iii) The standardized complaint form developed under section 1320a–7(f) of this title, including explanatory material on what complaint forms are, how they are used, and how to file a complaint with the State survey and certification program and the State long-term care ombudsman program.

(iv) Summary information on the number, type, severity, and outcome of substantiated complaints.

(v) The number of adjudicated instances of criminal violations by a facility or the employees of a facility—

(I) that were committed inside the facility;

(II) with respect to such instances of violations or crimes committed inside of the facility that were the violations or crimes of abuse, neglect, and explo-
tation, criminal sexual abuse, or other violations or crimes that resulted in serious bodily injury; and

(III) the number of civil monetary penalties levied against the facility, employees, contractors, and other agents.

(B) Deadline for provision of information

(i) In general

Except as provided in clause (ii), the Secretary shall ensure that the information described in subparagraph (A) is included on such website (or a successor website) not later than 1 year after March 23, 2010.

(ii) Exception

The Secretary shall ensure that the information described in subparagraph (A)(i) is included on such website (or a successor website) not later than the date on which the requirements under section 1320a–7(g) of this title are implemented.

(2) Review and modification of website

(A) In general

The Secretary shall establish a process—

(i) to review the accuracy, clarity of presentation, timeliness, and comprehensiveness of information reported on such website as of the day before March 23, 2010; and

(ii) not later than 1 year after March 23, 2010, to modify or revamp such website in accordance with the review conducted under clause (i).

(B) Consultation

In conducting the review under subparagraph (A)(i), the Secretary shall consult with—

(i) State long-term care ombudsman programs;

(ii) consumer advocacy groups;

(iii) provider stakeholder groups; and

(iv) any other representatives of programs or groups the Secretary determines appropriate.

(j) Construction

Where requirements or obligations under this section are identical to those provided under section 1396r of this title, the fulfillment of those requirements or obligations under section 1396r of this title shall be considered to be the fulfillment of the corresponding requirements or obligations under this section.

(2) Review and modification of website

(A) In general

The Secretary shall establish a process—

(i) to review the accuracy, clarity of presentation, timeliness, and comprehensiveness of information reported on such website as of the day before March 23, 2010; and

(ii) not later than 1 year after March 23, 2010, to modify or revamp such website in accordance with the review conducted under clause (i).

(B) Consultation

In conducting the review under subparagraph (A)(i), the Secretary shall consult with—

(i) State long-term care ombudsman programs;

(ii) consumer advocacy groups;

(iii) provider stakeholder groups; and

(iv) any other representatives of programs or groups the Secretary determines appropriate.

(j) Construction

Where requirements or obligations under this section are identical to those provided under section 1396r of this title, the fulfillment of those requirements or obligations under section 1396r of this title shall be considered to be the fulfillment of the corresponding requirements or obligations under this section.

(2) Review and modification of website

(A) In general

The Secretary shall establish a process—

(i) to review the accuracy, clarity of presentation, timeliness, and comprehensiveness of information reported on such website as of the day before March 23, 2010; and

(ii) not later than 1 year after March 23, 2010, to modify or revamp such website in accordance with the review conducted under clause (i).

(B) Consultation

In conducting the review under subparagraph (A)(i), the Secretary shall consult with—

(i) State long-term care ombudsman programs;

(ii) consumer advocacy groups;

(iii) provider stakeholder groups; and

(iv) any other representatives of programs or groups the Secretary determines appropriate.

(j) Construction

Where requirements or obligations under this section are identical to those provided under section 1396r of this title, the fulfillment of those requirements or obligations under section 1396r of this title shall be considered to be the fulfillment of the corresponding requirements or obligations under this section.


Subsec. (g)(1)(A). Pub. L. 100–360, §411(j)(5)(A), substituted "must use'' for "must employ'', and "at least 24-hour licensed nursing staff'' for "24-hour licensed nursing staff''.

Subsec. (g)(1)(B). Pub. L. 100–360, §411(j)(5)(B)(ii), substituted "24-hour licensed nursing staff'' for "24-hour licensed nursing staff''.


Subsec. (g)(3). Pub. L. 100–360, §411(j)(5)(B)(v), inserted "care of residents eligible for benefits for cognitive, behavioral and social care''.


Subsec. (g)(5). Pub. L. 100–360, §411(j)(5)(B)(vii), substituted "care of residents eligible for benefits for cognitive, behavioral and social care''.

Subsec. (g)(6). Pub. L. 100–360, §411(j)(5)(B)(viii), substituted "care of residents eligible for benefits for cognitive, behavioral and social care''.


Subsec. (h)(2)(C). Pub. L. 100–360, §411(i)(2)(C)(iii), inserted "care of residents eligible for benefits for cognitive, behavioral and social care''.

Subsec. (h)(2)(D). Pub. L. 100–360, §411(i)(2)(C)(iv), inserted "care of residents eligible for benefits for cognitive, behavioral and social care''.
to the individual involved and a reasonable opportunity for a hearing for the individual to rebut allegations, make a finding as to the accuracy of the allegations. If the State finds that a nurse aide has neglected or abused a resident or misappropriated resident property in a facility, the State shall notify the nurse aide and the registry of such finding. If the State finds that any other individual used by the facility has neglected or abused a resident or misappropriated resident property in a facility, the State shall notify the appropriate licensure authority. "If the State finds, after notice to the nurse aide involved and a reasonable opportunity for a hearing for the nurse aide to rebut allegations, that a nurse aide whose name is contained in a nurse aide registry has neglected or abused a resident or misappropriated resident property in a facility, the State shall notify the nurse aide and the registry of such finding." Subsec. (g)(1)(D). Pub. L. 100–360, § 411(i)(5)(D), substituted "issue regulations to carry out this subsection" for "to establish standards under subsection (f) of this section".

Subsec. (g)(2)(A)(i). Pub. L. 100–360, § 411(i)(5)(E), amended third sentence generally. Prior to amendment, third sentence read as 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 1320a–7a of this title."


Subsec. (g)(3)(D). Pub. L. 100–360, § 411(i)(5)(G), formerly § 411(i)(5)(F), as redesignated by Pub. L. 100–485, § 408(d)(27)(I), substituted "on the basis of that survey" for "on that basis".


Subsec. (h)(6). Pub. L. 100–360, § 411(i)(7)(B), inserted "by such facilities" after "be made available".

Subsec. (i)(1). Pub. L. 100–203, §§ 4202(a)(2), 4203(a)(2), 4206, added subsecs. (g), (h), and (i), respectively.

**Effective Date of 2010 Amendment**

Pub. L. 111–148, title VI, § 610(c)(2), Mar. 23, 2010, 124 Stat. 762, provided that: "The amendments made by paragraphs (1) [amending this section and section 1396r of this title] shall take effect on the date on which the Secretary of Health and Human Services makes the information described in subsection (b)(1) [probably means subsec. (b) of section 6101, which is set out as a note under section 1320a–7a of this title] available to the public under such subsection."


Pub. L. 111–148, title VI, § 6103(c)(3), Mar. 23, 2010, 124 Stat. 710, provided that: "The amendments made by this subsection [amending this section and section 1396r of this title] shall take effect 1 year after the date of the enactment of this Act [Mar. 23, 2010]."

**Effective Date of 2003 Amendment**

Pub. L. 108–173, title IX, § 932(d), Dec. 8, 2003, 117 Stat. 2462, provided that: "The amendments made by this section [amending this section and sections 1395cc, 1395ff, and 1396r of this title] shall apply to appeals filed on or after October 1, 2004."

**Effective Date of 2000 Amendment**


**Effective Date of 1997 Amendment**

Section 4432(d) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section and sections 1395k, 1395l, 1395u, 1395y, 1395cc, 1395tt, and 1395yy of this title] shall take effect 1 year after the date of enactment of this Act [Mar. 23, 2001]."

**Effective Date of 1994 Amendment**

Section 106(c)(1)(B) of Pub. L. 103–432 provided that: "The amendment made by subparagraph (A) [amending this section] shall take effect as if included in the enactment of OBRA–1990 [Pub. L. 101–508]."

Section 106(c)(2)(B) of Pub. L. 103–432 provided that: "The amendment made by subparagraph (A) [amending this section] shall take effect as if included in the enactment of OBRA–1997 [Pub. L. 100–203]."

Section 106(c)(3)(B) of Pub. L. 103–432 provided that: "The amendment made by subparagraph (A) [amending this section] shall take effect January 1, 1995."

Section 106(c)(4)(C) of Pub. L. 103–432 provided that: "The amendments made by this paragraph [amending this section] shall take effect January 1, 1995."

Section 106(d)(7) of Pub. L. 103–432 provided that: "The amendments made by this subsection [amending this section and provisions set out as a note below] shall take effect as if included in the enactment of OBRA–1990 [Pub. L. 101–508]."

**Effective Date of 1992 Amendment**


**Effective Date of 1990 Amendment**

actment of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203], except that a State may not approve a training and competency evaluation program or a competency evaluation program offered by or in a skilled nursing facility which, pursuant to any Federal or State law within the 2-year period beginning on October 1, 1988—

"(aa) had its participation terminated under title XVIII of the Social Security Act [this subchapter] or under the State plan under title XIX of such Act [subchapter XIX of this chapter];

"(bb) was subject to a denial of payment under either such title;

"(cc) was assessed a civil money penalty not less than $5,000 for deficiencies in skilled nursing facility standards;

"(dd) operated under a temporary management appointed to oversee the operation of the facility and to ensure the health and safety of the facility’s residents; or

"(ee) pursuant to State action, was closed or had its skilled nursing facility certificate revoked.

"(II) Notwithstanding subclause (I) and subject to section 1819(c)(2)(B)(iii)(I) of the Social Security Act [subsec. (f)(2)(B)(iii)(1) of this section] (as amended by section 4202 (enacting this section and enacting sections 1395x, 1395aa, 1395ct, and 1395yy of this title) relating to skilled nursing facility requirements and survey and certification requirements) shall apply to services furnished on or after October 1, 1988, without regard to whether regulations to implement such amendments are promulgated by such date.

Section 4008(h)(1)(H) of Pub. L. 101–508 provided that: '‘The amendments made by this subparagraph (F) [amending this section and enacting provisions set out as a note above], the amendments made by this subsection [probably means this paragraph, amending this section] shall take effect as if they were included in the enactment of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203].’’

Section 4008(h)(2)(P) of Pub. L. 101–508 provided that: '‘The amendments made by this subparagraph (P) [amending this section and sections 1395x and 1395yy of this title] shall take effect as if they were included in the enactment of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203].’’

Section 4206(c)(1) of Pub. L. 101–508 provided that: '‘The amendments made by subsections (a) and (d) [amending this section and sections 1395cc and 1396bb of this title] shall apply with respect to services furnished on or after the first day of the first month beginning more than 1 year after the date of the enactment of this Act [Nov. 5, 1990].’’

**Effective Date of 1989 Amendment**

Section 6001(b)(6) of Pub. L. 101–239 provided that:

"(A) IN GENERAL.—Except as provided in subparagraph (B), the amendments made by this subsection [amending this section and sections 1396b and 1396c of this title] shall take effect as if they were included in the enactment of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203].

"(B) EXCEPTION.—The amendments made by paragraph (3) [amending this section and section 1396r of this title] shall apply to nurse aide training and competency evaluation programs, and nurse aide competency evaluation programs, offered on or after the end of the 90-day period beginning on the date of the enactment of this Act [Dec. 19, 1989] but shall not affect competency evaluations conducted under programs offered before the end of such period.

Section 6001(b)(6) of Pub. L. 101–239 provided that:

"(A) IN GENERAL.—Except as provided in subparagraph (B), the amendments made by this subsection [amending this section and sections 1396b and 1396c of this title] shall take effect as if they were included in the enactment of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203].

"(B) EXCEPTION.—The amendment made by paragraph (1) [amending section 1396b of this title] shall take effect on the date of the enactment of this Act [Dec. 19, 1989].’’

**Effective Date of 1988 Amendments**

Amendment by Pub. L. 100–203 effective as if originally included in 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.

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**


"(a) New Requirements and Survey and Certification Process.—Except as otherwise specifically provided in section 1819 of the Social Security Act [this section], the amendments made by sections 4201 and 4202 [enacting and amending this section and enacting sections 1395x, 1395aa, 1395ct, and 1395yy of this title] relating to skilled nursing facility requirements and survey and certification requirements shall apply to services furnished on or after October 1, 1988, without regard to whether regulations to implement such amendments are promulgated by such date.

"(b) Enforcement.—(1) Except as otherwise specifically provided in section 1819 of the Social Security Act [this section], the amendments made by section 4203 of this Act [amending this section and section 1395aa of this title] apply January 1, 1988, without regard to whether regulations to implement such amendments are promulgated by such date.

"(2) In applying the amendments made by section 4203 of this Act for services furnished by a skilled nursing facility before October 1, 1990, any reference to a requirement of subsection (b), (c), or (d), of section 1819 of the Social Security Act is deemed a reference to the provisions of section 1861(j) of such Act [section 1395x(j) of this title].

"(c) Waiver of Paperwork Reduction.—Chapter 35 of title 44, United States Code, shall not apply to information required for purposes of carrying out this part [part 1 of subtitle C (§§ 4201–4206), enacting this section, amending sections 1395x, 1395aa, 1395ct, and 1395yy of this title, and enacting provisions set out as notes under this section] and implementing the amendments made by this part.

**Guidance to States on Form 2567 State Inspection Reports and Complaint Investigation Reports**


"(1) Guidance.—The Secretary of Health and Human Services (in this subtitle [subtitle B (§§ 6101–6121) of title VI of Pub. L. 111–148, enacting section 1393a–7) of this title, amending this section and sections 1320a–3, 1320a–7, 1395yy, 1396a, and 1396r of this title, and enacting provisions set out as notes under this section and sections 1320a–3, 1320a–7, 1395yy, 1396a, and 1396r of this title, and referred to as the ‘Secretary’ shall provide guidance to States on how States can establish electronic links to Form 2567 State inspection reports (or a successor form), complaint investigation reports, and a facility’s plan of correction or other response to such Form 2567 State inspection reports (or a successor form) on the Internet website of the State that provides information on skilled nursing facilities and nursing facilities and the Secretary shall, if possible, include such information on Nursing Home Compare.

"(3) Definitions.—In this subsection:

"(A) Nursing Facility.—The term ‘nursing facility’ has the meaning given such term in section 1919(a) of the Social Security Act (42 U.S.C. 1396a(a)).
“(B) SECRETARY.—The term ‘Secretary’ means the Secretary of Health and Human Services.

“(C) SKILLED NURSING FACILITY.—The term ‘skilled nursing facility’ has the meaning given such term in section 1819(a) of the Social Security Act (42 U.S.C. 1395–1(c)).”

DEVELOPMENT OF CONSUMER RIGHTS INFORMATION PAGE ON NURSING HOME COMPARE WEBSITE

Pub. L. 111–148, title VI, §6103(e), Mar. 23, 2010, 124 Stat. 716, provided that: “Not later than 1 year after the date of enactment of this Act (Mar. 23, 2010), the Secretary of Health and Human Services shall ensure that the Department of Health and Human Services, as part of the information provided for comparison of nursing facilities on the Change Management Care website develops and includes a consumer rights information page that contains links to descriptions of, and information with respect to, the following:

“(1) The documentation on nursing facilities that is available to the public.

“(2) General information and tips on choosing a nursing facility that meets the needs of the individual.

“(3) General information on consumer rights with respect to nursing facilities.

“(4) The nursing facility survey process (on a national and State-specific basis).

“(5) On a State-specific basis, the services available through the State long-term care ombudsman for such State.”

NATIONAL DEMONSTRATION PROJECTS ON CULTURE CHANGE AND USE OF INFORMATION TECHNOLOGY IN NURSING HOMES


“In GENERAL.—The Secretary of Health and Human Services shall conduct 2 demonstration projects, 1 for the development of best practices in skilled nursing facilities and nursing facilities that are involved in the culture change movement (including the development of resources for facilities to find and access funding in order to undertake culture change) and 1 for the development of best practices in skilled nursing facilities and nursing facilities for the use of information technology to improve resident care.

“(b) CONDUCT OF DEMONSTRATION PROJECTS.—

“(1) GRANT AWARD.—Under each demonstration project conducted under this section, the Secretary shall award 1 or more grants to facility-based settings for the development of best practices described in subsection (a) with respect to the demonstration project involved. Such award shall be made on a competitive basis and may be allocated in 1 lump-sum payment.

“(2) CONSIDERATION OF SPECIAL NEEDS OF RESIDENTS.—Each demonstration project conducted under this section shall take into consideration the special needs of residents of skilled nursing facilities and nursing facilities who have cognitive impairment, including dementia.

“(c) DURATION AND IMPLEMENTATION.—

“(1) DURATION.—The demonstration projects shall each be conducted for a period not to exceed 3 years.

“(2) IMPLEMENTATION.—The demonstration projects shall each be implemented not later than 1 year after the date of enactment of this Act (Mar. 23, 2010).

“(3) DEFINITIONS.—In this section:

“(1) NURSING FACILITY.—The term ‘nursing facility’ has the meaning given such term in section 1819(a) of the Social Security Act (42 U.S.C. 1395d–1(c)).

“(2) SECRETARY.—The term ‘Secretary’ means the Secretary of Health and Human Services.

“(3) SKILLED NURSING FACILITY.—The term ‘skilled nursing facility’ has the meaning given such term in section 1819(a) of the Social Security Act (42 U.S.C. 1395s–1(a)).

“(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

“(e) REPORT.—Not later than 9 months after the completion of the demonstration project, the Secretary shall submit to Congress a report on such project, together with recommendations for such legislation and administrative action as the Secretary determines appropriate.”

REVIEW AND REPORT ON CURRENT STANDARDS OF PRACTICE FOR PHARMACY SERVICES PROVIDED TO PATIENTS IN NURSING FACILITIES


“(1) REVIEW.—

“(A) IN GENERAL.—Not later than 12 months after the date of enactment of this Act (Dec. 8, 2003), the Secretary of Health and Human Services shall conduct a thorough review of the current standards of practice for pharmacy services provided to patients in nursing facilities.

“(B) SPECIFIC MATTERS REVIEWED.—In conducting the review under subparagraph (A), the Secretary shall—

“(i) assess the current standards of practice, clinical services, and other service requirements generally used for pharmacy services in long-term care settings; and

“(ii) evaluate the impact of those standards with respect to patient safety, reduction of medication errors and quality of care.

“(2) REPORT.—

“(A) IN GENERAL.—Not later than the date that is 18 months after the date of the enactment of this Act (Dec. 8, 2003), the Secretary shall submit a report to Congress on the study conducted under paragraph (1)(A).

“(B) CONTENTS.—The report submitted under subparagraph (A) shall contain—

“(i) a description of the plans of the Secretary to implement the provisions of this Act (see Tables for classification) in a manner consistent with applicable State and Federal laws designed to protect the safety and quality of care of nursing facility patients; and

“(ii) recommendations regarding necessary actions and appropriate reimbursement to ensure the provision of prescription drugs to Medicare beneficiaries residing in nursing facilities in a manner consistent with existing patient safety and quality of care standards under applicable State and Federal laws.

“STUDY AND REPORT REGARDING STATE LICENSURE AND CERTIFICATION STANDARDS AND RESPIRATORY THERAPY COMPETENCY EXAMINATIONS


“(a) STUDY.—The Secretary of Health and Human Services shall conduct a study that—

“(1) identifies variations in State licensure and certification standards for health care providers (including nursing and allied health professionals) and other individuals providing respiratory therapy in skilled nursing facilities;

“(2) examines State requirements relating to respiratory therapy competency examinations for such providers and individuals; and

“(3) determines whether regular respiratory therapy competency examinations or certifications should be required under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) for such providers and individuals.

“(b) REPORT.—Not later than 18 months after the date of enactment of this Act (Nov. 29, 1999), the Secretary of Health and Human Services shall submit to Congress a report on the results of the study conducted under this section, together with any recommendations for legislation that the Secretary determines to be appropriate as a result of such study.”

RETROACTIVE REVIEW

Section 4755(c) of Pub. L. 105–33 provided that: “The procedures developed by a State under the amendments
made by subsection(s) (a) and (b) [amending this section and section 1396r of this title] shall permit an individual to petition for a review of any finding made by a State under section 1319(e)(1)(C) or 1919(e)(1)(C) of the Social Security Act (42 U.S.C. 1395f-3(g)(1)(C) or 1396r(g)(1)(C) after January 1, 1995.''

**STUDY AND REPORT ON DEEMING FOR NURSING FACILITIES AND RENAL DIALYSIS FACILITIES**

Pub. L. 104–134, title I, §101(d) [title V, §516(d)], Apr. 21, 1996, 110 Stat. 1321–221, 1321–248; renumbered title I, that:

(1) a study concerning the effectiveness and appropriateness of the current mechanisms for surveying and certifying skilled nursing facilities for compliance with the conditions and requirements of sections 1819 and 1919 of the Social Security Act (this section and section 1395x(i) of this title) and nursing facilities for compliance with the conditions of section 1919 of such Act (section 1396i of this title), and

(2) a study concerning the effectiveness and appropriateness of the current mechanisms for surveying and certifying renal dialysis facilities for compliance with the conditions and requirements of section 1819(b) of the Social Security Act (section 1396r(b) of this title).

**MAINTAINING REGULATORY STANDARDS FOR CERTAIN SERVICES**

Section 4008(h)(2)(O) of Pub. L. 101–508 provided that:

'(A) Any regulations promulgated and applied by the Secretary of Health and Human Services after the date of the enactment of the Omnibus Budget Reconciliation Act of 1987 (Dec. 22, 1987) with respect to services described in clauses (ii), (iv), and (v) of section 1819(b)(4)(A) of the Social Security Act [subsec. (b)(4)(A)(ii), (iv), and (v) of this section] shall include requirements for providers of such services that are at least as strict as the requirements applicable to providers of such services prior to the enactment of the Omnibus Budget Reconciliation Act of 1987.''

**NURSE AIDE TRAINING AND COMPETENCY EVALUATION PROGRAMS; PROVISION OF PROPOSED REGULATIONS**

Section 6001(b)(2) of Pub. L. 101–239 provided that:

'(A) The Secretary of Health and Human Services shall issue proposed regulations to establish the requirements described in sections 1819(f)(2) and 1919(f)(2) of the Social Security Act [subsec. (f)(2) of this section and section 1396r(f)(2) of this title] by not later than 90 days after the date of the enactment of this Act [Dec. 19, 1989].'

**NURSE AIDE TRAINING AND COMPETENCY EVALUATION; SATISFACTION OF REQUIREMENTS; WAIVER**

Section 6001(b)(4)(B)–(D) of Pub. L. 101–239 provided that:

'(B) A nurse aide shall be considered to satisfy the requirements of sections 1819(b)(5)(A) and 1919(b)(5)(A) of the Social Security Act [subsec. (b)(5)(A) of this section and section 1396r(b)(5)(A) of this title] of having completed a training and competency evaluation program approved by a State under section 1819(e)(1)(A) or 1919(e)(1)(A) of such Act [subsec. (e)(1)(A) of this section and section 1396r(e)(1)(A) of this title], if such aide had received, before July 1, 1989, at least the difference in the number of such hours in supervised practical nurse aide training or in regular in-service nurse aide education.

'(C) A nurse aide shall be considered to satisfy the requirements of sections 1819(b)(5)(A) and 1919(b)(5)(A) of the Social Security Act (of having completed a training and competency evaluation program approved by a State under section 1819(e)(1)(A) or 1919(e)(1)(A) of such Act), if such aide was found competent (whether or not by the State), before July 1, 1989, after the completion of a course of nurse aide training of at least 100 hours duration.

'(D) With respect to the nurse aide competency evaluation requirements described in sections 1819(b)(5)(A) and 1919(b)(5)(A) of the Social Security Act, a State may waive such requirements with respect to an individual who can demonstrate to the satisfaction of the State that such individual has served as a nurse aide at one or more facilities of the same type in the State for at least 24 consecutive months before the date of the enactment of this Act [Dec. 19, 1989].'

**EVALUATION AND REPORT ON IMPLEMENTATION OF RESIDENT ASSESSMENT PROCESS**

Section 4201(c) of Pub. L. 100–203 provided that: 'The Secretary of Health and Human Services shall evaluate, and report to Congress by not later than January 1, 1992, on the implementation of the resident assessment process for residents of skilled nursing facilities under the amendments made by this section [enacting this section and amending sections 1395x, 1395aa, 1395tt, and 1396yy of this title].'

**ANNUAL REPORT ON STATUTORY COMPLIANCE AND ENFORCEMENT ACTIONS**

Section 4205 of Pub. L. 100–203 provided that: 'The Secretary of Health and Human Services shall report to the Congress annually on the extent to which skilled nursing facilities are complying with the requirements of subsections (b), (c), and (d) of section 1819(b) of the Social Security Act [subsecs. (b), (c), and (d) of this section] (as added by the amendments made by this part) and the number and type of enforcement actions taken by States and the Secretary under section 1819(b) of such Act (as added by section 4203 of this Act).'

§ 1395t–3a. Protecting residents of long-term care facilities

(1) National Training Institute for surveyors

(A) In general

The Secretary of Health and Human Services shall enter into a contract with an entity for the purpose of establishing and operating a National Training Institute for Federal and State surveyors. Such Institute shall provide and improve the training of surveyors with respect to investigating allegations of abuse, neglect, and misappropriation of property in programs and long-term care facilities that receive payments under title XVIII or XIX of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq.].

(B) Activities carried out by the Institute

The contract entered into under subparagraph (A) shall require the Institute established and operated under such contract to carry out the following activities:

(i) Assess the extent to which State agencies use specialized surveyors for the inves-
(2) Grants to State survey agencies

(A) In general

The Secretary of Health and Human Services shall make grants to State agencies that perform surveys of skilled nursing facilities or nursing facilities under sections 1819 and 1919, respectively, of the Social Security Act (42 U.S.C. 1395i–3; 1395r (1396r)).

(B) Use of funds

A grant awarded under subparagraph (A) shall be used for the purpose of designing and implementing complaint investigations systems that—

(i) promptly prioritize complaints in order to ensure a rapid response to the most serious and urgent complaints;

(ii) respond to complaints with optimum effectiveness and timeliness; and

(iii) optimize the collaboration between local authorities, consumers, and providers, including—

(I) such State agency;

(II) the State Long-Term Care Ombudsman;

(III) local law enforcement agencies;

(IV) advocacy and consumer organizations;

(V) State aging units;

(VI) Area Agencies on Aging; and

(VII) other appropriate entities.

(C) Authorization

There are authorized to be appropriated to carry out this paragraph, for each of fiscal years 2011 through 2014, $5,000,000.


REFERENCES IN TEXT

The Social Security Act, referred to in par. (1)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII and XIX of the Act are classified generally to this subchapter (§1395 et seq.) and subchapter XIX (§1396 et seq.), respectively, of this chapter. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

DEFINITIONS

Pub. L. 111–148, title VI, §6702, Mar. 23, 2010, 124 Stat. 782, provided that: “Except as otherwise specifically provided, any term that is defined in section 2011 of the Social Security Act [42 U.S.C. 1397i] (as added by section 6703(a)) and is used in this subtitle [subtitle H (§§ 6701–6703) of title VI of Pub. L. 111–148, enacting this section and sections 1320b–25, 1397i, 1397i–1, 1397k to 1397k–3, 1397l, and 1397m to 1397m–5 of this title, amending sections 602, 604, 622, 671 to 673, 1320a–7, 1320a–7a, 1320a–7d, 1397, 1397a, 1397c to 1397e, and 1397g of this title, and enacting provisions set out as notes under sections 602 and 1305 of this title] has the meaning given such term by such section.”

§1395i–4. Medicare rural hospital flexibility program

(a) Establishment

Any State that submits an application in accordance with subsection (b) of this section may establish a medicare rural hospital flexibility program described in subsection (c) of this section.

(b) Application

A State may establish a medicare rural hospital flexibility program described in subsection (c) of this section if the State submits to the Secretary at such time and in such form as the Secretary may require an application containing—

(1) assurances that the State—

(A) has developed, or is in the process of developing, a State rural health care plan that—

(1) grants to State survey agencies

(2) investigation of reported allegations of abuse, neglect, and misappropriation of property in such programs and long-term care facilities.

(ii) Evaluate how the competencies of surveyors may be improved to more effectively investigate reported allegations of such abuse, neglect, and misappropriation of property, and provide feedback to Federal and State agencies on the evaluations conducted.

(iii) Provide a national program of training, tools, and technical assistance to Federal and State surveyors on investigating reports of such abuse, neglect, and misappropriation of property.

(iv) Develop and disseminate information on best practices for the investigation of such abuse, neglect, and misappropriation of property.

(v) Assess the performance of State complaint intake systems, in order to ensure that the intake of complaints occurs 24 hours per day, 7 days a week (including holidays).

(vi) To the extent approved by the Secretary of Health and Human Services, provide a national 24 hours per day, 7 days a week (including holidays), back-up system to State complaint intake systems in order to ensure optimum national responsiveness to complaints of such abuse, neglect, and misappropriation of property.

(vii) Analyze and report annually on the following:

(I) The total number and sources of complaints of such abuse, neglect, and misappropriation of property.

(II) The extent to which such complaints are referred to law enforcement agencies.

(III) General results of Federal and State investigations of such complaints.

(viii) Conduct a national study of the cost to State agencies of conducting complaint investigations of skilled nursing facilities and nursing facilities under sections 1819 and 1919, respectively, of the Social Security Act (42 U.S.C. 1395i–3; 1395r), and making recommendations to the Secretary of Health and Human Services with respect to options to increase the efficiency and cost-effectiveness of such investigations.

(C) Authorization

There are authorized to be appropriated to carry out this paragraph, for each of fiscal years 2011 through 2014, $12,000,000.


REFERENCES IN TEXT

The Social Security Act, referred to in par. (1)(A), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Titles XVIII and XIX of the Act are classified generally to this subchapter (§§ 6701–6703) of title VI of Pub. L. 111–148, enacting this section and sections 1320b–25, 1397i, 1397i–1, 1397k to 1397k–3, 1397l, and 1397m to 1397m–5 of this title, amending sections 602, 604, 622, 671 to 673, 1320a–7, 1320a–7a, 1320a–7d, 1397, 1397a, 1397c to 1397e, and 1397g of this title, and enacting provisions set out as notes under sections 602 and 1305 of this title] has the meaning given such term by such section.”

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(1) grants to State survey agencies

(2) investigation of reported allegations of abuse, neglect, and misappropriation of property in such programs and long-term care facilities.

(ii) Evaluate how the competencies of surveyors may be improved to more effectively investigate reported allegations of such abuse, neglect, and misappropriation of property, and provide feedback to Federal and State agencies on the evaluations conducted.

(iii) Provide a national program of training, tools, and technical assistance to Federal and State surveyors on investigating reports of such abuse, neglect, and misappropriation of property.

(iv) Develop and disseminate information on best practices for the investigation of such abuse, neglect, and misappropriation of property.

(v) Assess the performance of State complaint intake systems, in order to ensure that the intake of complaints occurs 24 hours per day, 7 days a week (including holidays).

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(I) The total number and sources of complaints of such abuse, neglect, and misappropriation of property.

(II) The extent to which such complaints are referred to law enforcement agencies.

(III) General results of Federal and State investigations of such complaints.

(viii) Conduct a national study of the cost to State agencies of conducting complaint investigations of skilled nursing facilities and nursing facilities under sections 1819 and 1919, respectively, of the Social Security Act (42 U.S.C. 1395i–3; 1395r), and making recommendations to the Secretary of Health and Human Services with respect to options to increase the efficiency and cost-effectiveness of such investigations.

(C) Authorization

There are authorized to be appropriated to carry out this paragraph, for each of fiscal years 2011 through 2014, $12,000,000.


REFERENCES IN TEXT

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(i) provides for the creation of 1 or more rural health networks (as defined in subsection (d) of this section) in the State;

(ii) promotes regionalization of rural health services in the State; and

(iii) improves access to hospital and other health services for rural residents of the State; and

(B) has developed the rural health care plan described in subparagraph (A) in consultation with the hospital association of the State, rural hospitals located in the State, and the State Office of Rural Health (or, in the case of a State in the process of developing such plan, that assures the Secretary that the State will consult with its State hospital association, rural hospitals located in the State, and the State Office of Rural Health in developing such plan);

(2) assurances that the State has designated (consistent with the rural health care plan described in paragraph (1)(A), or is in the process of so designating, rural nonprofit or public hospitals or facilities located in the State as critical access hospitals; and

(3) such other information and assurances as the Secretary may require.

c) Medicare rural hospital flexibility program described

(1) In general

A State that has submitted an application in accordance with subsection (b) of this section, may establish a medicare rural hospital flexibility program that provides that—

(A) the State shall develop at least 1 rural health network (as defined in subsection (d) of this section) in the State; and

(B) at least 1 facility in the State shall be designated as a critical access hospital in accordance with paragraph (2).

(2) State designation of facilities

(A) In general

A State may designate 1 or more facilities as a critical access hospital in accordance with subparagraphs (B), (C), and (D).

(B) Criteria for designation as critical access hospital

A State may designate a facility as a critical access hospital if the facility—

(i) is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital, or another facility described in this subsection; or

(ii) is certified before January 1, 2006, by the State as being a necessary provider of health care services to residents in the area;

(iii) provides not more than 25 acute care inpatient beds (meeting such standards as the Secretary may establish) for providing inpatient care for a period that does not exceed, as determined on an annual, average basis, 96 hours per patient;

(iv) meets such staffing requirements as would apply under section 1395x(e) of this title to a hospital located in a rural area, except that—

(I) the facility need not meet hospital standards relating to the number of hours during a day, or days during a week, in which the facility must be open and fully staffed, except insofar as the facility is required to make available emergency care services as determined under clause (ii) and must have nursing services available on a 24-hour basis, but need not otherwise staff the facility except when an inpatient is present;

(II) the facility may provide any services otherwise required to be provided by a full-time, on site dietitian, pharmacist, laboratory technician, medical technologist, and radiological technologist on a part-time, off site basis under arrangements as defined in section 1395x(w)(1) of this title; and

(III) the inpatient care described in clause (iii) may be provided by a physician assistant, nurse practitioner, or clinical nurse specialist subject to the oversight of a physician who need not be present in the facility; and

(v) meets the requirements of section 1395x(aa)(2)(I) of this title.

(C) Recently closed facilities

A State may designate a facility as a critical access hospital if the facility—

(i) was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and

(ii) as of the effective date of such designation, meets the criteria for designation under subparagraph (B).

(D) Downsized facilities

A State may designate a health clinic or a health center (as defined by the State) as a critical access hospital if such clinic or center—

(i) is licensed by the State as a health clinic or a health center;

(ii) was a hospital that was downsized to a health clinic or health center; and

(iii) as of the effective date of such designation, meets the criteria for designation under subparagraph (B).

(E) Authority to establish psychiatric and rehabilitation distinct part units

(i) In general

Subject to the succeeding provisions of this subparagraph, a critical access hospital may establish—

(I) a psychiatric unit of the hospital that is a distinct part of the hospital; and
(d) “Rural health network” defined

(1) In general

In this section, the term “rural health network” means, with respect to a State, an organization consisting of—

(A) at least 1 facility that the State has designated or plans to designate as a critical access hospital; and

(B) at least 1 hospital that furnishes acute care services.

(2) Agreements

(A) In general

Each critical access hospital that is a member of a rural health network shall have an agreement with respect to each item described in subparagraph (B) with at least 1 hospital that is a member of the network.

(B) Items described

The items described in this subparagraph are the following:

(i) Patient referral and transfer.

(ii) The development and use of communications systems including (where feasible)—

(I) telemetry systems; and

(II) systems for electronic sharing of patient data.

(iii) The provision of emergency and non-emergency transportation among the facility and the hospital.

(C) Credentialing and quality assurance

Each critical access hospital that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least—

(i) 1 hospital that is a member of the network;

(ii) 1 peer review organization or equivalent entity; or

(iii) 1 other appropriate and qualified entity identified in the State rural health care plan.

(e) Certification by Secretary

The Secretary shall certify a facility as a critical access hospital if the facility—

(1) is located in a State that has established a Medicare rural hospital flexibility program in accordance with subsection (c) of this section;

(2) is designated as a critical access hospital by the State in which it is located; and

(3) meets such other criteria as the Secretary may require.

(f) Permitting maintenance of swing beds

Nothing in this section shall be construed to prohibit a State from designating or the Secretary from certifying a facility as a critical access hospital solely because, at the time the facility applies to the State for designation as a critical access hospital, there is in effect an agreement between the facility and the Secretary under section 1395tt of this title under which the facility’s inpatient hospital facilities are used for the provision of extended care services, so long as the total number of beds that may be used at any time for the furnishing of either such services or acute care inpatient services does not exceed 25 beds. For purposes of the previous sentence, any bed of a unit of the facility that is licensed as a distinct-part skilled nursing facility at the time the facility applies to the State for designation as a critical access hospital shall not be counted.

(g) Grants

(1) Medicare rural hospital flexibility program

The Secretary may award grants to States that have submitted applications in accordance with subsection (b) of this section for—

(A) engaging in activities relating to planning and implementing a rural health care plan;

(B) engaging in activities relating to planning and implementing rural health networks;

(C) designating facilities as critical access hospitals; and

(D) providing support for critical access hospitals for quality improvement, quality reporting, performance improvements, and benchmarking.

(2) Rural emergency medical services

(A) In general

The Secretary may award grants to States that have submitted applications in accordance with subparagraph (B) for the establishment or expansion of a program for the provision of rural emergency medical services.
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(B) Application
An application is in accordance with this subparagraph if the State submits to the Secretary at such time and in such form as the Secretary may require an application containing the assurances described in subparagraphs (A)(ii), (A)(iii), and (B) of subsection (b)(1) of this section and paragraph (3) of that subsection.

(3) Upgrading data systems

(A) Grants to hospitals
The Secretary may award grants to hospitals that have submitted applications in accordance with subparagraph (C) to assist eligible small rural hospitals in meeting the costs of implementing data systems required to meet requirements established under the medicare program pursuant to amendments made by the Balanced Budget Act of 1997 and to assist such hospitals in participating in delivery system reforms under the provisions of and amendments made by the Patient Protection and Affordable Care Act, such as value-based purchasing programs, accountable care organizations under section 1395ccc–4 of this title, and other delivery system reform programs determined appropriate by the Secretary.

(B) Eligible small rural hospital defined
For purposes of this paragraph, the term ‘eligible small rural hospital’ means a non-Federal, short-term general acute care hospital that—
(i) is located in a rural area (as defined for purposes of section 1395ww(d) of this title); and
(ii) has less than 50 beds.

(C) Application
A hospital seeking a grant under this paragraph shall submit an application to the Secretary on or before such date and in such form and manner as the Secretary specifies.

(D) Amount of grant
A grant to a hospital under this paragraph may not exceed $50,000.

(E) Use of funds
A hospital receiving a grant under this paragraph may use the funds for the purchase of computer software and hardware, the education and training of hospital staff on computer information systems, to offset costs related to the implementation of prospective payment systems and to participate in delivery system reforms under the provisions of and amendments made by the Patient Protection and Affordable Care Act, such as value-based purchasing programs, accountable care organizations under section 1395ccc–4 of this title, and other delivery system reform programs determined appropriate by the Secretary.

(F) Reports

(i) Information
A hospital receiving a grant under this section shall furnish the Secretary with such information as the Secretary may require to evaluate the project for which the grant is made and to ensure that the grant is expended for the purposes for which it is made.

(ii) Timing of submission

(I) Interim reports
The Secretary shall report to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate at least annually on the grant program established under this section, including in such report information on the number of grants made, the nature of the projects involved, the geographic distribution of grant recipients, and such other matters as the Secretary deems appropriate.

(II) Final report
The Secretary shall submit a final report to such committees not later than 180 days after the completion of all of the projects for which a grant is made under this section.

(4) Additional requirements with respect to FLEX grants
With respect to grants awarded under paragraph (1) or (2) from funds appropriated for fiscal year 2005 and subsequent fiscal years—

(A) Consultation with the state hospital association and rural hospitals on the most appropriate ways to use grants
A State shall consult with the hospital association of such State and rural hospitals located in such State on the most appropriate ways to use the funds under such grant.

(B) Limitation on use of grant funds for administrative expenses
A State may not expend more than the lesser of—
(i) 15 percent of the amount of the grant for administrative expenses; or
(ii) the State’s federally negotiated indirect rate for administering the grant.

(5) Use of funds for Federal administrative expenses
Of the total amount appropriated for grants under paragraphs (1) and (2) for a fiscal year (for each of fiscal years 2005 through 2008) and, of the total amount appropriated for grants under paragraphs (1), (2), and (6) for a fiscal year (beginning with fiscal year 2009), up to 5 percent of such amount shall be available to the Health Resources and Services Administration for purposes of administering such grants.

(6) Providing mental health services and other health services to veterans and other residents of rural areas

(A) Grants to States
The Secretary may award grants to States that have submitted applications in accord-
ance with subparagraph (B) for increasing the delivery of mental health services or other health care services deemed necessary to meet the needs of veterans of Operation Iraqi Freedom and Operation Enduring Freedom living in rural areas (as defined by the Administrator of the Health Resources and Services Administration), including for the provision of crisis intervention services and the detection of post-traumatic stress disorder, traumatic brain injury, and other signature injuries of veterans of Operation Iraqi Freedom and Operation Enduring Freedom, and for referral of such veterans to medical facilities operated by the Department of Veterans Affairs, and for the delivery of such services to other residents of such rural areas.

(B) Application

(i) In general

An application is in accordance with this subparagraph if the State submits to the Secretary at such time and in such form as the Secretary may require an application containing the assurances described in subparagraphs (A)(ii) and (A)(iii) of subsection (b)(1).

(ii) Consideration of regional approaches, networks, or technology

The Secretary may, as appropriate in awarding grants to States under subparagraph (A), consider whether the application submitted by a State under this subparagraph includes 1 or more proposals that utilize regional approaches, networks, health information technology, telehealth, or telemedicine to deliver services described in subparagraph (A) to individuals described in that subparagraph. For purposes of this clause, a network may, as the Secretary determines appropriate, include Federally qualified health centers (as defined in section 1395x(aa)(4) of this title), rural health clinics (as defined in section 1395x(aa)(2) of this title), home health agencies (as defined in section 1395x(o) of this title), community mental health centers (as defined in section 1395x(ff)(3)(B) of this title) and other providers of mental health services, pharmacists, local government, and other providers deemed necessary to meet the needs of veterans.

(iii) Coordination at local level

The Secretary shall require, as appropriate, a State to demonstrate consultation with the hospital association of such State, rural hospitals located in such State, providers of mental health services, or other appropriate stakeholders for the provision of services under a grant awarded under this paragraph.

(iv) Special consideration of certain applications

In awarding grants to States under subparagraph (A), the Secretary shall give special consideration to applications submitted by States in which veterans make up a high percentage (as determined by the Secretary) of the total population of the State. Such consideration shall be given without regard to the number of veterans of Operation Iraqi Freedom and Operation Enduring Freedom living in the areas in which mental health services and other health care services would be delivered under the application.

(C) Coordination with VA

The Secretary shall, as appropriate, consult with the Director of the Office of Rural Health of the Department of Veterans Affairs in awarding and administering grants to States under subparagraph (A).

(D) Use of funds

A State awarded a grant under this paragraph may, as appropriate, use the funds to reimburse providers of services described in subparagraph (A) to individuals described in that subparagraph.

(E) Limitation on use of grant funds for administrative expenses

A State awarded a grant under this paragraph may not expend more than 15 percent of the amount of the grant for administrative expenses.

(F) Independent evaluation and final report

The Secretary shall provide for an independent evaluation of the grants awarded under subparagraph (A). Not later than 1 year after the date on which the last grant is awarded to a State under such subparagraph, the Secretary shall submit a report to Congress on such evaluation. Such report shall include an assessment of the impact of such grants on the delivery of mental health services and other health services to veterans of the United States Armed Forces living in rural areas (as so defined and including such areas that are rural census tracks), with particular emphasis on the impact of such grants on increasing the delivery of mental health services and other health services to veterans of Operation Enduring Freedom and Operation Iraqi Freedom, and to other individuals living in such rural areas.

(7) Critical access hospitals transitioning to skilled nursing facilities and assisted living facilities

(A) Grants

The Secretary may award grants to eligible critical access hospitals that have submitted applications in accordance with subparagraph (B) for assisting such hospitals in the transition to skilled nursing facilities and assisted living facilities.

(B) Application

An applicable critical access hospital seeking a grant under this paragraph shall submit an application to the Secretary on or before such date and in such form and manner as the Secretary specifies.

(C) Additional requirements

The Secretary may not award a grant under this paragraph to an eligible critical access hospital unless—
Authorization of appropriations
the Federal Hospital Insurance Trust Fund for
as necessary to conduct the program estab-
visions of this part and part E of this subchapter

(D) Amount of grant
A grant to an eligible critical access hos-
grant under this paragraph may not exceed
$1,000,000.

(E) Funding
There are appropriated from the Federal Hospital Insurance Trust Fund under section 1395i of this title for making grants under this paragraph, $5,000,000 for fiscal year 2008.

(F) Eligible critical access hospital defined
For purposes of this paragraph, the term “eligible critical access hospital” means a critical access hospital that has an average daily acute census of less than 5.0 and an average daily swing bed census of greater than 10.0.

(h) Grandfathering provisions
(1) In general
Any medical assistance facility operating in
hospital is located provides

(2) Continuation of medical assistance facility and rural primary care hospital terms
Notwithstanding any other provision of this subchapter, with respect to any medical as-
sistance facility or rural primary care hospital described in paragraph (1), any reference in this subchapter to a “critical access hospital” shall be deemed to be a reference to a “medical assistance facility” or “rural primary care hospital”.

(3) State authority to waive 35-mile rule
In the case of a facility that was designated as a critical access hospital before January 1, 2006, and was certified by the State as being a necessary provider of health care services to residents in the area under subsection (c)(2)(B)(i)(II) of this section, as in effect before such date, the authority under such subsection with respect to any redesignation of such facility shall continue to apply notwithstanding the amendment made by section 305(h)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(i) Waiver of conflicting part A provisions
The Secretary is authorized to waive such pro-
visions of this part and part E of this subchapter

(j) Authorization of appropriations
There are authorized to be appropriated from the Federal Hospital Insurance Trust Fund for
making grants to all States under subsection (g) of this section, $25,000,000 in each of the fiscal years 1998 through 2002, for making grants to all States under paragraphs (1) and (2) of subsection (g) of this section, $35,000,000 in each of fiscal years 2003 through 2006, for making grants to all States under paragraphs (1) and (2) of subsection (g), $55,000,000 in each of fiscal years 2009 and 2010, for making grants to all States under paragraph (6) of subsection (g), $50,000,000 in each of fiscal years 2009 and 2010, to remain available until expended and for making grants to all States under subsection (g), such sums as may be necessary in each of fiscal years 2011 and 2012, to remain available until expended.


REFERENCES IN TEXT


Part E of this subchapter, referred to in subsec. (i), is classified to section 1395x et seq. of this title.

AMENDMENTS
2010—Subsec. (g)(3)(A). Pub. L. 111–148, §3129(b)(1), inserted “and to assist such hospitals in participating in delivery system reforms under the provisions of and amendments made by the Patient Protection and Affordable Care Act, such as value-based purchasing programs, accountable care organizations under section 1395jj of this title, the National pilot program on payment bundling under section 1395cc–4 of this title, and other delivery system reform programs determined appropriate by the Secretary” before period at end.

Subsec. (g)(3)(E). Pub. L. 111–148, §3129(b)(2), substituted “and to offset” for “and to offset” and inserted “and to participate in delivery system reforms under the provisions of and amendments made by the Patient Protection and Affordable Care Act, such as value-based purchasing programs, accountable care organizations under section 1395jj of this title, the National pilot program on payment bundling under section 1395cc–4 of this title, and other delivery system reform programs determined appropriate by the Secretary” before period at end.

Subsec. (j). Pub. L. 111–148, §3129(a), substituted “2010, for” for “2010, and for” and inserted “and for making
grants to all States under subsection (g), such sums as may be necessary in each of fiscal years 2011 and 2012, to remain available until expended” before period at end.


Subsec. (g)(5). Pub. L. 110–275, § 121(b)(2), which directed insertion of “and, of the total amount appropriated for grants under paragraphs (1), (2), and (6) for a fiscal year (beginning with fiscal year 2009)” after “2008”), was executed by making the insertion after “2008”) for paragraph (3) as (1) and struck out former par. (1) which read as follows: “is located in a rural area (as defined in section 1395ww(d)(2)(D) of this title) that is located in a county (or equivalent unit of local government) in a rural area (as defined in section 1395ww(d)(2)(D) of this title) for a fiscal year (beginning with fiscal year 2009)” after “2008”).

1997—Pub. L. 105–33, § 4201(a), amended section catchline and text generally, substituting provisions relating to Medicare rural hospital flexibility program for provisions relating to essential access community hospital program.


1994—Subsec. (c)(1). Pub. L. 103–432, § 102(b)(2)(B)(i), substituted “paragraph (3) or subsection (k) of this section” for “paragraph (3)”.

Subsec. (e)(1). Pub. L. 103–432, § 102(b)(1)(A)(ii), redesignated par. (2) as (1) and struck out former par. (1) which read as follows: “is located in a rural area (as defined in section 1395ww(d)(2)(D) of this title),”.

Subsec. (e)(2) to (6). Pub. L. 103–432, § 102(b)(1)(A)(i), redesignated pars. (2) to (6) as (1) to (5), respectively.

Subsec. (f)(1)(F). Pub. L. 103–432, § 102(a)(1), amended subpar. (F) generally. Prior to amendment, subpar. (F) read as follows: “provides not more than 6 inpatient beds (meeting such conditions as the Secretary may establish) for providing inpatient care for a period not to exceed 72 hours (unless a longer period is required because transfer to a hospital is precluded because of inclement weather or other emergency conditions) to patients requiring stabilization before discharge or transfer to a hospital”. Subsec. (f)(1)(H). Pub. L. 103–432, § 102(f), inserted before period at end “, except that in determining whether a facility meets the requirements of this subparagraph, subparagraphs (E) and (F) of that paragraph shall be applied as if any reference to a ‘physician’ is a reference to a physician as defined in section 1395v(d)(1) of this title”.

Subsec. (f)(2). Pub. L. 103–432, § 102(c), substituted “because, at the time the facility applies to the State for designation as a rural primary care hospital, there is in effect an agreement between the facility and the Secretary under section 1202 of this title under which the facility’s inpatient hospital facilities are used for the furnishing of extended care services, except that the number of beds used for the furnishing of such services may not exceed the total number of licensed inpatient beds at the time the facility applies to the State for such designation (minus the number of inpatient beds used for providing inpatient care pursuant to paragraph (1)(F)) for purposes of the previous sentence, the number of beds of the facility used for the furnishing of extended care services shall not include any beds of a unit of the facility that is licensed as a distinct-part skilled nursing facility at the time the facility applies to the State for designation as a rural primary care hospital”.

Subsec. (f)(3). Pub. L. 103–432, § 102(e), inserted before period at end “, except that in determining whether a facility meets the requirements of this subparagraph, subparagraphs (E) and (F) of that paragraph shall be applied as if any reference to a ‘physician’ is a reference to a physician as defined in section 1395v(d)(1) of this title”.

Subsec. (g)(2)(C), (D). Pub. L. 106–113, § 1000(a)(6) (title IV, § 403(c)(2)), added subpars. (C) and (D).


Subsec. (h)(4). Pub. L. 103–432, § 102(a)(2), added par. (4) that:

Subsec. (i)(1)(A). Pub. L. 103–432, § 102(b)(2)(B)(ii), in cl. (i) inserted “(except as provided in subsection (k) of this section)” and in cl. (ii) inserted “or subsection (k) of this section”.

Subsec. (i)(2)(A). Pub. L. 103–432, § 102(b)(2)(B)(ii), in cl. (i) inserted “(except as provided in subsection (k) of this section)” and in cl. (ii) inserted “or subsection (k) of this section”.


Subsec. (g)(1)(A). Pub. L. 101–508, §4008(d)(5), inserted before semicolon at end “, or is located in a county whose geographic area is substantially larger than the average geographic area for urban counties in the United States and whose hospital service area is characteristic of service areas of hospitals located in rural areas.”

Subsec. (f)(1)(B). Pub. L. 101–508, §4008(d)(2), which directed the substitution of “is a hospital (or, in the case of a facility that closed during the 12-month period that ends on the date the facility applies for such designation, at the time the facility closed),” for “is a hospital,” was executed by making the substitution for “is a hospital” to reflect the probable intent of Congress.


Subsec. (i)(2)(C). Pub. L. 101–508, §4008(d)(1), inserted at end “In designating facilities as rural primary care hospitals under this subparagraph, the Secretary shall give preference to facilities not meeting the requirements of clause (i) of subparagraph (A) that have entered into an agreement described in subsection (g)(12) of this section with a rural health network located in a State receiving a grant under subsection (a)(1) of this section.”

Subsec. (j). Pub. L. 101–508, §4008(m)(2)(B)(iii), inserted “and part C of this subchapter” after “this part.”

Effective Date of 2010 Amendment

Effective Date of 2003 Amendment
Pub. L. 108–173, title IV, §405(c)(3), Dec. 8, 2003, 117 Stat. 2267, provided that: “The amendments made by this subsection (amending this section) shall apply to designs made before, on, or after January 1, 2004, but any election made pursuant to regulations promulgated to carry out such amendments shall only apply prospectively.”


Effective Date of 1999 Amendment


Effective Date of 1997 Amendment
Amendment by section 201(a) of Pub. L. 105–33 applicable to services furnished on or after Oct. 1, 1997, see section 201(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Effective Date of 1990 Amendment
Section 4008(d)(4) of Pub. L. 101–508 provided that: “The amendments made by paragraphs (1), (2), and (3) [amending this section] shall take effect on the date of the enactment of this Act [Nov. 5, 1990].”

Demonstration Project on Community Health Integration Models in Certain Rural Counties

“(a) In General.—The Secretary shall establish a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties for the purpose of improving access to, and better integrating the delivery of, acute care, extended care, and other essential health care services to Medicare beneficiaries.

“(b) Purpose.—The purpose of the demonstration project under this section is to—

“(1) explore ways to increase access to, and improve the adequacy of, payments for acute care, extended care, and other essential health care services provided under the Medicare and Medicaid programs in eligible counties; and

“(2) evaluate regulatory challenges facing such providers and the communities they serve.

“(c) Requirements.—The following requirements shall apply under the demonstration project:

“(1) Health care providers in eligible counties selected to participate in the demonstration project under subsection (d)(3) shall (when determined appropriate by the Secretary), instead of the payment rates otherwise applicable under the Medicare program, be reimbursed at a rate that covers at least the reasonable costs of the provider in furnishing acute care, extended care, and other essential health care services to Medicare beneficiaries.

“(2) Methods to coordinate the survey and certification process under the Medicare program and the Medicaid program across all health service categories included in the demonstration project shall be tested with the goal of assuring quality and safety while reducing administrative burdens, as appropriate, related to completing such survey and certification process.

“(3) Health care providers in eligible counties selected to participate in the demonstration project under subsection (d)(3) and the Secretary shall work with the State to explore ways to revise reimbursement policies under the Medicaid program to improve access to the range of health care services available in such eligible counties.

“(4) The Secretary shall identify regulatory requirements that may be revised appropriately to improve access to care in eligible counties.

“(5) Other essential health care services necessary to ensure access to the range of health care services in eligible counties selected to participate in the demonstration project under subsection (d)(3) shall be identified. Ways to ensure adequate funding for such services shall also be explored.

“(d) Application Process.—

“(1) Eligibility.—

“(A) In General.—Eligibility to participate in the demonstration project under this section shall be limited to eligible entities.

“(B) Eligible Entity Defined.—In this section, the term ‘eligible entity’ means an entity that—

“(i) is a Rural Hospital Flexibility Program grantee under section 1820(g) of the Social Security Act (42 U.S.C. 1395f–4(g)); and

“(ii) is located in a State in which at least 65 percent of the counties in the State are counties that have 6 or less residents per square mile.

“(2) Application.—
"(A) IN GENERAL.—An eligible entity seeking to participate in the demonstration project under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

"(B) LIMITATION.—The Secretary shall select eligible entities located in not more than 4 States to participate in the demonstration project under this section.

"(3) SELECTION OF ELIGIBLE COUNTIES.—An eligible entity selected by the Secretary to participate in the demonstration project under this section shall select eligible counties in the State in which the entity is located in which to conduct the demonstration project.

"(4) ELIGIBLE COUNTY DEFINED.—In this section, the term 'eligible county' means a county that meets the following requirements:

(A) The county has 6 or less residents per square mile.

(B) As of the date of the enactment of this Act [July 15, 2008], a facility designated as a critical access hospital which meets the following requirements was located in the county:

(i) As of the date of the enactment of this Act, the critical access hospital furnished 1 or more of the following:

(I) Home health services.

(II) Hospice care.

(ii) As of the date of the enactment of this Act, the critical access hospital has an average daily inpatient census of 5 or less.

(C) As of the date of the enactment of this Act, skilled nursing facility services were available in the county in:

(i) a critical access hospital using swing beds; or

(ii) a local nursing home.

(e) ADMINISTRATION.—

(1) IN GENERAL.—The demonstration project under this section shall be administered jointly by the Administrator of the Centers for Medicare & Medicaid Services, the Health Resources and Services Administration and the Administrator of the Office of Rural Health Policy of the Health Resources and Services Administration, in accordance with paragraphs (2) and (3).

(2) HRSA DUTIES.—In administering the demonstration project under this section, the Administrator of the Office of Rural Health Policy of the Health Resources and Services Administration shall—

(A) award grants to the eligible entities selected to participate in the demonstration project; and

(B) work with such entities to provide technical assistance related to the requirements under the project.

(3) CMS DUTIES.—In administering the demonstration project under this section, the Administrator of the Centers for Medicare & Medicaid Services shall determine which provisions of titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq.; 1396 et seq.) the Secretary may waive under the waiver authority under subsection (1) that are relevant to the development of alternative reimbursement methodologies, which may include, as appropriate, covering at least the reasonable costs of the provider in furnishing acute care, extended care, and other essential health care services to Medicare beneficiaries and coordinating the survey and certification process under the Medicare and Medicaid programs, as appropriate, across all service categories included in the demonstration project.

(f) DURATION.—

(1) IN GENERAL.—The demonstration project under this section shall be conducted for a 3-year period beginning on October 1, 2009.

(2) BEGINNING DATE OF DEMONSTRATION PROJECT.—The demonstration project under this section shall be considered to have begun in a State on the date on which the eligible counties selected to participate in the demonstration project under subsection (d)(3) begin operations in accordance with the requirements under the demonstration project.

(g) FUNDING.—

(1) CMS.—

(A) IN GENERAL.—The Secretary shall provide for the transfer, in appropriate part from the Federal Hospital Insurance Trust Fund established under section 1817 of the Social Security Act (42 U.S.C. 1395i-3) and the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of such Act (42 U.S.C. 1395t), of such sums as are necessary for the costs to the Centers for Medicare & Medicaid Services of carrying out its duties under the demonstration project under this section.

(B) BUDGET NEUTRALITY.—In conducting the demonstration project under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under this section was not implemented.

(2) HRSA.—There are authorized to be appropriated to the Office of Rural Health Policy of the Health Resources and Services Administration $800,000 for each of fiscal years 2010, 2011, and 2012 for the purpose of carrying out the duties of such Office under the demonstration project under this section, to remain available for the duration of the demonstration project.

(h) REPORT.—

(1) INTERIM REPORT.—Not later than the date that is 2 years after the date on which the demonstration project under this section is implemented, the Administrator of the Office of Rural Health Policy of the Health Resources and Services Administration, in coordination with the Administrator of the Centers for Medicare & Medicaid Services, shall submit a report to Congress on the status of the demonstration project that includes initial recommendations on ways to improve access to, and the availability of, health care services in eligible counties based on the findings of the demonstration project.

(2) FINAL REPORT.—Not later than 1 year after the completion of the demonstration project, the Administrator of the Office of Rural Health Policy of the Health Resources and Services Administration, in coordination with the Administrator of the Centers for Medicare & Medicaid Services, shall submit a report to Congress on such project, together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

(i) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq.; 1396 et seq.) as may be necessary and appropriate for the purpose of carrying out the demonstration project under this section.

(j) DEFINITIONS.—In this section:

(1) EXTENDED CARE SERVICES.—The term 'extended care services' means the following:

(A) Home health services.

(B) Covered skilled nursing facility services.

(C) Hospice care.

(2) COVERED SKILLED NURSING FACILITY SERVICES.—The term 'covered skilled nursing facility services' has the meaning given such term in section 1861(m) of such Act (42 U.S.C. 1395x(m)).

(3) CRITICAL ACCESS HOSPITAL.—The term 'critical access hospital' means a facility designated as a critical access hospital under section 1522(c) of such Act (42 U.S.C. 1395kk-1(c)).

(4) HOSPICE CARE.—The term 'hospice care' has the meaning given such term in section 1861(dd) of such Act (42 U.S.C. 1395dd).

(6) MEDICAID PROGRAM.—The term 'Medicaid program' means the program under title XIX of such Act (42 U.S.C. 1396 et seq.).
Title 42—The Public Health and Welfare

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Subject to subsections (c) and (d) of this section, payment under this part may be made for inpatient hospital services or post-hospital extended care services furnished an individual in a religious nonmedical health care institution and for home health services furnished an individual by a religious nonmedical health care institution only if—

(1) the individual has an election in effect for such benefits under subsection (b) of this section; and

(2) the individual has a condition such that the individual would qualify for benefits under this part for inpatient hospital services, extended care services, or home health services, respectively, if the individual were an inpatient or resident in a hospital or skilled nursing facility, or receiving services from a home health agency, that was not such an institution.

(b) Election

(1) In general

An individual may make an election under this subsection in a form and manner specified by the Secretary consistent with this subsection. Unless otherwise provided, such an election shall take effect immediately upon its execution. Such an election, once made, shall continue in effect until revoked.

(2) Form

The election form under this subsection shall include the following:

(A) A written statement, signed by the individual (or such individual’s legal representative), that—

(i) the individual is conscientiously opposed to acceptance of nonexcepted medical treatment; and

(ii) the individual’s acceptance of nonexcepted medical treatment would be inconsistent with the individual’s sincere religious beliefs.

(B) A statement that the receipt of nonexcepted medical services shall constitute a revocation of the election and may limit fur-
ther receipt of services described in subsection (a) of this section.

(3) Revocation
An election under this subsection by an individual may be revoked by voluntarily notifying the Secretary in writing of such revocation and shall be deemed to be revoked if the individual receives nonexcepted medical treatment for which reimbursement is made under this subchapter.

(4) Limitation on subsequent elections
Once an individual’s election under this subsection has been made and revoked twice—
(A) the next election may not become effective until the date that is 1 year after the date of most recent previous revocation, and
(B) any succeeding election may not become effective until the date that is 5 years after the date of the most recent previous revocation.

(5) Excepted medical treatment
For purposes of this subsection:
(A) Excepted medical treatment
The term “excepted medical treatment” means medical care or treatment (including medical and other health services)—
(i) received involuntarily, or
(ii) required under Federal or State law or law of a political subdivision of a State.
(B) Nonexcepted medical treatment
The term “nonexcepted medical treatment” means medical care or treatment (including medical and other health services) other than excepted medical treatment.

c) Monitoring and safeguard against excessive expenditures

(1) Estimate of expenditures
Before the beginning of each fiscal year (beginning with fiscal year 2000), the Secretary shall estimate the level of expenditures under this part for services described in subsection (a) of this section for that fiscal year.

(2) Adjustment in payments
(A) Proportional adjustment
If the Secretary determines that the level estimated under paragraph (1) for a fiscal year will exceed the trigger level (as defined in subparagraph (C)) for that fiscal year, the Secretary shall, subject to subparagraph (B), provide for such a proportional reduction in payment amounts under this part for services described in subsection (a) of this section for the fiscal year involved as will assure that such level (taking into account any adjustment under subparagraph (B)) does not exceed the trigger level for that fiscal year.

(B) Alternative adjustments
The Secretary may, instead of making some or all of the reduction described in subparagraph (A), impose such other conditions or limitations with respect to the coverage of covered services (including limitations on new elections of coverage and new facilities) as may be appropriate to reduce the level of expenditures described in paragraph (1) to the trigger level.

(C) Trigger level
For purposes of this subsection—
(i) In general
Subject to adjustment under paragraph (3)(B), the “trigger level” for a year is the unadjusted trigger level described in clause (ii).

(ii) Unadjusted trigger level
The “unadjusted trigger level” for—
(I) fiscal year 1998, is $20,000,000, or
(II) a succeeding fiscal year is the amount specified under this clause for the previous fiscal year increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with July preceding the beginning of the fiscal year.

(D) Prohibition of administrative and judicial review
There shall be no administrative or judicial review under section 1395ff of this title, 1395f of this title, or otherwise of the estimation of expenditures under subparagraph (A) or the application of reduction amounts under subparagraph (B).

(E) Effect on billing
Notwithstanding any other provision of this subchapter, in the case of a reduction in payment provided under this subsection for services of a religious nonmedical health care institution provided to an individual, the amount that the institution is otherwise permitted to charge the individual for such services is increased by the amount of such reduction.

(3) Monitoring expenditure level
(A) In general
The Secretary shall monitor the expenditure level described in paragraph (2)(A) for each fiscal year (beginning with fiscal year 1999).

(B) Adjustment in trigger level
(i) In general
If the Secretary determines that such level for a fiscal year exceeded, or was less than, the trigger level for that fiscal year, then, subject to clause (ii), the trigger level for the succeeding fiscal year shall be reduced, or increased, respectively, by the amount of such excess or deficit.
(ii) Limitation on carryforward
In no case may the increase effected under clause (i) for a fiscal year exceed $50,000,000.

(d) Sunset
If the Secretary determines that the level of expenditures described in subsection (c)(1) of this section for 3 consecutive fiscal years (with the first such year being not earlier than fiscal year 2002) exceeds the trigger level for such ex-
penditures for such years (as determined under subsection (c)(2) of this section), benefits shall be paid under this part for services described in subsection (a) of this section and furnished on or after the first January 1 that occurs after such 3 consecutive years only with respect to an individual who has an election in effect under subsection (b) of this section as of such January 1 and only during the duration of such election.

(e) Annual report

At the beginning of each fiscal year (beginning with fiscal year 1999), the Secretary shall submit to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate an annual report on coverage and expenditures for services described in subsection (a) of this section under this part and under State plans under subchapter XIX of this chapter. Such report shall include—

(1) level of expenditures described in subsection (c)(1) of this section for the previous fiscal year and estimated for the fiscal year involved;

(2) trends in such level; and

(3) facts and circumstances of any significant change in such level from the level in previous fiscal years.


Amendments


Subsec. (a)(2). Pub. L. 108–173, § 706(a)(2), substituted ‘‘extended care services, or home health services’’ for ‘‘or extended care services’’ and inserted ‘‘or receiving services from a home health agency,’’ after ‘‘skilled nursing facility’’.

Effective Date

Section 4454(d) of Pub. L. 105–33 provided that: ‘‘The amendments made by this section (enacting this section and amending sections 1320a–1, 1320c–11, 1395x, 1396a, and 1396g of this title) shall take effect on the date of the enactment of this Act [Aug. 5, 1997] and shall apply to items and services furnished on or after such date. By not later than July 1, 1998, the Secretary of Health and Human Services shall first issue regulations to carry out such amendments. Such regulations may be issued so they are effective on an interim basis pending notice and opportunity for public comment. For periods before the effective date of such regulations, such regulations shall recognize elections entered into in good faith in order to comply with the requirements of section 1821(b) of the Social Security Act [subsec. (b) of this section].’’

Part B—Supplementary Medical Insurance Benefits for Aged and Disabled

§ 1395j. Establishment of supplementary medical insurance program for aged and disabled

There is hereby established a voluntary insurance program to provide medical insurance benefits in accordance with the provisions of this part for aged and disabled individuals who elect to enroll under such program, to be financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government.


Amendments

1972—Pub. L. 92–603 substituted ‘‘aged and disabled individuals’’ for ‘‘individuals 65 years of age or over’’.

Study Regarding Coverage Under Part B of Medicare for Nonreimbursable Services Provided by Optometrists for Prosthetic Lenses for Patients With Aphakia

Pub. L. 94–182, title I, § 109, Dec. 31, 1975, 89 Stat. 1053, provided that the Secretary of Health, Education, and Welfare conduct a study on the appropriateness of reimbursement under the insurance program established by this part for services performed by optometrists with respect to the provision of prosthetic lenses for patients with aphakia and submit such study to Congress not later than 4 months after Dec. 31, 1975.

Study to Determine Feasibility of Inclusion of Certain Additional Services Under Part B

Pub. L. 90–248, title I, § 141, Jan. 2, 1968, 81 Stat. 855, directed Secretary to conduct a study relating to inclusion under the supplementary medical insurance program under this part of services of additional types of licensed practitioners performing health services in independent practice and submit such study to Congress prior to Jan. 1, 1969.

§ 1395k. Scope of benefits; definitions

(a) Scope of benefits

The benefits provided to an individual by the insurance program established by this part shall consist of—

(1) entitlement to have payment made to him or on his behalf (subject to the provisions of this part) for medical and other health services, except those described in subparagraphs (B) and (D) of paragraph (2) and subparagraphs (E) and (F) of section 1395u(b)(6) of this title; and

(2) entitlement to have payment made on his behalf (subject to the provisions of this part) for—

(A) home health services (other than items described in subparagraph (G) or subparagraph (I));

(B) medical and other health services (other than items described in subparagraph (G) or subparagraph (I)) furnished by a provider of services or by others under arrangement with them made by a provider of services, excluding—

(i) physician services except where furnished by—

(I) a resident or intern of a hospital, or

(II) a physician to a patient in a hospital which has a teaching program approved as specified in paragraph (6) of section 1395x(b) of this title (including services in conjunction with the teaching programs of such hospital whether or not such patient is an inpatient of such hospital) where the conditions specified in paragraph (7) of such section are met,

(ii) services for which payment may be made pursuant to section 1395n(b)(2) of this title,
(iii) services described by section 1395x(s)(2)(K)(i)(i) of this title, certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist;

(iv) services of a nurse practitioner or clinical nurse specialist but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services; and 2

(C) outpatient physical therapy services (other than services to which the second sentence of section 1395x(p) of this title applies), outpatient occupational therapy services (other than services to which such sentence applies through the operation of section 1395x(g) of this title), and outpatient speech-language pathology services (other than services to which the second sentence of section 1395x(p) of this title applies through the application of section 1395x(ll)(2) of this title);

(I) rural health clinic services and (ii) Federally qualified health center services;

(II) comprehensive outpatient rehabilitation facility services;

(F) facility services furnished in connection with surgical procedures specified by the Secretary—

(i) pursuant to section 1395l(1)(1)(A) of this title and performed in an ambulatory surgical center (which meets health, safety, and other standards specified by the Secretary in regulations) if the center has an agreement in effect with the Secretary by which the center agrees to accept the standard overhead amount determined under section 1395l(1)(2)(A) of this title as full payment for such services (including intraocular lens in cases described in section 1395l(1)(2)(A)(iii) of this title) and to accept an assignment described in section 1395u(b)(3)(B)(ii) of this title with respect to payment for all such services (including intraocular lens in cases described in section 1395l(1)(2)(A)(iii) of this title) furnished by the center to individuals enrolled under this part, or

(ii) pursuant to section 1395l(1)(1)(B) of this title and performed by a physician, described in paragraph (1), (2), or (3) of section 1395x(r) of this title, in his office, if the Secretary has determined that—

(I) a quality control and peer review organization (having a contract with the Secretary under part B of subchapter XI of this chapter) is willing, able, and has agreed to carry out a review (on a sample or other reasonable basis) of the physician's performing such procedures in the physician's office,

(II) the particular physician involved has agreed to make available to such organization such records as the Secretary determines to be necessary to carry out the review, and

(III) the physician is authorized to perform the procedure in a hospital located in the area in which the office is located, and if the physician agrees to accept the standard overhead amount determined under section 1395l(1)(2)(B) of this title as full payment for such services and to accept payment on an assignment-related basis with respect to payment for all services (including all pre- and post-operative services) described in paragraphs (1) and (2)(A) of section 1395x(s) of this title and furnished in connection with such surgical procedure to individuals enrolled under this part;

(G) covered items (described in section 1395m(a)(13) of this title) furnished by a provider of services or by others under arrangements with them made by a provider of services;

(H) outpatient critical access hospital services (as defined in section 1395x(mm)(3) of this title);

(I) prosthetic devices and orthotics and prosthetics (described in section 1395m(h)(4) of this title) furnished by a provider of services or by others under arrangements with them made by a provider of services; and

(J) partial hospitalization services provided by a community mental health center (as described in section 1395x(ff)(2)(B) of this title).

(b) Definitions

For definitions of "spell of illness", "medical and other health services", and other terms used in this part, see section 1395x of this title.


1 So in original. The comma should not appear.

2 So in original. The word "and" probably should not appear.
REFERENCES IN TEXT

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

AMENDMENTS

2008—Subsec. (a)(2)(C). Pub. L. 110–275 substituted ‘‘, outpatient’’ for ‘‘and outpatient’’ and inserted ‘‘, and outpatient speech-language pathology services (other than services to which the second sentence of section 1395x(p) of this title applies through the application of section 1395u(l)(2) of this title)’’ before semicolon at end.

2000—Subsecs. (b), (c). Pub. L. 106–554 redesignated subsec. (c) as (b) and struck out former subsec. (b), which related to extension of coverage of immunosuppressive drugs for individuals who would exhaust benefits under section 1395x(s)(2)(J)(v) of this title in a year during the 5-year period beginning with 2000, and set forth provisions relating to extension periods for each year.

1999—Subsec. (a)(2)(B). Pub. L. 106–113 added subsec. (b) and redesignated former subsec. (b) as (c).

1997—Subsec. (a)(1). Pub. L. 105–33, § 4603(c)(2)(B)(ii), substituted ‘‘subparagraphs (E) and (F) of section 1395u(b)(6) of this title;’’ for ‘‘(2);’’.


Subsec. (a)(2)(B)(v). Pub. L. 105–33, § 4432(b)(5)(B), substituted ‘‘section 1395u(b)(5)(E) of this title;’’ for ‘‘section 1395u(b)(6) of this title;’’.

Pub. L. 105–33, §§ 4322(b)(5)(B), substituted ‘‘(2) and section 1395u(b)(6)(E) of this title;’’ for ‘‘(2);’’.

Subsec. (a)(2)(B)(iv). Pub. L. 105–33, § 4511(c), substituted ‘‘but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services’’ for ‘‘provided in a rural area (as defined in section 1395ww(d)(2)(D) of this title)’’.

Subsec. (a)(2)(H). Pub. L. 105–33, § 4201(c)(1), substituted ‘‘critical access’’ for ‘‘rural primary care’’.

Subsec. (a)(2)(A)(i). Pub. L. 101–508, § 1311(b)(2)(A)(i), substituted ‘‘subparagraph (G) or subparagraph (l)’’ for ‘‘subparagraph (G)’’.

Subsec. (a)(2)(B)(ii). Pub. L. 101–508, § 1415(b)(2)(A)(v), substituted ‘‘and the services for which payment may be made pursuant to section 1395n(b)(2) of this title’’ after ‘‘involves an emergency’’.


Subsec. (a)(2)(C). Pub. L. 99–509, § 9337(a), amended subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: ‘‘outpatient physical therapy services, other than services to which the next to last sentence of section 1395x(r)(1) of this title applies;’’.

Subsec. (a)(2)(F). Pub. L. 99–509, § 9343(e)(1), substituted ‘‘(other than services to which the next to last sentence of section 1395x(p) of this title applies)’’.


Subsec. (a)(2)(G). Pub. L. 98–369, § 3954(b), substituted ‘‘(other than items described in subparagraph (G) and paragraph (2)’’ for ‘‘(other than items described in subparagraph (G)’’ after ‘‘health services’’.


Subsec. (a)(2)(F)(i). Pub. L. 100–360, § 4603(e)(2), as added by Pub. L. 100–360, § 411(g)(2)(E), inserted ‘‘including intravenous drug therapy services, was repealed by Pub. L. 100–360, § 1311(h)(7)(B).’’

Subsec. (a)(2)(F)(ii). Pub. L. 99–369, § 3954(b), substituted ‘‘(other than items described in subparagraph (G) and paragraph (2)’’ for ‘‘(other than items described in subparagraph (G)’’ after ‘‘health services’’.

Subsec. (a)(2)(B). Pub. L. 96–999, § 930(g), struck out restriction on home health services of 100 visits during a calendar year.

Subsec. (a)(2)(B)(ii). Pub. L. 96–999, § 948(a)(2), substituted ‘‘where the conditions specified in paragraph (7) of such section are met’’ for ‘‘unless either clause (A) or (B) of paragraph (7) of such section is met’’.


Subsec. (a)(2)(F). Pub. L. 96–999, § 934(a), inserted ‘‘standard overhead’’ in cl. (i) and concluding provisions of cl. (i).

1984—Subsec. (a)(2)(F)(i)(II). Pub. L. 98–369, § 3954(b), substituted ‘‘paragraph (1), (2), or (3) of section 1395x(r) of this title’’ for ‘‘paragraph (1), (2), or (3) of such section’’.


Subsec. (a)(2)(F)(iii). Pub. L. 97–218 substituted ‘‘quality control and peer review organization having a contract with the Secretary for ‘‘Professional Standards Review Organization (designated, conditionally or otherwise’’.’’.


Subsec. (a)(2)(B). Pub. L. 96–999, § 948(a)(2), substituted ‘‘where the conditions specified in paragraph (7) of such section are met’’ for ‘‘unless either clause (A) or (B) of paragraph (7) of such section is met’’.


1977—Subsec. (a)(1). Pub. L. 95–210, § 1(a)(1), substituted ‘‘subparagraphs (B) and (D) of paragraph (2)’’ for ‘‘paragraph (2)(B)’’.


1972—Subsec. (a)(2)(B). Pub. L. 92–603, § 227(e)(1), inserted provisions relating to medical and other health services performed by a physician to a patient in a hospital which has an approved teaching program.

Subsec. (a)(2)(C). Pub. L. 92–603, § 221(a)(4), inserted ‘‘other than services to which the next to last sentence of section 1395x(r)(1) of this title applies’’ after ‘‘hospital’’.

1968—Subsec. (a)(2)(B). Pub. L. 90–238, § 129(c)(6)(B), inserted ‘‘and the services for which payment may be made pursuant to section 1395n(b)(2) of this title’’ after ‘‘hospital’’.

Effective Date of 2008 Amendment
Pub. L. 110–275, title I, §143(c), July 15, 2008, 122 Stat. 2543, provided that: "The amendments made by this section [amending this section and sections 1395f, 1395m, 1395x, 1395y, 1395cc, and 1395yy of this title] shall apply to services furnished on or after July 1, 2008.

Effective Date of 1997 Amendment
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 4432(b)(5)(B) 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.

Section 451(e) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section and sections 1395f, 1395x, 1395y, 1395cc, and 1395yy of this title] shall apply with respect to services furnished and supplies provided on and after January 1, 1998."

Amendment by section 4603(c)(2)(B)(ii) 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 1395fff of this title.

Effective Date of 1996 Amendment
Section 4153(a)(3) of Pub. L. 101–508 provided that: "The amendments made by paragraphs (1) and (2) [amending this section and sections 1395f and 1395m of this title] shall apply to items furnished on or after January 1, 1991."

Section 4155(e) of Pub. L. 101–508 provided that: "The amendments made by this section [amending this section and sections 1395f, 1395u, and 1395x of this title] shall apply to services furnished on or after January 1, 1991."

Section 4157(d) of Pub. L. 101–508 provided that: "(A) Subject to subparagraphs (B) and (C), the amendments made by this section [probably means this subsection, which amended this section and sections 1320a–7b, 1395u, 1395x, and 1395cc of this title] apply to services furnished on or after January 1, 1991.

"(B) In the case of a Federally qualified health care center that has elected, as of January 1, 1990, under section 1395k, to have the amount of payments for services applicable to covered items (other than oxygen and oxygen equipment) furnished on or after January 1, 1989, and to oxygen and oxygen equipment furnished on or after June 1, 1989, see section 4062(e) of Pub. L. 100–203, as amended, set out as a note under section 1395f of this title.

"(C) The amendment made by paragraph (6) [amending section 1395cc of this title] shall apply to reports for periods beginning on or after October 1, 1991."

Section 4161(a)(8) of Pub. L. 101–508 provided that: "The amendments made by this subsection [amending this section and sections 1395f and 1395x of this title] shall be effective with respect to services performed on or after July 1, 1994."

Effective Date of 2006 Amendment
 Amendment by section 205(e) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 205(c) of Pub. L. 100–360, set out as a note under section 1395c–3 of this title.

Section 205(f) of Pub. L. 100–360, which provided that the amendments made by section 205 of Pub. L. 100–360 [amending this section and sections 1395f, 1395m, 1395x, and 1395y of this title] were applicable to items and services furnished on or after January 1, 1990, was repealed by Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1381.

Except as specifically provided in section 401 of Pub. L. 100–360, amendment by section 411(g)(2)(E), (7)(A), (7)(B), (1)(4)(C)(VI) 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 4062(d)(2) 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 4062(e) of Pub. L. 100–203, as amended, set out as a note under section 1395f of this title.

Section 4077(b)(5), formerly §4077(b)(6), of Pub. L. 100–203, as renumbered by Pub. L. 100–360, title IV, §411(h)(7)(F), July 1, 1986, 102 Stat. 787, provided that: "The amendments made by this section [amending this section and sections 1395f and 1395x of this title] shall be effective with respect to services performed on or after July 1, 1988."

Effective Date of 1986 Amendment
Section 9320(i) of Pub. L. 99–509, as amended by Pub. L. 100–485, title VI, §608(c)(1), Oct. 13, 1988, 102 Stat. 2412, provided that: "Except as provided in subsection (k) [set out below], the amendments made by this section (other than subsection (a)) [amending this section and sections 1395f, 1395u, 1395x, and 1395cc of this title] shall apply to expenses incurred for outpatient occupational therapy services furnished on or after July 1, 1987."

Effective Date of 1984 Amendment
Section 2341(d) of Pub. L. 98–369 provided that: "The amendments made by this section [amending this section and section 1395x of this title] apply to services furnished on or after the date of the enactment of this Act [July 18, 1984]."

Amendment by section 2354(b)(6) 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.
Amendment by 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 1395k of this title.

Amendment by Pub. L. 96–499 effective with respect to services furnished on or after July 1, 1981, see section 930(e)(1) of Pub. L. 96–499, set out as a note under section 1395x of this title.

Amendment of this section and sections 1395u, 1395x, 1395aa, and 1395bb of this title applicable with respect to fiscal years beginning after the date of enactment of this Act, Dec. 21, 2000, 114 Stat. 2673, 2763A–473.

Quality and Utilization of In-Home Care for Chronically Dependent Individuals

Section 205(e)(2) of Pub. L. 100–360 directed Secretary of Health and Human Services to take appropriate efforts to assure quality and provide for appropriate utilization of in-home care for chronically dependent individuals under the amendments made by section 205 of Pub. L. 100–360 (amending this section and sections 1395l, 1395x, 1395y, and 1395y of this title), prior to repeal by Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1981.

Study of Alternative Out-of-Home Services

Section 205(g) of Pub. L. 100–360, which required Secretary of Health and Human Services to study and report to Congress, not later than 18 months after July 1, 1988, on advisability of providing, to chronically dependent individuals eligible for in-home care under amendments made by section 205 of Pub. L. 100–360 (amending this section and sections 1395l, 1395x, 1395y, and 1395y of this title), out-of-home services as alternative services to in-home care, was repealed by Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1981.

Continuation of Cost Pass-Through for Certified Registered Nurse Anesthetists


"(1) Subject to paragraph (2), the amendments made by this section [amending this section and sections 1395l, 1395x, 1395y, 1395aa, 1395bb, 1395cc, 1395ww, 1396a, and 1396b of this title and provisions set out as notes under section 1395ww of this title] shall not apply during a year (beginning with 1989) to a hospital located in a rural area (as defined for purposes of section 1866(d) of the Social Security Act [section 1395ww(d) of this title]) if the hospital establishes, at any time before the year[,] to the satisfaction of the Secretary of Health and Human Services that—

"(A) as of January 1, 1986, the hospital employed or contracted with a certified registered nurse anesthetist (but not more than one full-time equivalent certified registered nurse anesthetist);

"(B) in 1987 the hospital had a volume of surgical procedures (including inpatient and outpatient procedures) requiring anesthesia services that did not exceed 500 (or such higher number as the Secretary determines to be appropriate), and

"(C) each certified registered nurse anesthetist employed by, or under contract with, the hospital has agreed not to bill under part B of title XVIII of such Act [this part] for professional services furnished by the anesthetist at the hospital.

"(2) Paragraph (1) shall not apply in a year (after 1989) to a hospital unless the hospital establishes, before the beginning of the year, that the hospital has had a volume of surgical procedures (including inpatient and outpatient procedures) requiring anesthesia services in the previous year that did not exceed 500 (or such higher number as the Secretary determines to be appropriate)."

[Section 6132(b) of Pub. L. 101–239 provided that: "The amendments made by this section [amending section..."
PAYMENT FOR SERVICES 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)(2), Dec. 31, 1973, 87 Stat. 966, provided that for the cost accounting periods beginning after June 30, 1975, and prior to Oct. 1, 1978, subsec. (a)(2)(B)(i) of this section will be administered as if subclause II of subsec. (a)(2)(B)(i) read as follows: "(II) a physician to a patient in a hospital which has a teaching program approved as specified in paragraph (6) of section 1861(b) [section 1395x(b)(6) of this title] (including services in conjunction with the teaching programs of such hospital whether or not such patient is an inpatient of such hospital), where the conditions specified in paragraph (7) of such section [section 1395x(b)(7) of this title] are met and".

§1395f. Payment of benefits
(a) Amounts

Except as provided in section 1395mm of this title, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—

(1) in the case of services described in section 1395k(a)(1) of this title—80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis (and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services) may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost payable by them as a result of subsection (b) of this section, (B) with respect to items and services described in section 1395x(s)(10)(A) of this title, the amounts paid shall be 100 percent of the reasonable charges for such items and services, (C) with respect to expenses incurred for those physicians’ services for which payment may be made under this part that are described in section 1395y(a)(4) of this title, the amounts paid shall be subject to such limitations as may be prescribed by regulations, (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i) on the basis of a fee schedule under subsection (h)(1) of this section or section 1395m(d)(1) of this title, the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B) of this section, or the amount of the charges billed for the tests, or (ii) on the basis of a negotiated rate established under subsection (h)(6) of this section, the amount paid shall be equal to 100 percent of such negotiated rate, (E) with respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1395rr of this title, (F) with respect to clinical social worker services under section 1395x(s)(2)(N) of this title, the amounts paid shall be 80 percent of the lesser of (1) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist under clause (L), (G) with respect to facility services furnished in connection with a surgical procedure specified pursuant to subsection (I)(1)(A) of this section and furnished to an individual in an ambulatory surgical center described in such subsection, for services furnished beginning with the implementation date of a revised payment system for such services in such facilities specified in subsection (I)(2)(D) of this section, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by the Secretary under such revised payment system, (H) with respect to services of a certified registered nurse anesthetist under section 1395x(s)(11) of this title, the amounts paid shall be 80 percent of the least of the actual charge, the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1395w–4 of this title) if the services had been performed by an anesthesiologist, or the fee schedule for such services established by the Secretary in accordance with subsection (l) of this section, (I) with respect to covered items (described in section 1395m(a)(13) of this title), the amounts paid shall be the amounts described in section 1395m(a)(1) of this title, and (J) with respect to expenses incurred for radiologist services (as defined in section 1395m(b)(6) of this title), subject to section 1395w–4 of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount provided under the fee schedule established under section 1395m(b) of this title, (K) with respect to certified nurse-midwife services under section 1395x(s)(2)(L) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph (but in no event shall such fee schedule exceed 65 percent of the prevailing charge that would be allowed for the same service performed by a physician, or, for services furnished on or after January 1, 1992, 65 percent (or 100 percent for services furnished on or after January 1, 2011) of the fee schedule amount provided under section 1395w–4 of this title for the same service performed by a physician), (L) with respect to services under section 1395x(s)(12)(M) of this title, the amounts paid shall be 80 percent

1 So in original.
2 So in original. The word “and” probably should not appear.
of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, (M) with respect to prosthetic devices and orthotics and prosthetics (as defined in section 1395m(h)(4) of this title), the amounts paid shall be the amounts described in section 1395m(h)(1) of this title, (N) with respect to expenses incurred for physicians' services (as defined in section 1395w–4(j)(3) of this title) other than personalized prevention plan services (as defined in section 1395w–4 of this title) (relating to services furnished by physician assistants, nurse practitioners, or clinic nurse specialists), the amounts paid shall be equal to 80 percent of (i) the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1395w–4 of this title or (ii) in the case of services as an assistant at surgery, the lesser of the actual charge or 85 percent of the amount that would otherwise be recognized if performed by a physician who is serving as an assistant at surgery, (P) with respect to surgical dressings, the amounts paid shall be the amounts determined under section 1395m(i) of this title, (Q) with respect to items or services for which fee schedules are established pursuant to section 1395u(u) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge or the fee schedule established in such section, (R) with respect to ambulance services, (i) the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary under section 1395m(f)(8) of this title, the amounts paid shall be the amounts determined under section 1395m(g) of this title for outpatient critical access hospital services, (S) with respect to drugs and biologicals (including intravenous immune globulin (as defined in section 1395x(zz) of this title)) not paid on a cost or prospective payment basis as otherwise provided in this part (other than items and services described in subparagraph (B)), the amounts paid shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1395u(o) of this title (or, if applicable, under section 1395w–3, 1395w–3a, or 1395w–3b of this title), (T) with respect to medical nutrition therapy services (as defined in section 1395x(vv) of this title), the amount paid shall be 80 percent (or 100 percent if such services are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual) of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1395w–4(b) of this title for the same services if furnished by a physician, (U) with respect to facility fees described in section 1395m(m)(2)(B) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section, (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1395u(s) items), with respect to competitively priced items and services (described in section 1395w–3(a)(2) of this title) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1395w–3(b)(5) of this title, (W) with respect to additional preventive services (as defined in section 1395x(ddd)(1) of this title), the amounts paid shall be (i) in the case of such services which are clinical diagnostic laboratory tests, the amount paid shall be 100 percent of the amount determined under subparagraph (D) (if such subparagraph were applied, by substituting "100 percent" for "80 percent"), and (ii) in the case of all other such services, 100 percent of the lesser of the actual charge for the service or the amount determined under the payment basis determined under section 1395w–4 of this title, (Y) with respect to preventive services described in subparagraphs (A) and (B) of section 1395x(ddd)(3) of this title that are appropriate for the individual and, in the case of such services described in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population, the amount paid shall be 100 percent of (i) the amount determined under the fee schedule that applies to such services under this part, and (ii) in the case of such services that are covered OPD services (as defined in subsection (t)(1)(B)), the amount determined under subsection (t), and (Z) with respect to Federally qualified health center services for which payment is made under section 1395m(o) of this title, the amounts paid shall be 80 percent of the lesser of the actual charge or the amount determined under such section; (2) in the case of services described in section 1395k(a)(2) of this title (except those services described in subparagraphs (C), (D), (E), (F), (G), (H), and (I) of such section and unless otherwise specified in section 1395ff of this title)— (A) with respect to home health services (other than a covered osteoporosis drug) (as defined in section 1395x(kk) of this title), the amount determined under the prospective payment system under section 1395ff of this title; (B) with respect to other items and services (except those described in subparagraph (C), (D), or (E) of this paragraph and except as may be provided in section 1395w of this title or section 1395yy(y)(9) of this title)— (i) furnished before January 1, 1999, the lesser of—
(I) the reasonable cost of such services, as determined under section 1395x(v) of this title, or

(II) the customary charges with respect to such services, less the amount a provider may charge as described in clause (ii) of section 1395cc(a)(2)(A) of this title, but in no case may the payment for such other services exceed 80 percent of such reasonable cost, or

(ii) if such services are furnished before January 1, 1999, by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this clause), free of charge or at nominal charges to the public, 80 percent of the amount determined in accordance with section 1395f(b)(2) of this title, or

(iii) if such services are furnished on or after January 1, 1999, the amount determined under subsection (t) of this section, or

(iv) if (and for so long as) the conditions described in section 1395f(b)(3) of this title are met, the amounts determined under the reimbursement system described in such section;

(C) with respect to services described in the second sentence of section 1395x(p) of this title, 80 percent of the reasonable charges for such services;

(D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i) on the basis of a fee schedule determined under subsection (h)(1) of this section or section 1395m(d)(1) of this title, the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis or to a provider having an agreement under section 1395k(a)(3) of this title) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B) of this section, or the amount of the charges billed for the tests, or

(ii) on the basis of a negotiated rate established under subsection (h)(6) of this section, the amount paid shall be equal to 100 percent of such negotiated rate for such tests;

(E) with respect to—

(i) outpatient hospital radiology services (including diagnostic and therapeutic radiology, nuclear medicine and CAT scan procedures, magnetic resonance imaging, and ultrasound and other imaging services, but excluding screening mammography and, for services furnished on or after January 1, 2005, diagnostic mammography), and

(ii) effective for procedures performed on or after October 1, 1989, diagnostic procedures (as defined by the Secretary) described in section 1395x(s)(3) of this title (other than diagnostic x-ray tests and diagnostic laboratory tests), the amount determined under subsection (n) of this section or, for services or procedures performed on or after January 1, 1999, subsection (t) of this section;

(F) with respect to a covered osteoporosis drug (as defined in section 1395x(kk) of this title) furnished by a home health agency, 80 percent of the reasonable cost of such service, as determined under section 1395x(v) of this title;

(G) with respect to items and services described in section 1395x(s)(10)(A) of this title, the lesser of—

(i) the reasonable cost of such services, as determined under section 1395x(v) of this title, or

(ii) the customary charges with respect to such services; and

(H) with respect to personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title) furnished by an outpatient department of a hospital, the amount determined under paragraph (1)(X), or, if such services are furnished by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this provision), free of charge or at nominal charges to the public, the amount determined in accordance with section 1395f(b)(2) of this title,

(3) in the case of services described in section 1395k(a)(2)(D) of this title—

(A) except as provided in subparagraph (B), the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1395x(v) of this title, less the amount a provider may charge as described in clause (ii) of section 1395cc(a)(2)(A) of this title, but in no case may the payment for such services (other than for items and services described in section 1395x(s)(10)(A) of this title) exceed 80 percent of such costs; or

(B) with respect to the services described in clause (i) of section 1395k(a)(2)(D) of this title that are furnished to an individual enrolled with a MA plan under part C of this subchapter pursuant to a written agreement described in section 1395w–23(a)(4) of this title, the amount (if any) by which—

(i) the amount of payment that would have otherwise been provided (I) under subparagraph (A) (calculated as if “100 percent” were substituted for “80 percent” in such subparagraph) for such services if the individual had not been so enrolled, or (II) in the case of such services furnished on or after the implementation date of the prospective payment system under section 1395m(o) of this title, under such section (calculated as if “100 percent” were substituted for “80 percent” in such section) for such services if the individual had not been so enrolled; exceeds

(ii) the amount of the payments received under such written agreement for such services (not including any financial in-
President, the amount the federally qualified health center may charge as described in section 1395w-27(e)(3)(B) of this title;

(4) in the case of facility services described in section 1395k(a)(2)(F) of this title, and outpatient hospital facility services furnished in connection with surgical procedures specified by the Secretary pursuant to subsection (1)(A) of this section, the applicable amount as determined under paragraph (2) or (3) of subsection (1) of this section or subsection (t) of this section;

(5) in the case of covered items (described in section 1395m(a)(13) of this title) the amounts described in section 1395m(a)(1) of this title;

(6) in the case of outpatient critical access hospital services, the amounts described in section 1395m(g) of this title;

(7) in the case of prosthetic devices and orthotics and prosthetics (as described in section 1395m(h)(4) of this title), the amounts described in section 1395m(h) of this title;

(8) in the case of—

(A) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a rehabilitation agency, public health agency, clinic, comprehensive outpatient rehabilitation facility, or skilled nursing facility,

(ii) by a home health agency to an individual who is not homebound, or

(iii) by another entity under an arrangement with an entity described in clause (i) or (ii); and

(B) outpatient physical therapy services, outpatient speech-language pathology services, and outpatient occupational therapy services furnished—

(i) by a hospital to an outpatient or to a hospital inpatient who is entitled to benefits under part A of this subchapter but has exhausted benefits for inpatient hospital services during a spell of illness or is not so entitled to benefits under part A of this subchapter, or

(ii) by another entity under an arrangement with a hospital described in clause (i),

the amounts described in section 1395m(k) of this title; and

(9) in the case of services described in section 1395k(a)(2)(E) of this title that are not described in paragraph (8), the amounts described in section 1395m(k) of this title.

Paragraph (3)(A) shall not apply to Federally qualified health center services furnished on or after the implementation date of the prospective payment system under section 1395m(0) of this title.

(b) Deductible provision

Before applying subsection (a) of this section with respect to expenses incurred by an individual during any calendar year, the total amount of the expenses incurred by such individual during such year (which would, except for this subsection, constitute incurred expenses from which benefits payable under subsection (a) of this section are determinable) shall be reduced by a deductible of $75 for calendar years before 1991, $100 for 1991 through 2004, $110 for 2005, and for a subsequent year the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1395(a)(1) of this title ending with such subsequent year (rounded to the nearest $1); except that (1) such total amount shall not include expenses incurred for preventive services described in subparagraph (A) of section 1395x(ddd)(3) of this title that are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual; (2) such deductible shall not apply for respect to home health services (other than a covered osteoporosis drug prescribed for a subsequent year (as defined in section 1395k(k) of this title)), such deductible shall not apply with respect to clinical diagnostic laboratory tests for which payment is made under this part (A) under subsection (a)(1)(D)(i) or (a)(2)(D)(i) of this section on an assignment-related basis, or to a provider having an agreement under section 1395cc of this title, or (B) on the basis of a negotiated rate determined under subsection (h)(6) of this section, (4) such deductible shall not apply to Federally qualified health center services, (5) such deductible shall not apply with respect to screening mammography (as described in section 1395x(jj) of this title), (6) such deductible shall not apply with respect to personalized preventive services (as described in section 1395x(pp)(1) of this title), (9) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1395x(ww) of this title), and (10) such deductible shall not apply with respect to colorectal cancer screening tests (as defined in section 1395x(hhh)(1) of this title). The total amount of the expenses incurred by an individual as determined under the preceding sentence shall, after the reduction specified in such sentence, be further reduced by an amount equal to the expenses incurred for the first three pints of whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished to the individual during the calendar year, except that such deductible for such blood shall in accordance with regulations be appropriately reduced to the extent that there has been a replacement of such blood (or equivalent quantities of packed red blood cells, as so defined); and for such purposes blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual shall be deemed replaced when the institution or other person furnishing such blood (or such equivalent quantities of packed red blood cells, as so defined) is

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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 made under this sentence. The deductible under the previous sentence for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1395e(a)(2) of this title to blood or blood cells furnished the individual in the year. Paragraph (1) of the first sentence of this subsection shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test.

d) Mental disorders

(1) Notwithstanding any other provision of this part, with respect to expenses incurred in a calendar year in connection with the treatment of mental, psychoneurotic, and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b)—

(A) for expenses incurred in years prior to 2010, only 621⁄2 percent of such expenses;
(B) for expenses incurred in 2010 or 2011, only 683⁄4 percent of such expenses;
(C) for expenses incurred in 2012, only 75 percent of such expenses;
(D) for expenses incurred in 2013, only 811⁄4 percent of such expenses; and
(E) for expenses incurred in 2014 or any subsequent calendar year, 100 percent of such expenses.

(2) For purposes of subparagraphs (A) through (D) of paragraph (1), the term “treatment” does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by a physician.

d) Nonduplication of payments

No payment may be made under this part with respect to services furnished an individual to the extent that such individual is entitled (or would be entitled except for section 1395e of this title) to have payment made with respect to such services under part A of this subchapter.

e) Information for determination of amounts due

No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

f) Maximum rate of payment per visit for independent rural health clinics

In establishing limits under subsection (a) of this section on payment for rural health clinic services provided by rural health clinics (other than such clinics in hospitals with less than 50 beds), the Secretary shall establish such limit, for services provided—

(1) in 1988, after March 31, at $36 per visit, and
(2) in a subsequent year, at the limit established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) applicable to primary care services (as defined in section 1395u(i)(4) of this title) furnished as of the first day of that year.

g) Physical therapy services

(1) Subject to paragraphs (4) and (5), in the case of physical therapy services of the type described in section 1395x(p) of this title and speech-language pathology services of the type described in such section through the application of section 1395x(l)(2) of this title, but not described in subsection (a)(8)(B) of this section, and physical therapy services and speech-language pathology services of such type which are furnished by a physician or as incident to physicians’ services, with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b) of this section.

(2) The amount specified in this paragraph—

(A) for 1999, 2000, and 2001, is $1,500, and
(B) for a subsequent year is the amount specified in this paragraph for the preceding year increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for such subsequent year; except that if an increase under subparagraph (B) for a year is not a multiple of $10, it shall be rounded to the nearest multiple of $10.

(3) Subject to paragraphs (4) and (5), in the case of occupational therapy services (of the type that are described in section 1395x(p) of this title but not described in subsection (a)(8)(B) of this section) through the operation of section 1395x(y) of this title and of such type which are furnished by a physician or as incident to physicians’ services, with respect to expenses incurred in any calendar year, no more than the amount specified in paragraph (2) for the year shall be considered as incurred expenses for purposes of subsections (a) and (b) of this section.


(5) With respect to expenses incurred during the period beginning on January 1, 2006, and ending on December 31, 2011, for services, the Secretary shall implement a process under which an individual enrolled under this part may, upon request of the individual or a person on behalf of the individual, obtain an exception from the uniform dollar limitation specified in paragraph (2), for services described in paragraphs (1) and (3) if the provision of such services is determined to be medically necessary. Under such process, if the Secretary does not make a decision on such a request for an exception within 10 business days of the date of the Secretary’s receipt of the request, the Secretary shall be deemed to have found the services to be medically necessary.
(h) Fee schedules for clinical diagnostic laboratory tests; percentage of prevailing charge level; nominal fee for samples; adjustments; recipients of payments; negotiated payment rate

(1)(A) Subject to section 1395m(d)(1) of this title, the Secretary shall establish fee schedules for clinical diagnostic laboratory tests (including prostate cancer screening tests under section 1395k(a)(a) of this title consisting of prostate-specific antigen blood tests) for which payment is made under this part, other than such tests performed by a provider of services for an inpatient of such provider.

(B) In the case of clinical diagnostic laboratory tests performed by a physician or by a laboratory (other than tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital), the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(C) In the case of clinical diagnostic laboratory tests performed by a qualified hospital laboratory (as defined in subparagraph (D)) for outpatients of such hospital, the fee schedules established under subparagraph (A) shall be established on a regional, statewide, or carrier service area basis (as the Secretary may determine to be appropriate) for tests furnished on or after July 1, 1984.

(D) In this subsection, the term "qualified hospital laboratory" means a hospital laboratory, in a sole community hospital (as defined in section 1395ww(d)(5)(D)(ii) of this title), which provides some clinical diagnostic laboratory tests 24 hours a day in order to serve a hospital emergency room which is available to provide services 24 hours a day and 7 days a week.

(2)(A)(i) Except as provided in paragraph (4), the Secretary shall set the fee schedules at 60 percent (or, in the case of a test performed by a qualified hospital laboratory (as defined in paragraph (1)(D)) for outpatients of such hospital, 62 percent) of the prevailing charge level determined pursuant to the third and fourth sentences of section 1395u(b)(3) of this title, which provides the third sentence of section 1395u(b)(3) of this title for each of the years 1991, 1992, and 1993 shall be 2 percent, otherwise established for 1988, and such reduced fee schedules shall serve as the base for 1989 and subsequent years.

(ii) Notwithstanding clause (i), any change in the fee schedules which would have become effective under this subsection for tests furnished on or after January 1, 1988, shall not be effective for tests furnished during the 3-month period beginning on January 1, 1988.

(ii) The Secretary shall not adjust the fee schedules under clause (i) to take into account any increase in the consumer price index for 1988.

(iii) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1991, 1992, and 1993 shall be 2 percent, and

(iv) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1994 and 1995, 1998 through 2002, and 2004 through 2008 shall be 0 percent.

Subclause (I) shall not apply in a year where the adjustment to the fee schedules determined under clause (i) is 0.0 or a percentage decrease for a year. The application of the productivity adjustment under subclause (I) shall not result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year. The application of subclause (II) may result in an adjustment to the fee schedules under clause (i) being less than 0.0 for a year, and may result in payment rates for a year being less than such payment rates for the preceding year.

(B) The Secretary may make further adjustments or exceptions to the fee schedules to assure adequate reimbursement of (i) emergency laboratory tests needed for the provision of bona fide emergency services, and (ii) certain low volume high-cost tests where highly sophisticated equipment or extremely skilled personnel are necessary to assure quality.

(3) In addition to the amounts provided under the fee schedules, the Secretary shall provide for and establish (A) a nominal fee to cover the appropriate costs in collecting the sample on which a clinical diagnostic laboratory test was performed and for which payment is made under this part, except that not more than one such fee may be provided under this paragraph with respect to samples collected in the same encounter, and (B) a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect the sample, except that such a fee may be provided only with respect to an individual who is homebound or an inpatient in an inpatient facility (other than a hospital). In establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample, but the Secretary shall...
only be required to apply such method in the case of tests furnished during the period beginning on April 1, 1989, and ending on December 31, 1990, by a laboratory that establishes to the satisfaction of the Secretary based on data for the 12-month period ending June 30, 1988 that (i) the laboratory is dependent upon payments under this subchapter for at least 80 percent of its collected revenues for clinical diagnostic laboratory tests, (ii) at least 85 percent of its gross revenues for such tests are attributable to tests performed with respect to individuals who are homebound or who are residents in a nursing facility, and (iii) the laboratory provided such tests for residents in nursing facilities representing at least 20 percent of the number of such facilities in the State in which the laboratory is located.

(4)(A) In establishing any fee schedule under this subsection, the Secretary may provide for an adjustment to take into account, with respect to the portion of the expenses of clinical diagnostic laboratory tests attributable to wages, the relative difference between a region’s or local area’s wage rates and the wage rate presumed in the data on which the schedule is based.

(B) For purposes of subsections (a)(1)(D)(i) and (a)(2)(D)(i) of this section, the limitation amount for a clinical diagnostic laboratory test performed—

(i) on or after July 1, 1986, and before April 1, 1988, is equal to 115 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(ii) after March 31, 1988, and before January 1, 1990, is equal to the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iii) after December 31, 1989, and before January 1, 1991, is equal to 93 percent of the median of all the fee schedules established for that test for that laboratory setting under paragraph (1),

(iv) after December 31, 1990, and before January 1, 1991, is equal to 88 percent of such median,

(v) after December 31, 1991, and before January 1, 1993, is equal to 84 percent of such median,

(vi) after December 31, 1993, and before January 1, 1995, is equal to 76 percent of such median,

(vii) after December 31, 1994, and before January 1, 1996, is equal to 68 percent of such median,

(viii) after December 31, 1995, and before January 1, 1998, is equal to 74 percent of such median, and

(ix) after December 31, 1997, is equal to 70 percent of such median (or 100 percent of such median in the case of a clinical diagnostic laboratory test performed on or after January 1, 2001, that the Secretary determines is a new test for which no limitation amount has previously been established under this subparagraph).

(5)(A) In the case of a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part on an assignment-related basis or under a provider agreement under section 1395cc of this title, payment may be made only to the person or entity which performed or supervised the performance of such test; except that—

(i) if a physician performed or supervised the performance of such test, payment may be made to another physician with whom he shares his practice,

(ii) in the case of a test performed at the request of a laboratory by another laboratory, payment may be made to the referring laboratory but only if—

(I) the referring laboratory is located in, or is part of, a rural hospital,

(II) the referring laboratory is wholly owned by the entity performing such test, the referring laboratory wholly owns the entity performing such test, the referring laboratory and the entity performing such test are wholly-owned by a third entity, or

(iii) in the case of a clinical diagnostic laboratory test provided under an arrangement (as defined in section 1395x(w)(1) of this title) made by a hospital, critical access hospital, or skilled nursing facility, payment shall be made to the hospital or skilled nursing facility.

(B) In the case of such a bill or request for payment for a clinical diagnostic laboratory test for which payment may otherwise be made under this part, and which is not described in subparagraph (A), payment may be made to the beneficiary only on the basis of the itemized bill of the person or entity which performed or supervised the performance of the test.

(C) Payment for a clinical diagnostic laboratory test, including a test performed in a physician’s office but excluding a test performed by a rural health clinic may only be made on an assignment-related basis or to a provider of services with an agreement in effect under section 1395cc of this title.

(D) A person may not bill for a clinical diagnostic laboratory test, including a test performed in a physician’s office but excluding a test performed by a rural health clinic, other than on an assignment-related basis. If a person knowingly and willfully and on a repeated basis bills for a clinical diagnostic laboratory test in violation of the previous sentence, the Secretary may apply sanctions against the person in the same manner as the Secretary may apply sanctions against a physician in accordance with paragraph (2) of section 1395u(j) of this title in the same manner such paragraphs apply with respect to a physician. Paragraph (4) of such section shall apply in this subparagraph in the same manner as such paragraph applies to such section.

(E) In the case of any diagnostic laboratory test payment for which is not made on the basis

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4 So in original. Probably should be “such paragraph applies.”

8 So in original. The comma after “subclause (II)” probably should follow “is performed.”
of a fee schedule under paragraph (1), the Secretary may establish a payment rate which is acceptable to the person or entity performing the test and which would be considered the full charge for such tests. Such negotiated rate shall be limited to an amount not in excess of the total payment that would have been made for the services in the absence of such rate.

(7) Notwithstanding paragraphs (1) and (4), the Secretary shall establish a national minimum payment amount under this subsection for a diagnostic or screening pap smear laboratory test (including all cervical cancer screening technologies that have been approved by the Food and Drug Administration as a primary screening method for detection of cervical cancer) equal to $14.60 for tests furnished in 2000. For such tests furnished in subsequent years, such national minimum payment amount shall be adjusted annually as provided in paragraph (2).

(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as “new tests”).

(B) Determinations under subparagraph (A) shall be made only after the Secretary—

(i) makes available to the public (through an Internet website and other appropriate mechanisms) a list that includes any such test for which establishment of a payment amount under this subsection is being considered for a year;

(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are based);

(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

(v) taking into account the comments received during the public comment period, develops and makes available to the public (through an Internet website and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and responses to comments and suggestions received from the public.

(C) Under the procedures established pursuant to subparagraph (A), the Secretary shall—

(i) set forth the criteria for making determinations under subparagraph (A); and

(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary deems appropriate.

(E) For purposes of this paragraph:

(i) The term “HCPCS” refers to the Health Care Procedure Coding System.

(ii) A code shall be considered to be “substantially revised” if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test).

(9) Notwithstanding any other provision in this section as the Secretary deems appropriate.

(i) Outpatient surgery

(1) The Secretary shall, in consultation with appropriate medical organizations—

(A) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in an ambulatory surgical center (meeting the standards specified under section 1395k(a)(2)(F)(i) of this title), critical access hospital, hospital outpatient department, and

(B) specify those surgical procedures which are appropriately (when considered in terms of the proper utilization of hospital inpatient facilities) performed on an inpatient basis in a hospital but which also can be performed safely on an ambulatory basis in a physician’s office.

The lists of procedures established under subparagraphs (A) and (B) shall be reviewed and updated not less often than every 2 years, in consultation with appropriate trade and professional organizations.

(2)(A) For services furnished prior to the implementation of the system described in subparagraph (D), subject to subparagraph (E), the amount of payment to be made for facility services furnished in connection with a surgical procedure specified pursuant to paragraph (1)(A) and furnished to an individual in an ambulatory surgical center described in such paragraph shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary’s estimate of a fair fee which—
(i) takes into account the costs incurred by such centers, or classes of centers, generally in providing services furnished in connection with the performance of such procedure, as determined in accordance with a survey (based upon a representative sample of procedures and facilities) of the actual audited costs incurred by such centers in providing such services.

(ii) takes such costs into account in such a manner as will assure that the performance of the procedure in such a center will result in substantially less amounts paid under this subchapter than would have been paid if the procedure had been performed on an inpatient basis in a hospital, and

(iii) in the case of insertion of an intraocular lens during or subsequent to cataract surgery includes payment which is reasonable and related to the cost of acquiring the class of lens involved.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(B) The amount of payment to be made under this part for facility services furnished, in connection with a surgical procedure specified pursuant to paragraph (A)(i), in a physician’s office shall be equal to 80 percent of a standard overhead amount established by the Secretary (with respect to each such procedure) on the basis of the Secretary’s estimate of a fair fee which—

(i) takes into account additional costs, not usually included in the professional fee, incurred by physicians in securing, maintaining, and staffing the facilities and ancillary services appropriate for the performance of such procedure in the physician’s office, and

(ii) takes such items into account in such a manner which will assure that the performance of such procedure in the physician’s office will result in substantially less amounts paid under this subchapter than would have been paid if the services had been furnished on an inpatient basis in a hospital.

Each amount so established shall be reviewed and updated not later than July 1, 1987, and annually thereafter to take account of varying conditions in different areas.

(C)(i) Notwithstanding the second sentence of each of subparagraphs (A) and (B), except as otherwise specified in clauses (ii), (iii), and (iv), if the Secretary has not updated amounts established under such subparagraphs or under subparagraph (D), with respect to facility services furnished during a fiscal year (beginning with fiscal year 1986 or a calendar year (beginning with 2006)), such amounts shall be 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 year involved.

(ii) In each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points.

(iii) In fiscal year 2004, beginning with April 1, 2004, the increase under this subparagraph shall be the Consumer Price Index for all urban consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with March 31, 2003, minus 3.0 percentage points.

(iv) In fiscal year 2005, the last quarter of calendar year 2005, and each of calendar years 2006 through 2009, the increase under this subparagraph shall be 0 percent.

(D)(i) Taking into account the recommendations in the report under section 626(d) of Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the Secretary shall implement a revised payment system for payment of surgical services furnished in ambulatory surgical centers.

(ii) In the year the system described in clause (i) is implemented, such system shall be designed to result in the same aggregate amount of expenditures for such services as would be made if this subparagraph did not apply, as estimated by the Secretary and taking into account reduced expenditures if subparagraph (E) were to continue to apply, as estimated by the Secretary.

(iii) The Secretary shall implement the system described in clause (i) for periods in a manner so that it is first effective beginning on or after January 1, 2006, and not later than January 1, 2008.

(iv) The Secretary may implement such system in a manner so as to provide for a reduction in any annual update for failure to report on quality measures in accordance with paragraph (7).

(v) In implementing the system described in clause (i) for 2011 and each subsequent year, any annual update under such system for the year, after application of clause (iv), shall be reduced 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 update being less than 0.0 for a year, and may result in payment rates under the system described in clause (i) for a year being less than such payment rates for the preceding year.

(vi) There shall be no administrative or judicial review under section 1395ff, 1395oo of this title, or otherwise, of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, under this subparagraph.

(E) With respect to surgical procedures furnished on or after January 1, 2007, and before the effective date of the implementation of a revised payment system under subparagraph (D), if—

(i) the standard overhead amount under subparagraph (A) for a facility service for such procedure, without the application of any geographic adjustment, exceeds

(ii) the Medicare OPPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of subsection (t) for such service for such year, determined without regard to geographic adjustment under paragraph (2)(D) of such subsection, the Secretary shall substitute under subparagraph (A) the amount described in clause (ii) for the standard overhead amount for such service referred to in clause (i).

(3)(A) The aggregate amount of the payments to be made under this part for outpatient hos-
(4)(A) In the case of a hospital that—
   (i) makes application to the Secretary and demonstrates that it specializes in eye services or eye and ear services (as determined by the Secretary), (ii) receives more than 30 percent of its total revenues from outpatient services, and (iii) on October 1, 1987—
   (I) was an eye specialty hospital or an eye and ear specialty hospital, or (II) was operated as an eye or eye and ear unit (as defined in subparagraph (B)) of a general acute care hospital which, on the date of the application described in clause (i), operates less than 20 percent of the beds that the hospital operated on October 1, 1987, and has sold or otherwise disposed of a substantial portion of the hospital’s other acute care operations.

the cost proportion and ASC proportion in effect under subclauses (I) and (II) of paragraph (3)(B)(ii) for cost reporting periods beginning in fiscal year 1988 shall remain in effect for cost reporting periods beginning on or after October 1, 1988.

(5)(A) The Secretary is authorized to provide by regulations that in the case of a surgical procedure, specified by the Secretary pursuant to paragraph (1)(A), performed in an ambulatory surgical center described in such paragraph, there shall be paid (in lieu of any amounts otherwise payable under this part) with respect to the facility services furnished by such center and with respect to all related services (including physicians’ services, laboratory, X-ray, and diagnostic services) a single all-inclusive fee established pursuant to subparagraph (B), if all parties furnishing all such services agree to accept such fee (to be divided among the parties involved in such manner as they shall have previously agreed upon) as full payment for the services furnished.

(B) In implementing this paragraph, the Secretary shall establish with respect to each surgical procedure specified pursuant to paragraph (1)(A) the amount of the all-inclusive fee for such procedure, taking into account such factors as may be appropriate. The amount so established with respect to any surgical procedure shall be reviewed periodically and may be adjusted by the Secretary, when appropriate, to take account of varying conditions in different areas.

(6) Any person, including a facility having an agreement under section 1395cc(a)(2)(F)(i) of this title, who knowingly and willfully presents, or causes to be presented, a bill or request for payment, for an intraocular lens inserted during or subsequent to cataract surgery for which payment may be made under paragraph (2)(A)(iii), 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.

(7)(A) For purposes of paragraph (2)(D)(iv), the Secretary may provide, in the case of an ambulatory surgical center that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to a year, any annual increase provided under the system established under paragraph (2)(D) for such year shall be reduced by 2.0 percentage points. A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing any annual increase factor for a subsequent year.

(B) Except as the Secretary may otherwise provide, the provisions of subparagraphs (B), (C), (D), and (E) of paragraph (17) of subsection (t) shall apply with respect to services of ambulatory surgical centers under this paragraph in a similar manner to the manner in which they apply under such paragraph and, for purposes of this subparagraph, any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ambulatory surgical center, the setting of such a center, or services of such a center, respectively.

So in original. The word “this” probably should not appear.
(j) Accrual of interest on balance of excess or deficit not paid

Whenever a final determination is made that the amount of payment made under this part either to a provider of services or to another person pursuant to an assignment under section 1395u(b)(3)(B)(i) of this title was in excess of or less than the amount of payment that is due, and payment of such excess or deficit is not made (or effected by offset) within 30 days of the date of the determination, interest shall accrue on the balance of such excess or deficit not paid or offset (to the extent that the balance is owed by or owing to the provider) at a rate determined in accordance with the regulations of the Secretary of the Treasury applicable to charges for late payments.

(k) Hepatitis B vaccine

With respect to services described in section 1395x(s)(10)(B) of this title, the Secretary may provide, instead of the amount of payment otherwise provided under this part, for payment of such an amount or amounts as reasonably reflects the general cost of efficiently providing such services.

(l) Fee schedule for services of certified registered nurse anesthetists

(1)(A) The Secretary shall establish a fee schedule for services of certified registered nurse anesthetists under section 1395x(s)(11) of this title.

(B) In establishing the fee schedule under this paragraph the Secretary may utilize a system of time units, a system of base and time units, or any appropriate methodology.

(C) The provisions of this subsection shall not apply to certain services furnished in certain hospitals in rural areas under the provisions of section 1395w–4 of this title, as amended by section 6326 of the Omnibus Budget Reconciliation Act of 1986. A reduced prevailing charge under this subparagraph shall become the prevailing charge but for subsequent years for purposes of applying the economic index under the fourth sentence of section 1395u(b)(3) of this title.

(4)(A) Except as provided in subparagraphs (C) and (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, by a certified registered nurse anesthetist who is not medically directed—

(i) the conversion factor shall be—

(1) for services furnished in 1991, $15.50,
(2) for services furnished in 1992, $15.75,
(3) for services furnished in 1993, $16.00,
(4) for services furnished in 1994, $16.25,
(5) for services furnished in 1995, $16.50,
(6) for services furnished in 1996, $16.75, and
(7) for services furnished in calendar years after 1996, the previous year’s conversion factor increased by the update determined under section 1395w–4(d) of this title for physician anesthesia services for that year;

(ii) the payment areas to be used shall be the fee schedule areas used under section 1395w–4 of this title (or, in the case of services furnished during 1991, the localities used under section 1395u(b) of this title) for purposes of computing payments for physicians’ services that are anesthesia services;

(iii) the geographic adjustment factors to be applied to the conversion factor under clause (i) for services in a fee schedule area or locality is—

(1) in the case of services furnished in 1991, the geographic work index value and the geographic practice cost index value specified in section 1395u(q)(1)(B) of this title for physicians’ services that are anesthesia services furnished in the area or locality, and
(2) in the case of services furnished after 1991, the geographic work index value, the geographic practice cost index value, and the geographic malpractice index value used for determining payments for physicians’ services that are anesthesia services under section 1395w–4 of this title,

with 70 percent of the conversion factor treated as attributable to work and 30 percent as attributable to overhead for services furnished in 1991 (and the portions attributable to work, practice expenses, and malpractice expenses in 1992 and thereafter being the same as is applied under section 1395w–4 of this title),

(B)(i) Except as provided in clause (ii) and subparagraph (D), in determining the amount paid under the fee schedule under this subsection for services furnished on or after January 1, 1991, and before January 1, 1994, by a certified reg-
istered nurse anesthetist who is medically directed, the Secretary shall apply the same methodology specified in subparagraph (A).

(ii) The conversion factor used under clause (i) shall be—

(I) for services furnished in 1991, $10.50,

(II) for services furnished in 1992, $10.75, and

(III) for services furnished in 1993, $11.00.

(iii) In the case of services of a certified registered nurse anesthetist who is medically directed or medically supervised by a physician which are furnished on or after January 1, 1994, the fee schedule amount shall be one-half of the amount described in section 1395w–4(a)(5)(B) of this title with respect to the physician.

(C) Notwithstanding subparagraphs (I) through (V) of subparagraph (A)(i)—

(i) in the case of a 1990 conversion factor that is greater than $15.50, the conversion factor for a calendar year after 1990 and before 1996 shall be the 1990 conversion factor reduced by the product of the last digit of the calendar year and one-fifth of the amount by which the 1990 conversion factor exceeds $15.50; and

(ii) in the case of a 1990 conversion factor that is greater than $15.49 but less than $16.51, the conversion factor for a calendar year after 1990 and before 1996 shall be the greater of—

(I) the 1990 conversion factor, or

(II) the conversion factor specified in subparagraph (A)(i) for the year involved.

(D) Notwithstanding subparagraph (C), in no case may the conversion factor used to determine payment for services in a fee schedule area or locality under this subsection, as adjusted by the adjustment factors specified in subparagraphs (A)(iii), exceed the conversion factor used to determine the amount paid for physicians’ services that are anesthesia services in the area or locality.

(5)(A) Payment for the services of a certified registered nurse anesthetist (for which payment may otherwise be made under this part) may be made on the basis of a claim or request for payment presented by the certified registered nurse anesthetist furnishing such services, or by a hospital, critical access hospital, physician, group practice, or ambulatory surgical center with which the certified registered nurse anesthetist furnishing such services has an employment or contractual relationship that provides for payment to be made under this part for such services to such hospital, critical access hospital, physician, group practice, or ambulatory surgical center.

(B) No hospital or critical access hospital that presents a claim or request for payment for services of a certified nurse anesthetist under this part may treat any uncollected coinsurance amount imposed under this part with respect to such services as a bad debt of such hospital or critical access hospital for purposes of this subchapter.

(6) If an adjustment under paragraph (3)(B) results in a reduction in the reasonable charge for a physicians’ service and a nonparticipating physician furnishes the service to an individual entitled to benefits under this part after the effective date of the reduction, the physician’s actual charge is subject to a limit under section 1395u(j)(1)(D) of this title.

(m) Incentive payments for physicians’ services furnished in underserved areas

(1) In the case of physicians’ services furnished in a year to an individual, who is covered under the insurance program established by this part and who incurs expenses for such services, in an area that is designated (under section 1395w–4(a)(1)(A) of this title) as a health professional shortage area as identified by the Secretary prior to the beginning of such year, in addition to the amount otherwise paid under this part, there shall also be paid to the physician (or to an employer or facility in the cases described in clause (A) of section 1395u(b)(6) of this title) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance Trust Fund an amount equal to 10 percent of the payment amount for the service under this part.

(2) For each health professional shortage area identified in paragraph (1) that consists of an entire county, the Secretary shall provide for the additional payment under paragraph (1) without any requirement on the physician to identify the health professional shortage area involved. The Secretary may implement the previous sentence using the method specified in subsection (u)(4)(C) of this section.

(3) The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services a list of the health professional shortage areas identified in paragraph (1) that consist of a partial county to facilitate the additional payment under paragraph (1) in such areas.

(4) There shall be no administrative or judicial review under section 1395f of this title, section 1395oo of this title, or otherwise, respecting—

(A) the identification of a county or area;

(B) the assignment of a specialty of any physician under this paragraph;

(C) the assignment of a physician to a county under this subsection; or

(D) the assignment of a postal ZIP Code to a county or other area under this subsection.

(n) Payments to hospital outpatient departments for radiology; amount; definitions

(1)(A) The aggregate amount of the payments to be made for all or part of a cost reporting period for services described in subsection (a)(2)(E)(i) of this section furnished under this part on or after October 1, 1988, and before January 1, 1999, and for services described in subsection (a)(2)(E)(ii) of this section furnished under this part on or after October 1, 1989, and before January 1, 1999, shall be equal to the lesser of—

(i) the amount determined with respect to such services under subsection (a)(2)(B) of this section, or

(ii) the blend amount for radiology services and diagnostic procedures determined in accordance with subparagraph (B).

(B) The blend amount for radiology services and diagnostic procedures for a cost reporting period is the sum of—

8So in original. Probably should be “subparagraph”.

9So in original. No par. (2) has been enacted.
(I) the cost proportion (as defined in clause (ii)) of the amount described in subparagraph (A)(i); and

(II) the charge proportion (as defined in clause (i)(II)) of 62 percent (for services described in subsection (a) of this section), or (for procedures described in subsection (a)(2)(B)(ii) of this section), 42 percent or such other percent established by the Secretary (or carriers acting pursuant to guidelines issued by the Secretary) based on prevailing charges established with actual charge data, of the prevailing charge or (for services described in subsection (a)(2)(E)(i) of this section) furnished on or after April 1, 1989 and for services described in subsection (a)(2)(E)(ii) of this section furnished on or after January 1, 1992 the fee schedule amount established for participating physicians for the same services as if they were furnished in a physician’s office in the same locality as determined under section 1395u(b) of this title (or, in the case of services furnished on or after January 1, 1992, under section 1395w-4 of this title), less the amount a provider may charge as described in clause (i) of section 1395cc(a)(2)(A) of this title.

(ii) in this subparagraph:

(1) the term “cost proportion” means 50 percent, except that such term means 65 percent in the case of outpatient radiology services for portions of cost reporting periods which occur in fiscal year 1990 and in the case of diagnostic procedures described in subsection (a)(2)(E)(i) of this section for portions of cost reporting periods which occur in fiscal year 1990, and such term means 42 percent in the case of outpatient radiology services for portions of cost reporting periods beginning on or after January 1, 1991.

(2) the term “charge proportion” means 100 percent minus the cost proportion.

(o) Limitation on benefit for payment for therapeutic shoes for individuals with severe diabetic foot disease

(1) In the case of a request for payment for an item or service furnished by an entity under this part on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included, payment may be denied under this part.

(A) no payment may be made under this part, with respect to any individual for any year, for the furnishing of—

(i) more than one pair of custom molded shoes (including inserts provided with such shoes) and 2 additional pairs of inserts for such shoes, or

(ii) more than one pair of extra-depth shoes (not including inserts provided with such shoes) and 3 pairs of inserts for such shoes, and

(B) with respect to expenses incurred in any calendar year, no more than the amount of payment applicable under paragraph (2) shall be considered as incurred expenses for purposes of subparagraph (A) and (B) of this section.

Payment for shoes (or inserts) under this part shall be considered to include payment for any expenses for the fitting of such shoes (or inserts).

(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra-depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1395m(h) of this title.

(B) the Secretary may establish payment amounts for shoes and inserts that are lower than the amount established under section 1395m(h) of this title if the Secretary finds that shoes and inserts of an appropriate quality are readily available at or below the amount established under such section.

(C) in accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1395x(s)(12) of this title may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1395m(h) of this title, a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph.

(3) In this subchapter, the term “shoes” includes, except for purposes of subparagraphs (A)(ii) and (B) of paragraph (2), inserts for extra-depth shoes.


(q) Requests for payment to include information on referring physician

(1) Each request for payment, or bill submitted, for an item or service furnished by an entity for which payment may be made under this part and for which the entity knows or has reason to believe there has been a referral by a referring physician (within the meaning of section 1395nn of this title) shall include the name and unique physician identification number for the referring physician.

(2)(A) In the case of a request for payment for an item or service furnished by an entity under this part on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included, payment may be denied under this part.

(B) in the case of a request for payment for an item or service furnished by an entity under this part not submitted on an assignment-related basis and for which information is required to be provided under paragraph (1) but not included—

(i) if the entity knowingly and willfully fails to provide such information promptly upon request of the Secretary or a carrier, the entity may be subject to a civil money penalty in an amount not to exceed $2,000, and

(ii) if the entity knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection to provide the information required under paragraph (1), the entity may be subject to exclusion from participation in the programs under this chapter for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1320a–7 of this title.

The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply
to civil money penalties under clause (i) in the same manner as they apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(r) Cap on prevailing charge; billing on assignment-related basis

(1) With respect to services described in section 1395x(s)(2)(K)(i) of this title (relating to nurse practitioner or clinical nurse specialist services), payment may be made on the basis of a claim or request for payment presented by the nurse practitioner or clinical nurse specialist furnishing such services, or by a hospital, critical access hospital, skilled nursing facility or nursing facility (as defined in section 1396r(s) of this title) for purposes of this subpart with respect to such services as a bad debt of such hospital for purposes of this subchapter.

(s) Other prepaid organizations

The Secretary may not provide for payment under subsection (a)(1)(A) of this section with respect to an organization unless the organization provides assurances satisfactory to the Secretary that the organization meets the requirements of section 1395cc(f) of this title (relating to maintaining written policies and procedures respecting advance directives).

(t) Prospective payment system for hospital outpatient department services

(1) Amount of payment

(A) In general

With respect to covered OPD services (as defined in subparagraph (B)) furnished during a year beginning with 1999, the amount of payment under this part shall be determined under a prospective payment system established by the Secretary in accordance with this subsection.

(B) Definition of covered OPD services

For purposes of this subsection, the term "covered OPD services"—

(i) means hospital outpatient services designated by the Secretary;

(ii) subject to clause (iv), includes inpatient hospital services designated by the Secretary that are covered under this part and furnished to a hospital inpatient who (I) is entitled to benefits under part A of this subchapter but has exhausted benefits for inpatient hospital services during a spell of illness, or (II) is not so entitled;

(iii) includes implantable items described in paragraph (3), (6), or (8) of section 1395x(s) of this title; but

(iv) does not include any therapy services described in subsection (a)(8) of this section or ambulance services, for which payment is made under a fee schedule described in section 1395m(k) of this title or section 1395m(l) of this title and does not include screening mammography (as defined in section 1395x(jj) of this title), diagnostic mammography, personalized prevention plan services (as defined in section 1395x(hh)(1) of this title), or preventive services described in subparagraphs (A) and (B) of section 1395x(ddd)(3) of this title that are appropriate for the individual and, in the case of such services described in subparagraph (A), are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population.

(2) System requirements

Under the payment system—

(A) the Secretary shall develop a classification system for covered OPD services;

(B) the Secretary may establish groups of covered OPD services, within the classification system described in subparagraph (A), so that services classified within each group are comparable clinically and with respect to the use of resources and so that an implantable item is classified to the group that includes the service to which the item relates;

(C) the Secretary shall, using data on claims from 1996 and using data from the most recent available cost reports, establish relative payment weights for covered OPD services (and any groups of such services described in subparagraph (A), based on median (or, at the election of the Secretary, mean) hospital costs and shall determine projections of the frequency of utilization of each such service (or group of services) in 1999;

(D) subject to paragraph (19), the Secretary shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner;

(E) the Secretary shall establish, in a budget neutral manner, outlier adjustments under paragraph (5) and transitional pass-through payments under paragraph (6) and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals;

(F) the Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services;

(G) the Secretary shall create additional groups of covered OPD services that classify separately those procedures that utilize contrast agents from those that do not; and

(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices fur-
nished, including separate groups for palladium-103 and iodine-125 devices and for stranded and non-stranded devices furnished on or after July 1, 2007.

For purposes of subparagraph (B), items and services within a group shall not be treated as “comparable with respect to the use of resources” if the highest median cost (or mean cost, if elected by the Secretary under subparagraph (C)) for an item or service within the group is more than 2 times greater than the lowest median cost (or mean cost, if so elected) for an item or service within the group, except that the Secretary may make exceptions in unusual cases, such as low volume items and services, but may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 360bb of title 21.

(3) Calculation of base amounts

(A) Aggregate amounts that would be payable if deductibles were disregarded

The Secretary shall estimate the sum of—

(i) the total amounts that would be payable from the Trust Fund under this part for covered OPD services in 1999, determined without regard to this subsection, as though the deductible under subsection (b) of this section did not apply, and

(ii) the total amounts of copayments estimated to be paid under this subsection by beneficiaries to hospitals for covered OPD services in 1996, updated to 1999 using the Secretary’s estimate of charge growth during the period.

(B) Unadjusted copayment amount

(i) In general

For purposes of this subsection, subject to clause (ii), the “unadjusted copayment amount” applicable to a covered OPD service (or group of such services) is 20 percent of the national median of the charges for the service (or services within the group) furnished during 1996, updated to 1999 based upon its classification within a group of such services.

(ii) Adjusted to be 20 percent when fully phased in

If the pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year would be equal to or exceed 80 percent, then the unadjusted copayment amount shall be 20 percent of amount determined under subparagraph (D).

(iii) Rules for new services

The Secretary shall establish rules for establishment of an unadjusted copayment amount for a covered OPD service not furnished during 1996, based upon its classification within a group of such services.

(C) Calculation of conversion factors

(i) For 1999

(I) In general

The Secretary shall establish a 1999 conversion factor for determining the medicare OPD fee schedule amounts for each covered OPD service (or group of such services) furnished in 1999. Such conversion factor shall be established on the basis of the weights and frequencies described in paragraph (2)(C) and in such a manner that the sum for all services and groups of the products (described in subclause (II) for each such service or group) equals the total projected amount described in subparagraph (A).

(II) Product described

The Secretary shall determine for each service or group the product of the medicare OPD fee schedule amounts (taking into account appropriate adjustments described in paragraphs (2)(D) and (2)(E)) and the estimated frequencies for such service or group.

(ii) Subsequent years

Subject to paragraph (8)(B), the Secretary shall establish a conversion factor for covered OPD services furnished in subsequent years in an amount equal to the conversion factor established under this subparagraph and applicable to such services furnished in the previous year increased by the OPD fee schedule increase factor specified under clause (iv) for the year involved.

(iii) Adjustment for service mix changes

Insofar as the Secretary determines that the adjustments for service mix under paragraph (2) for a previous year (or estimates that such adjustments for a future year) did (or are likely to) result in a change in aggregate payments under this subsection during the year that are a result of changes in the coding or classification of covered OPD services that do not reflect real changes in service mix, the Secretary may adjust the conversion factor computed under this subparagraph for subsequent years so as to eliminate the effect of such coding or classification changes.

(iv) OPD fee schedule increase factor

For purposes of this subparagraph, subject to paragraph (17) and subparagraph (F) of this paragraph, the “OPD fee schedule increase factor” for services furnished in a year is equal to the market basket percentage increase applicable under section 1395ww(b)(3)(B)(ii) of this title to hospital discharges occurring during the fiscal year ending in such year, reduced by 1 percentage point for such factor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.
(D) Calculation of medicare OPD fee schedule amounts

The Secretary shall compute a medicare OPD fee schedule amount for each covered OPD service (or group of such services) furnished in a year, in an amount equal to the product of—

(i) the conversion factor computed under subparagraph (C) for the year, and

(ii) the relative payment weight (determined under paragraph (2)(C)) for the service or group.

(E) Pre-deductible payment percentage

The pre-deductible payment percentage for a covered OPD service (or group of such services) furnished in a year is equal to the ratio—

(i) the medicare OPD fee schedule amount established under subparagraph (D) for the year, minus the unadjusted copayment amount determined under subparagraph (B) for the service or group, to

(ii) the medicare OPD fee schedule amount determined under subparagraph (D) for the year for such service or group.

(F) Productivity and other adjustment

After determining the OPD fee schedule increase factor under subparagraph (C)(iv), the Secretary shall reduce such increase factor—

(i) for 2012 and subsequent years, by the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title; and

(ii) for each of 2010 through 2019, by the adjustment described in subparagraph (G).

The application of this subparagraph may result in the increase factor under subparagraph (C)(iv) being less than 0.0 for a year, and may result in payment rates under the payment system under this subsection for a year being less than such payment rates for the preceding year.

(G) Other adjustment

For purposes of subparagraph (F)(ii), the adjustment described in this subparagraph is—

(i) for each of 2010 and 2011, 0.25 percentage point;

(ii) for each of 2012 and 2013, 0.1 percentage point;

(iii) for 2014, 0.3 percentage point;

(iv) for each of 2015 and 2016, 0.2 percentage point; and

(v) for each of 2017, 2018, and 2019, 0.75 percentage point.

(4) Medicare payment amount

The amount of payment made from the Trust Fund under this part for a covered OPD service (and such services classified within a group) furnished in a year is determined, subject to paragraph (7), as follows:

(A) Fee schedule adjustments

The medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service or group and year is adjusted for relative differences in the cost of labor and other factors determined by the Secretary, as computed under paragraphs (2)(D) and (2)(E).

(B) Subtract applicable deductible

Reduce the adjusted amount determined under subparagraph (A) by the amount of the deductible under subsection (b) of this section, to the extent applicable.

(C) Apply payment proportion to remainder

The amount of payment is the amount so determined under subparagraph (B) multiplied by the pre-deductible payment percentage (as determined under paragraph (3)(E)) for the service or group and year involved, plus the amount of any reduction in the copayment amount attributable to paragraph (8)(C).

(5) Outlier adjustment

(A) In general

Subject to subparagraph (D), the Secretary shall provide for an additional payment for each covered OPD service (or group of services) for which a hospital’s charges, adjusted to cost, exceed—

(i) a fixed multiple of the sum of—

(I) the applicable medicare OPD fee schedule amount determined under paragraph (3)(D), as adjusted under paragraph (4)(A) (other than for adjustments under this paragraph or paragraph (6)); and

(II) any transitional pass-through payment under paragraph (6); and

(ii) at the option of the Secretary, such fixed dollar amount as the Secretary may establish.

(B) Amount of adjustment

The amount of the additional payment under subparagraph (A) shall be determined by the Secretary and shall approximate the marginal cost of care beyond the applicable cutoff point under such subparagraph.

(C) Limit on aggregate outlier adjustments

(i) In general

The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) Applicable percentage

For purposes of clause (i), the term “applicable percentage” means a percentage specified by the Secretary up to (but not to exceed)—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, 3.0 percent.

(D) Transitional authority

In applying subparagraph (A) for covered OPD services furnished before January 1, 2002, the Secretary may—
(i) apply such subparagraph to a bill for such services related to an outpatient encounter (rather than for a specific service or group of services) using OPP fee schedule amounts and transitional pass-through payments covered under the bill; and
(ii) use an appropriate cost-to-charge ratio for the hospital involved (as determined by the Secretary), rather than for specific departments within the hospital.

(E) Exclusion of separate drug and biological APCS from outlier payments

No additional payment shall be made under subparagraph (A) in the case of ambulatory payment classification groups established separately for drugs or biologicals.

(6) Transitional pass-through for additional costs of innovative medical devices, drugs, and biologicals

(A) In general

The Secretary shall provide for an additional payment under this paragraph for any of the following that are provided as part of a covered OPD service (or group of services):

(i) Current orphan drugs

A drug or biological that is used for a rare disease or condition with respect to which the drug or biological has been designated as an orphan drug under section 360bb of title 21 if payment for the drug or biological as an outpatient hospital service under this part was being made on the first date that the system under this subsection is implemented.

(ii) Current cancer therapy drugs and biologicals and brachytherapy

A drug or biological that is used in cancer therapy, including (but not limited to) a chemotherapeutic agent, an antiemetic, a hematopoietic growth factor, a colony stimulating factor, a biological response modifier, a bisphosphonate, and a device of brachytherapy or temperature monitored cryoablation, if payment for such drug, biological, or device as an outpatient hospital service under this part was being made on such first date.

(iii) Current radiopharmaceutical drugs and biological products

A radiopharmaceutical drug or biological product used in diagnostic, monitoring, and therapeutic nuclear medicine procedures if payment for the drug or biological as an outpatient hospital service under this part was being made on such first date.

(iv) New medical devices, drugs, and biologicals

A medical device, drug, or biological not described in clause (i), (ii), or (iii) if—
(I) payment for the device, drug, or biological as an outpatient hospital service under this part was not being made as of December 31, 1996; and
(II) the cost of the drug or biological or the average cost of the category of devices is not insignificant in relation to the OPD fee schedule amount (as calculated under paragraph (3)(D)) payable for the service (or group of services) involved.

(B) Use of categories in determining eligibility of a device for pass-through payments

The following provisions apply for purposes of determining whether a medical device qualifies for additional payments under clause (ii) or (iv) of subparagraph (A):

(i) Establishment of initial categories

(I) In general

The Secretary shall initially establish under this clause categories of medical devices based on type of device by April 1, 2001. Such categories shall be established in a manner such that each medical device that meets the requirements of clause (ii) or (iv) of subparagraph (A) as of January 1, 2001, is included in such a category and no such device is included in more than one category. For purposes of the preceding sentence, whether a medical device meets such requirements as of such date shall be determined on the basis of the program memoranda issued before such date.

(II) Authorization of implementation other than through regulations

The Secretary may be established under this clause by program memorandum or otherwise, after consultation with groups representing hospitals, manufacturers of medical devices, and other affected parties.

(ii) Establishing criteria for additional categories

(I) In general

The Secretary shall establish criteria that will be used for creation of additional categories (other than those established under clause (i)) through rule-making (which may include use of an interim final rule with comment period).

(II) Standard

Such categories shall be established under this clause in a manner such that no medical device is described by more than one category. Such criteria shall include a test of whether the average cost of devices that would be included in a category and are in use at the time the category is established is not insignificant, as described in subparagraph (A)(iv)(II).

(III) Deadline

Criteria shall first be established under this clause by July 1, 2001. The Secretary may establish in compelling circumstances categories under this clause before the date such criteria are established.

(IV) Adding categories

The Secretary shall promptly establish a new category of medical devices under
this clause for any medical device that meets the requirements of subparagraph (A)(iv) and for which none of the categories in effect (or that were previously in effect) is appropriate.

(iii) Period for which category is in effect

A category of medical devices established under clause (i) or (ii) shall be in effect for a period of at least 2 years, but not more than 3 years, that begins—

(I) in the case of a category established under clause (i), on the first date on which payment was made under this paragraph for any device described by such category (including payments made during the period before April 1, 2001); and

(II) in the case of any other category, on the first date on which payment is made under this paragraph for any medical device that is described by such category.

(iv) Requirements treated as met

A medical device shall be treated as meeting the requirement of subparagraph (A)(iv), regardless of whether the device meets the requirement of subclause (I) of such subparagraph, if—

(I) the device is described by a category established and in effect under clause (i); or

(II) the device is described by a category established and in effect under clause (ii) and an application under section 360e of title 21 has been approved with respect to the device, or the device has been cleared for market under section 360(k) of title 21, or the device is exempt from the requirements of section 360(k) of title 21 pursuant to subsection (l) or (m) of section 360 of title 21.

Nothing in this clause shall be construed as requiring an application or prior approval (other than that described in subclause (I)) in order for a covered device described by a category to qualify for payment under this paragraph.

(C) Limited period of payment

(i) Drugs and biologicals

The payment under this paragraph with respect to a drug or biological shall only apply during a period of at least 2 years, but not more than 3 years, that begins—

(I) on the first date this subsection is implemented in the case of a drug or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug or biological described in subparagraph (A)(iv) and for which payment under this part is made as an outpatient hospital service before such first date; or

(II) in the case of a drug or biological described in subparagraph (A)(iv) not described in subclause (I), on the first date on which payment is made under this part for the drug or biological as an outpatient hospital service.

(ii) Medical devices

Payment shall be made under this paragraph with respect to a medical device only if such device—

(I) is described by a category of medical devices established and in effect under subparagraph (B); and

(II) is provided as part of a service (or group of services) paid for under this subsection and provided during the period for which such category is in effect under such subparagraph.

(D) Amount of additional payment

Subject to subparagraph (E)(iii), the amount of the payment under this paragraph with respect to a device, drug, or biological provided as part of a covered OPD service is—

(i) in the case of a drug or biological, the amount by which the amount determined under section 1395u(o) of this title (or if the drug or biological is covered under a competitive acquisition contract under section 1395w–3b of this title, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary for purposes of this paragraph) for the drug or biological exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the drug or biological; or

(ii) in the case of a medical device, the amount by which the hospital’s charges for the device, adjusted to cost, exceeds the portion of the otherwise applicable medicare OPD fee schedule that the Secretary determines is associated with the device.

(E) Limit on aggregate annual adjustment

(i) In general

The total of the additional payments made under this paragraph for covered OPD services furnished in a year (as estimated by the Secretary before the beginning of the year) may not exceed the applicable percentage (specified in clause (ii)) of the total program payments estimated to be made under this subsection for all covered OPD services furnished in that year. If this paragraph is first applied to less than a full year, the previous sentence shall apply only to the portion of such year.

(ii) Applicable percentage

For purposes of clause (i), the term “applicable percentage” means—

(I) for a year (or portion of a year) before 2004, 2.5 percent; and

(II) for 2004 and thereafter, a percentage specified by the Secretary up to (but not to exceed) 2.0 percent.

(iii) Uniform prospective reduction if aggregate limit projected to be exceeded

If the Secretary estimates before the beginning of a year that the amount of the additional payments under this paragraph
for the year (or portion thereof) as determined under clause (i) without regard to this clause will exceed the limit established under such clause, the Secretary shall reduce pro rata the amount of each of the additional payments under this paragraph for that year (or portion thereof) in order to ensure that the aggregate additional payments under this paragraph (as so estimated) do not exceed such limit.

(F) Limitation of application of functional equivalence standard

(i) In general

The Secretary may not publish regulations that apply a functional equivalence standard to a drug or biological under this paragraph.

(ii) Application

Clause (i) shall apply to the application of a functional equivalence standard to a drug or biological on or after December 8, 2003, unless:

(I) such application was being made to such drug or biological prior to December 8, 2003; and

(II) the Secretary applies such standard to such drug or biological only for the purpose of determining eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this subchapter.

(iii) Rule of construction

Nothing in this subparagraph shall be construed to effect the Secretary's authority to deem a particular drug to be identical to another drug if the 2 products are pharmaceutically equivalent and bioequivalent, as determined by the Commissioner of Food and Drugs.

(7) Transitional adjustment to limit decline in payment

(A) Before 2002

Subject to subparagraph (D), for covered OPD services furnished before January 1, 2002, for which the PPS amount (as defined in subparagraph (F)), the amount of payment under this subsection shall be increased by 80 percent of the amount of such difference; or

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 21 percent of the pre-BBA amount.

(B) 2002

Subject to subparagraph (D), for covered OPD services furnished during 2002, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 70 percent of the amount of such difference; or

(ii) at least 80 percent, but less than 90 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount by which (I) the product of 0.61 and the pre-BBA amount, exceeds (II) the product of 0.60 and the PPS amount; or

(iii) less than 80 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 13 percent of the pre-BBA amount.

(C) 2003

Subject to subparagraph (D), for covered OPD services furnished during 2003, for which the PPS amount is—

(i) at least 90 percent, but less than 100 percent, of the pre-BBA amount, the amount of payment under this subsection shall be increased by 60 percent of the amount of such difference; or

(ii) less than 90 percent of the pre-BBA amount, the amount of payment under this subsection shall be increased by 6 percent of the pre-BBA amount.

(D) Hold harmless provisions

(i) Temporary treatment for certain rural hospitals

(I) In the case of a hospital located in a rural area and that has not more than 100 beds or a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title) located in a rural area, for covered OPD services furnished before January 1, 2006, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(II) In the case of a hospital located in a rural area and that has not more than 100 beds and that is not a sole community hospital (as defined in section 1395ww(d)(5)(D)(iii) of this title), for covered OPD services furnished on or after January 1, 2006, and before January 1, 2012, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the applicable percentage of the amount of such difference. For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to such services furnished in 2008, 2009, 2010, or 2011.

(III) In the case of a sole community hospital (as defined in section
§ 1395w(d)(5)(D)(iii) of this title that has not more than 100 beds, for covered OPD services furnished on or after January 1, 2009, and before January 1, 2012, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by 85 percent of the amount of such difference. In the case of covered OPD services furnished on or after January 1, 2010, and before January 1, 2012, the preceding sentence shall be applied without regard to the 100-bed limitation.

(ii) Permanent treatment for cancer hospitals and children's hospitals

In the case of a hospital described in clause (iii) or (v) of section 1395ww(d)(1)(B) of this title, for covered OPD services for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the amount of such difference.

(E) PPS amount defined

In this paragraph, the term “PPS amount” means, with respect to covered OPD services, the amount payable under this subsection for such services (determined without regard to this paragraph), including amounts payable as copayment under paragraph (8), coinsurance under section 1395cc(a)(2)(A)(ii) of this title, and the deductible under subsection (b) of this section.

(F) Pre-BBA amount defined

(i) In general

In this paragraph, the “pre-BBA amount” means, with respect to covered OPD services furnished by a hospital in a year, an amount equal to the product of the reasonable cost of the hospital for such services for the portions of the hospital’s cost reporting period (or periods) occurring in the year and the base OPD payment-to-cost ratio for the hospital (as defined in clause (ii)).

(ii) Base payment-to-cost ratio defined

For purposes of this subparagraph, the “base payment-to-cost ratio” for a hospital means the ratio of—

(I) the hospital’s reimbursement under this part for covered OPD services furnished during the cost reporting period ending in 1996 (or in the case of a hospital that did not submit a cost report for such period, during the first subsequent cost reporting period ending before 2001 for which the hospital submitted a cost report), including any reimbursement for such services through cost-sharing described in subparagraph (E), and

(II) the reasonable cost of such services for such period.

The Secretary shall determine such ratios as if the amendments made by section 4521 of the Balanced Budget Act of 1997 were in effect in 1996.

(G) Interim payments

The Secretary shall make payments under this paragraph to hospitals on an interim basis, subject to retrospective adjustments based on settled cost reports.

(H) No effect on copayments

Nothing in this paragraph shall be construed to affect the unadjusted copayment amount described in paragraph (3)(B) or the copayment amount under paragraph (8).

(I) Application without regard to budget neutrality

The additional payments made under this paragraph—

(i) shall not be considered an adjustment under paragraph (2)(E); and

(ii) shall not be implemented in a budget neutral manner.

(8) Copayment amount

(A) In general

Except as provided in subparagraphs (B) and (C), the copayment amount under this subsection is the amount by which the amount described in paragraph (4)(B) exceeds the amount of payment determined under paragraph (4)(C).

(B) Election to offer reduced copayment amount

The Secretary shall establish a procedure under which a hospital, before the beginning of a year (beginning with 1999), may elect to reduce the copayment amount otherwise established under subparagraph (A) for some or all covered OPD services to an amount that is not less than 20 percent of the Medicare OPD fee schedule amount (computed under paragraph (3)(D)) for the service involved. Under such procedures, such reduced copayment amount may not be further reduced or increased during the year involved and the hospital may disseminate information on the reduction of copayment amount effected under this subparagraph.

(C) Limitation on copayment amount

(i) To inpatient hospital deductible amount

In no case shall the copayment amount for a procedure performed in a year exceed the amount of the inpatient hospital deductible established under section 1395e(b) of this title for that year.

(ii) To specified percentage

The Secretary shall reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed the following percentage:

(I) For procedures performed in 2001, on or after April 1, 2001, 57 percent.

(II) For procedures performed in 2002 or 2003, 55 percent.

(III) For procedures performed in 2004, 50 percent.

(IV) For procedures performed in 2005, 45 percent.

(V) For procedures performed in 2006 and thereafter, 40 percent.
(D) No impact on deductibles

Nothing in this paragraph shall be construed as affecting a hospital’s authority to waive the charging of a deductible under subsection (b) of this section.

(E) Computation ignoring outlier and pass-through adjustments

The copayment amount shall be computed under subparagraph (A) as if the adjustments made under paragraphs (5) and (6) and any adjustment made under paragraph (2)(E) in relation to such adjustments had not occurred.

(9) Periodic review and adjustments components of prospective payment system

(A) Periodic review

The Secretary shall review not less often than annually and revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. The Secretary shall consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the groups and weights. Such panel may use data collected or developed by entities and organizations (other than the Department of Health and Human Services) in conducting such review.

(B) Budget neutrality adjustment

If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made. In determining adjustments under the preceding sentence for 2004 and 2005, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.

(3) Authorization of adjustment for rural hospitals

(A) Study

The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas.

(B) Authorization of adjustment

Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals located in rural areas exceed those costs incurred by hospitals located in urban areas, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs by January 1, 2006.

(14) Drug APC payment rates

(A) In general

The amount of payment under this subsection for a specified covered outpatient drug (defined in subparagraph (B)) that is furnished as part of a covered OPD service (or group of services)—

(i) in 2004, in the case of—

(I) a sole source drug shall in no case be less than 88 percent, or exceed 95 percent, of the reference average wholesale price for the drug;
(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug;

(ii) in 2005, in the case of—

(I) a sole source drug shall in no case be less than 83 percent, or exceed 95 percent, of the reference average wholesale price for the drug;

(II) an innovator multiple source drug shall in no case exceed 68 percent of the reference average wholesale price for the drug; or

(III) a noninnovator multiple source drug shall in no case exceed 46 percent of the reference average wholesale price for the drug; or

(iii) in a subsequent year, shall be equal, subject to subparagraph (E)—

(I) to the average acquisition cost for the drug for that year (which, at the option of the Secretary, may vary by hospital group (as defined by the Secretary based on hospital volume of covered OPD services or other relevant characteristics)), as determined by the Secretary taking into account the hospital acquisition cost survey data under subparagraph (D); or

(II) if hospital acquisition cost data are not available, the average price for the drug in the year established under section 1395u(o) of this title, section 1395w–3a of this title, or section 1395w–3b of this title, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of this paragraph.

(B) Specified covered outpatient drug defined

(i) In general

In this paragraph, the term ‘specified covered outpatient drug’ means, subject to clause (ii), a covered outpatient drug (as defined in section 1395w–3b of this title) to which a separate ambulatory payment classification group (APC) has been established and that is—

(I) an innovator multiple source drug; or

(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

(ii) Exception

Such term does not include—

(I) a drug or biological for which payment is first made on or after January 1, 2003, under paragraph (6);

(II) a drug or biological for which a temporary HCPCS code has not been assigned; or

(III) during 2004 and 2005, an orphan drug (as designated by the Secretary).

(C) Payment for designated orphan drugs during 2004 and 2005

The amount of payment under this subsection for an orphan drug designated by the Secretary under subparagraph (B)(ii)(III) that is furnished as part of a covered OPD service (or group of services) during 2004 and 2005 shall equal such amount as the Secretary may specify.

(D) Acquisition cost survey for hospital outpatient drugs

(i) Annual GAO surveys in 2004 and 2005

(I) In general

The Comptroller General of the United States shall conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each specified covered outpatient drug. Not later than April 1, 2005, the Comptroller General shall furnish data from such surveys to the Secretary for use in setting the payment rates under subparagraph (A) for 2006.

(II) Recommendations

Upon the completion of such surveys, the Comptroller General shall recommend to the Secretary the frequency and methodology of subsequent surveys to be conducted by the Secretary under clause (II).

(ii) Subsequent secretarial surveys

The Secretary, taking into account such recommendations, shall conduct periodic subsequent surveys to determine the hospital acquisition cost for each specified covered outpatient drug for use in setting the payment rates under subparagraph (A).

(iii) Survey requirements

The surveys conducted under clauses (i) and (ii) shall have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. With respect to the surveys conducted under clause (i), the Comptroller General shall report to Congress on the justification for the size of the sample used in order to assure the validity of such estimates.

(iv) Differentiation in cost

In conducting surveys under clause (i), the Comptroller General shall determine and report to Congress if there is (and the extent of any) variation in hospital acquisition costs for drugs among hospitals based on the volume of covered OPD services performed by such hospitals or other relevant characteristics of such hospitals (as defined by the Comptroller General).

(v) Comment on proposed rates

Not later than 30 days after the date the Secretary promulgated proposed rules setting forth the payment rates under subparagraph (A) for 2006, the Comptroller General shall evaluate such proposed rates and submit to Congress a report regarding the appropriateness of such rates based on the surveys the Comptroller General has conducted under clause (I).
(E) Adjustment in payment rates for overhead costs

(i) MedPAC report on drug APC design

The Medicare Payment Advisory Commission shall submit to the Secretary, not later than July 1, 2005, a report on adjustment of payment for ambulatory payment classifications for specified covered outpatient drugs to take into account overhead and related expenses, such as pharmacy services and handling costs. Such report shall include—

(I) a description and analysis of the data available with regard to such expenses;

(II) a recommendation as to whether such a payment adjustment should be made; and

(III) if such adjustment should be made, a recommendation regarding the methodology for making such an adjustment.

(ii) Adjustment authorized

The Secretary may adjust the weights for ambulatory payment classifications for specified covered outpatient drugs to take into account the recommendations contained in the report submitted under clause (i).

(F) Classes of drugs

For purposes of this paragraph:

(i) Sole source drugs

The term “sole source drug” means—

(I) a biological product (as defined under section 1395x(b)(1) of this title); or

(II) a single source drug (as defined in section 1396r–8(k)(7)(A)(ii) of this title).

(ii) Innovator multiple source drugs

The term “innovator multiple source drug” has the meaning given such term in section 1396r–8(k)(7)(A)(i) of this title.

(iii) Noninnovator multiple source drugs

The term “noninnovator multiple source drug” has the meaning given such term in section 1396r–8(k)(7)(A)(ii) of this title.

(G) Reference average wholesale price

The term “reference average wholesale price” means, with respect to a specified covered outpatient drug, the average wholesale price for the drug as determined under section 1395u(a) of this title as of May 1, 2003.

(H) Inapplicability of expenditures in determining conversion, weighting, and other adjustment factors

Additional expenditures resulting from this paragraph shall not be taken into account in determining the conversion, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9), but shall be taken into account for subsequent years.

(15) Payment for new drugs and biologicals until HCPCS code assigned

With respect to payment under this part for an outpatient drug or biological that is covered under this part and is furnished as part of covered OPD services for which a HCPCS code has not been assigned, the amount provided for payment for such drug or biological under this part shall be equal to 95 percent of the average wholesale price for the drug or biological.

(16) Miscellaneous provisions

(A) Application of reclassification of certain hospitals

If a hospital is being treated as being located in a rural area under section 1395ww(d)(8)(E) of this title, that hospital shall be treated under this subsection as being located in that rural area.

(B) Threshold for establishment of separate APCS for drugs

The Secretary shall reduce the threshold for the establishment of separate ambulatory payment classification groups (APCs) with respect to drugs or biologicals to $50 per administration for drugs and biologicals furnished in 2005 and 2006.

(C) Payment for devices of brachytherapy and therapeutic radiopharmaceuticals at charges adjusted to cost

Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before January 1, 2010, and for therapeutic radiopharmaceuticals furnished on or after January 1, 2008, the payment basis for the device or therapeutic radiopharmaceutical under this subsection shall be equal to the hospital’s charges for each device or therapeutic radiopharmaceutical furnished, adjusted to cost. Charges for such devices or therapeutic radiopharmaceuticals shall not be included in determining any outlier payment under this subsection.

(17) Quality reporting

(A) Reduction in update for failure to report

(i) In general

For purposes of paragraph (3)(C)(iv) for 2009 and each subsequent year, in the case of a subsection (d) hospital (as defined in section 1395ww(d)(1)(B) of this title) that does not submit, to the Secretary in accordance with this paragraph, data required to be submitted on measures selected under this paragraph with respect to such a year, the OPD fee schedule increase factor for such year shall be reduced by 2.0 percentage points.

(ii) Non-cumulative application

A reduction under this subparagraph shall apply only with respect to the year involved and the Secretary shall not take into account such reduction in computing the OPD fee schedule increase factor for a subsequent year.

(B) Form and manner of submission

Each subsection (d) hospital shall submit data on measures selected under this para-
graph to the Secretary in a form and manner, and at a time, specified by the Secretary for purposes of this paragraph.

(C) Development of outpatient measures
   (i) In general
   The Secretary shall develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and 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.

   (ii) Construction
   Nothing in this paragraph shall be construed as preventing the Secretary from selecting measures that are the same as (or a subset of) the measures for which data are required to be submitted under section 1395ww(b)(3)(B)(vii) of this title.

(D) Replacement of measures
   For purposes of this paragraph, 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.

(E) Availability of data
   The Secretary shall establish procedures for making data submitted under this paragraph 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 outpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(18) Authorization of adjustment for cancer hospitals
   (A) Study
   The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals described in section 1395ww(d)(1)(B)(v) of this title with respect to ambulatory payment classification groups exceed those costs incurred by other hospitals furnishing services under this subsection, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.

   (B) Limitation
   Subject to subparagraph (B), with respect to covered OPD services furnished on or after January 1, 2011, the area wage adjustment factor applicable under the payment system established under this subsection to any hospital outpatient department which is located in a frontier State (as defined in section 1395ww(d)(3)(E)(ii) of this title) may not be less than 1.00. The preceding sentence shall not be applied in a budget neutral manner.

   (C) Development of outpatient measures
   (i) In general
   The Secretary shall develop measures that the Secretary determines to be appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings and 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.

   (ii) Construction
   Nothing in this paragraph shall be construed as preventing the Secretary from selecting measures that are the same as (or a subset of) the measures for which data are required to be submitted under section 1395ww(b)(3)(B)(vii) of this title.

(D) Replacement of measures
   For purposes of this paragraph, 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.

(E) Availability of data
   The Secretary shall establish procedures for making data submitted under this paragraph 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 outpatient settings in hospitals on the Internet website of the Centers for Medicare & Medicaid Services.

(19) Floor on area wage adjustment factor for hospital outpatient department services in frontier States
   (A) In general
   Subject to subparagraph (B), with respect to covered OPD services furnished on or after January 1, 2011, the area wage adjustment factor applicable under the payment system established under this subsection to any hospital outpatient department which is located in a frontier State (as defined in section 1395ww(d)(3)(E)(ii) of this title) may not be less than 1.00. The preceding sentence shall not be applied in a budget neutral manner.

   (B) Limitation
   This paragraph shall not apply to any hospital outpatient department located in a State that receives a non-labor related share adjustment under section 1395ww(d)(5)(H) of this title.

   (u) Incentive payments for physician scarcity areas
   (1) In general
   In the case of physicians’ services furnished on or after January 1, 2005, and before July 1, 2006—
      (A) by a primary care physician in a primary care scarcity county (identified under paragraph (4)); or
      (B) by a physician who is not a primary care physician in a specialist care scarcity county (as so identified),

   in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid an amount equal to 5 percent of the payment amount for the service under this part.

   (2) Determination of ratios of physicians to medicare beneficiaries in area
   Based upon available data, the Secretary shall establish for each county or equivalent area in the United States, the following:

      (A) Number of physicians practicing in the area
      The number of physicians who furnish physicians’ services in the active practice of medicine or osteopathy in that county or area, other than physicians whose practice is exclusively for the Federal Government, physicians who are retired, or physicians who only provide administrative services. Of such number, the number of such physicians who are—
         (i) primary care physicians; or
         (ii) physicians who are not primary care physicians.

      (B) Number of medicare beneficiaries residing in the area
      The number of individuals who are residing in the county and are entitled to benefits
under part A of this subchapter or enrolled under this part, or both (in this subsection referred to as “individuals”).

(C) Determination of ratios

(i) Primary care ratio

The ratio (in this paragraph referred to as the “primary care ratio”) of the number of primary care physicians (determined under subparagraph (A)(i)), to the number of individuals determined under subparagraph (B).

(ii) Specialist care ratio

The ratio (in this paragraph referred to as the “specialist care ratio”) of the number of other physicians (determined under subparagraph (A)(ii)), to the number of individuals determined under subparagraph (B).

(3) Ranking of counties

The Secretary shall rank each such county or area based separately on its primary care ratio and its specialist care ratio.

(4) Identification of counties

(A) In general

The Secretary shall identify—

(i) those counties and areas (in this paragraph referred to as “primary care scarcity counties”) with the lowest primary care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph; and

(ii) those counties and areas (in this subsection referred to as “specialist care scarcity counties”) with the lowest specialist care ratios that represent, if each such county or area were weighted by the number of individuals determined under paragraph (2)(B), an aggregate total of 20 percent of the total of the individuals determined under such paragraph.

(B) Periodic revisions

The Secretary shall periodically revise the counties or areas identified in subparagraph (A) (but not less often than once every three years) unless the Secretary determines that there is no new data available on the number of physicians practicing in the county or area or the number of individuals residing in the county or area, as identified in paragraph (2).

(C) Identification of counties where service is furnished

For purposes of paying the additional amount specified in paragraph (1), if the Secretary uses the 5-digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code (as determined by the United States Postal Service, or otherwise) shall be used to determine whether the postal ZIP Code is in a scarcity county identified in subparagraph (A) or revised in subparagraph (B).

(D) Special rule

With respect to physicians’ services furnished on or after January 1, 2008, and before July 1, 2008, for purposes of this subsection, the Secretary shall use the primary care scarcity counties and the specialty care scarcity counties (as identified under the preceding provisions of this paragraph) that the Secretary was using under this subsection with respect to physicians’ services furnished on December 31, 2007.

(E) Judicial review

There shall be no administrative or judicial review under section 1395ff, 1395oo of this title, or otherwise, respecting—

(i) the identification of a county or area;

(ii) the assignment of a specialty of any physician under this paragraph;

(iii) the assignment of a physician to a county under paragraph (2); or

(iv) the assignment of a postal ZIP Code to a county or other area under this subsection.

(5) Rural census tracts

To the extent feasible, the Secretary shall treat 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)), as an equivalent area for purposes of qualifying as a primary care scarcity county or specialist care scarcity county under this subsection.

(6) Physician defined

For purposes of this paragraph, the term “physician” means a physician described in section 1395x(r)(1) of this title and the term “primary care physician” means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

(7) Publication of list of counties; posting on website

With respect to a year for which a county or area is identified or revised under paragraph (4), the Secretary shall identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1395w–4 of this title for the applicable year. The Secretary shall post the list of counties identified or revised under paragraph (4) on the Internet website of the Centers for Medicare & Medicaid Services.

(v) Increase of FQHC payment limits

In the case of services furnished by Federally qualified health centers (as defined in section 1395x(aa)(4) of this title), the Secretary shall establish payment limits with respect to such services under this part for services furnished—

(1) in 2010, at the limits otherwise established under this part for such year increased by $5; and

(2) in a subsequent year, at the limits established under this subsection for the previous year increased by the percentage increase in the MEI (as defined in section 1395u(1)(3) of this title) for such subsequent year.

(w) Methods of payment

The Secretary may develop alternative methods of payment for items and services provided
under clinical trials and comparative effectiveness studies sponsored or supported by an agency of the Department of Health and Human Services, as determined by the Secretary, to those that would otherwise apply under this section, to the extent such alternative methods are necessary to preserve the scientific validity of such trials or studies, such as in the case where masking the identity of interventions from patients and investigators is necessary to comply with the particular trial or study design.

(x) Incentive payments for primary care services

(1) In general
In the case of primary care services furnished on or after January 1, 2011, and before January 1, 2016, by a primary care practitioner, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) Definitions
In this subsection:

(A) Primary care practitioner
The term "primary care practitioner" means an individual—
(i) who—
(I) is a physician (as described in section 1395x(r)(1) of this title) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or
(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1395x(aa)(5) of this title); and
(ii) for whom primary care services accounted for at least 60 percent of the allowed charges under this part for such physician or practitioner in a prior period as determined appropriate by the Secretary.

(B) Primary care services
The term "primary care services" means services identified, as of January 1, 2009, by the following HCPCS codes (and as subsequently modified by the Secretary):
(i) 99201 through 99215.
(ii) 99304 through 99340.
(iii) 99341 through 99350.

(3) Coordination with other payments
The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively.

(4) Limitation on review
There shall be no administrative or judicial review under section 1395ff of this title, 1395oo of this title, or otherwise, respecting the identification of primary care practitioners under this subsection.

(y) Incentive payments for major surgical procedures furnished in health professional shortage areas

(1) In general
In the case of major surgical procedures furnished on or after January 1, 2011, and before January 1, 2016, by a general surgeon in an area that is designated (under section 254e(a)(1)(A) of this title) as a health professional shortage area as identified by the Secretary prior to the beginning of the year involved, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

(2) Definitions
In this subsection:

(A) General surgeon
In this subsection, the term “general surgeon” means a physician (as described in section 1395x(r)(1) of this title) who has designated CMS specialty code 02–General Surgery as their primary specialty code in the physician’s enrollment under section 1395ccc(j) of this title.

(B) Major surgical procedures
The term “major surgical procedures” means physicians’ services which are surgical procedures for which a 10-day or 90-day global period is used for payment under the fee schedule under section 1395w–4(b) of this title.

(3) Coordination with other payments
The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively.

(4) Application
The provisions of paragraph (2) and (4) of subsection (m) shall apply to the determination of additional payments under this subsection in the same manner as such provisions apply to the determination of additional payments under subsection (m).

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Subsec. (a)(1)(N). Pub. L. 111-148, § 4104(b)(2), as amended by Pub. L. 111-148, § 10406, inserted “(if such subparagraph were applied, by substituting ‘100 percent’ for ‘80 percent’)” after “paragraph (D)” in cl. (I) and substituted “100 percent” for “80 percent” in cl. (I).


Subsec. (a)(3)(B)(i). Pub. L. 111-148, § 10501(i)(3)(B), inserted subcl. (I) designation after “otherwise been provided” and “or” in the case of such services furnished on or after the implementation date of the prospective payment system under section 13955(m) of this title, under such section (calculated as if 100 percent were substituted for 80 percent in such section) for such services if the individual had not been so enrolled “after been so enrolled”.

Subsec. (b). Pub. L. 111-148, § 4109(c)(2), inserted at end “Paragraph (1) of the first sentence of this subsection shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment as a result of the test, or the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test”.

Subsec. (b)(1). Pub. L. 111-148, § 4103(c)(1), substituted “preventive services described in subparagraph (A) of section 1395x(ddd)(3) of this title that are recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population and are appropriate for the individual” for “items and services described in section 1395x(s)(10)(A) of this title”.


Subsec. (g)(5). Pub. L. 111-309, § 104, substituted “and ending on December 31, 2011” for “and ending on March 31, 2010”.

Pub. L. 111-148, § 3103, which directed substitution of “December 31, 2009” for “December 31, 2008” could not be executed because “December 31, 2009” did not appear in the preceding sentence, was executed by striking out “December 31, 2009” from the following: “subject to clause (iv)” in the case of such services furnished on or after March 31, 2010, and before January 1, 2011, the preceding sentence shall be applied without regard to the 100-bed limitation.”

Subsec. (h)(2)(A)(i). Pub. L. 111-148, § 3401(i)(1), inserted “subject to clause (iv)” after “after year” in cl. (i) and substituted “and 2010” after “through 2013”.


Subsec. (t)(1)(D)(v). Pub. L. 111-148, § 10406, struck out “or” after “diagnostic mammography,” and inserted “—inserted with a grade of A or B by the United States Preventive Services Task Force for any indication or population” after “1395x(hhh)(1) of this title)”.

Pub. L. 111-148, § 4103(c)(3)(A), substituted “diagnostic mammography,” or personalized prevention plan services (as defined in section 1395x(hhh)(1) of this title)” for “and diagnostic mammography”.

Subsec. (t)(1)(D)(v). Pub. L. 111-148, § 10324(b)(1), substituted “subject to paragraph (19), the Secretary” for “the Secretary”.

Subsec. (t)(1)(C)(iv). Pub. L. 111-148, § 3401(i)(1), inserted “and subparagraph (F) of this paragraph” after “(17)”.


Subsec. (t)(3)(G). Pub. L. 111-152, § 1105(e)(1)(A), struck out cl. (l) designation and heading, redesignated subcls. (I) to (V) of former cl. (l) as clss. (i) to (v), respectively, and realigned margins.


Pub. L. 111-148, § 4103(g)(3), which directed addition of subicl. (II) “after subclause (II),” could not be executed, See Amendment note below.

Subsec. (t)(3)(G)(vii). Pub. L. 111-152, § 1105(e)(1), placed subcl. (II), which was directed to be inserted after subcl. (II) by Pub. L. 111-148, § 10501(g)(3), in immediately after subcl. (i) and struck out “and” at end. See Amendment note below.

Pub. L. 111-148, § 10319(g)(4), which read as follows: “subject to clause (ii), for each of 2014 through 2019, 0.2 percentage point,” added subcl. (II) and struck out former subcl. (II) which read as follows: “subject to clause (ii), for each of 2014 through 2019, 0.2 percentage point”.


Subsec. (t)(3)(G)(i)(IV), (V). Pub. L. 111-152, § 1105(e)(1), added subcls. (IV) and (V).

Subsec. (t)(3)(G)(ii). Pub. L. 111-152, § 1105(e)(2), struck out cl. (ii). Prior to amendment, text read as follows: “Clause (i)(II) shall be applied with respect to any of 2014 through 2019 by substituting ‘0.0 percentage points’ for ‘0.2 percentage point’, if for such year—

(1) the excess (if any) of—

(aa) the total percentage of the non-elderly insured population for the preceding 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 year (as estimated by the Secretary);

(2) 5 percentage points,” if for such year—

(1) the excess (if any) of—

(aa) the total percentage of the non-elderly insured population for the preceding 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 year (as estimated by the Secretary);

(2) 5 percentage points.”

Subsec. (t)(7)(D)(i)(II). Pub. L. 111-152, § 1105(e)(1), inserted at end “In the case of covered OPD services furnished on or after January 1, 2011, and before January 1, 2011, the preceding sentence shall be applied without regard to the 100-bed limitation.”

Pub. L. 111-148, § 3121(b), inserted at end in “In the case of covered OPD services furnished on or after January 1, 2010, and before January 1, 2011, the preceding sentence shall be applied without regard to the 100-bed limitation.”


Subsecs. (x), (y). Pub. L. 111-148, §§ 3501, 10324(b)(2), added subsec. (x) and (y).

2006—Subsec. (a)(1)(D)(iii). Pub. L. 110-275, § 1450(a)(2), before comma at end of subpar. (D), struck out cl. (iii), which read “on the basis of a rate established under a
demonstration project under section 1395w–3(e) of this title, the amount paid shall be equal to 100 percent of such rate.”
Subsec. (c). Pub. L. 110–275, §102, amended subsec. (c) generally. Prior to amendment, text read as follows: “Notwithstanding any other provision of this part, with respect to expenses incurred in any calendar year in connection with the treatment of mental, psycho-neurotic, and personality disorders of an individual who is not an inpatient of a hospital at the time such expenses are incurred, there shall be considered as incurred expenses for purposes of subsections (a) and (b) of this section only 62½ percent of such expenses. For purposes of the preceding sentence, the applicable percentage term ‘treatment’ does not include brief office visits (as defined by the Secretary) for the sole purpose of monitoring or changing drug prescriptions used in the treatment of such disorders or partial hospitalization services that are not directly provided by a physician.”
Subsec. (g)(1). Pub. L. 110–275, §148(b)(3), inserted “and speech-language pathology services of the type described in such section through the application of section 1395x(l)(2) of this title” and “and speech-language pathology services” after “physical therapy services”.
Subsec. (h)(2)(A). Pub. L. 110–275, §146(b), inserted “‘minus, for each of the years 2009 through 2013, 0.5 percentage points’ after ‘city average)’.
Subsec. (t)(7)(D)(ii). Pub. L. 110–275, §147(b)(1), substituted “‘For services furnished prior to the implementation of the system described in clause (i) of section 1395cc(a)(2)(A) of this title, less the amount a provider may charge as determined in regulations, in accordance with such procedures, as the Secretary may prescribe in regulations, in effect as of July 1, 2008’” after “‘and for stranded and non-stranded devices furnished on or after July 1, 2007’ before period at end.
Subsec. (a)(1)(S). Pub. L. 108–173, §642(b), inserted “(including intravenous immune globulin (as defined in section 1395x(22) of this title))” after “with respect to drugs and biologicals.”
Subsec. (t)(7)(D)(ii). Pub. L. 110–275, §147(b)(1), inserted “‘(including intravenous immune globulin (as defined in section 1395x(22) of this title)) after ‘with respect to drugs and biologicals’.”
Subsec. (t)(7)(D)(ii). Pub. L. 110–275, §147(b)(1), inserted “‘(including intravenous immune globulin (as defined in section 1395x(22) of this title)) after ‘with respect to drugs and biologicals’.”
Subsec. (a)(1)(S). Pub. L. 108–173, §642(b), inserted “(including intravenous immune globulin (as defined in section 1395x(22) of this title))” after “with respect to drugs and biologicals.”
Subsec. (a)(3). Pub. L. 108–173, §237(a), amended par. (3) generally. Prior to amendment, par. (3) read as follows: “in the case of services described in section 1395x(a)(2)(D) of this title, the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1395x(v)(1)(A) of this title, less the amount a provider may charge as described in clause (i) of section 1395cc(a)(2)(A) of this title, but in no case may the payment for such services (other than for items and services described in section 1395x(i)(10)(A) of this title) exceed 80 percent of such costs.”
Subsec. (b). Pub. L. 108–173, §629, substituted “$100 for 1991 through 2004, $110 for 2005, and for a subsequent year the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1395a(a)(1) of this title ending with such subsequent year (rounded to the nearest $1)” for “$100 for 1991 and subsequent years” before semicolon in first sentence.
Subsec. (i)(2)(A). Pub. L. 108–173, §626(b)(1)(A), substituted “For services furnished prior to the implementation of the system described in paragraph (D), the” for “The” in introductory provisions.
every 5 years thereafter,” before “of the actual audited costs”.


Subsec. (m). Pub. L. 108–173, §413(b)(1), designated existing provisions as par. (1), inserted “in a year” after “‘in the case of physicians’ services furnished” and “as determined by the Secretary prior to the beginning of such year” after “as a health professional shortage area”, and added pars. (2) to (4).

Subsec. (a)(1)(B). Pub. L. 108–173, §627(a)(1), substituted “no more than the amount of payment applicable under paragraph (2)” for “no more than the limits established under paragraph (2)”.


Subsec. (t)(1)(B)(iv). Pub. L. 108–173, §614(a), inserted before period at end “and does not include screening mammography (as defined in section 1395x(j)) of this title and diagnostic mammography”.

Subsec. (t)(2)(H). Pub. L. 108–173, §621(b)(2), which directed the amendment of par. (2) by adding a new subpar. (H) at the end, was executed by adding subpar. (H) after subpar. (G), to reflect the probable intent of Congress.


Subsec. (t)(6)(B). Pub. L. 108–173, §406(a), inserted “the case of a device, drug, or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug, biological, or device described in clause (i), (ii), or (iii) of subparagraph (A) or the second sentence of subparagraph (D) as calculated and adjusted by the Secretary for purposes of this part” before period at end “in introductory provisions”.


Subsec. (i)(2)(G). Pub. L. 108–173, §614(a), inserted before period at end “on an assignment-related basis”.


Subsec. (a)(3). Pub. L. 108–173, §614(a), inserted before period at end “and inserted before commencement of this subpart”.


Subsec. (t)(6)(A)(iv)(II). Pub. L. 108–173, §406(a), inserted “the case of a device, drug, or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug, biological, or device described in clause (i), (ii), or (iii) of subparagraph (A) or the second sentence of subparagraph (D)” before period at end “in introductory provisions”.

Subsec. (t)(6)(B). Pub. L. 108–173, §406(a), inserted “the case of a device, drug, or biological described in clause (i), (ii), or (iii) of subparagraph (A) and in the case of a drug, biological, or device described in clause (i), (ii), or (iii) of subparagraph (A) or the second sentence of subparagraph (D) as calculated and adjusted by the Secretary for purposes of this part” before period at end “in introductory provisions”.

Subsec. (a)(1)(R). Pub. L. 106–554, §1(a)(6) [title II, §201(b)(1)], struck out “or which are furnished on an outpatient basis by a critical access hospital” after “on an assignment-related basis”.

Subsec. (t)(14). Former par. (13) redesignated (16).

Subsec. (t)(4). Pub. L. 106–113, §1000(a)(6) [title II, §202(a)(1)], inserted “, subject to paragraph (7),” after “is determined” in introductory provisions.


clinic nurse specialists” for “nurse practitioner or clinical nurse specialist services”.

Pub. L. 105–33, §4511(b)(1), amended subpar. (O) generally. Prior to amendment, subpar. (O) read as follows: “with respect to services described in section 1395x(s)(2)(K)(iii) of this title (relating to practice nurse practitioner or clinical nurse specialist services provided in a rural area), the amounts paid shall be 80 percent of the lesser of the actual charge or the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount or the amounts paid under section 1395w–4 of this title) if the services had been performed by a physician (subject to the limitation described in subsection (r)(2) of this section),”.


Subsec. (a)(2)(A). Pub. L. 105–33, §4603(c)(2)(A)(I), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: “with respect to home health services (other than a covered osteoporosis drug (as defined in section 1395x(s)(3)(B) of this title) and to items and services described in section 1395x(s)(10)(A) of this title, the lesser of—

(i) the reasonable cost of such services, as determined under section 1395x(v) of this title, or

(ii) the customary charges with respect to such services, or, if such services are furnished by a public provider of services, by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this provision), free of charge or at nominal charges to the public, the amount determined in accordance with section 1395f(b)(2) of this title,”.

Subsec. (a)(2)(B). Pub. L. 105–33, §4432(b)(5)(C), inserted or “section 1395x(v) of this title” after “1395fw of this title”.


Pub. L. 105–33, §4511(b)(2), substituted “Subject to section 1395mi(d)(1) of this title, the Secretary” for “The Secretary”.

Pub. L. 105–33, §4523(d)(2)(B), substituted “critical access” for “rural primary care”.

Subsec. (i)(1)(A). Pub. L. 105–33, §4555, inserted at end “in each of the fiscal years 1998 through 2002, the increase under this subparagraph shall be reduced (but not below zero) by 2.0 percentage points”.


Subsec. (r)(1). Pub. L. 105–33, §4511(b)(1)(II), Pub. L. 105–33, §4521(a), struck out “of 80 percent” before “of the standard overhead amount” and inserted before period at end “, less the amount a provider may charge as described in clause (ii) of section 1395cc(a)(2)(A) of this title”.

Subsec. (r)(2). Pub. L. 105–33, §4511(b)(2)(B), (D), redesignated par. (3) as (2) and struck out former par. (2) which read as follows: “(2)(A) For purposes of subsection (a)(1)(O) of this section, the prevailing charge for services described in section 1395x(s)(2)(K)(ii) of this title may not exceed the applicable percentage (as defined in subsection (a)(8)(B) of this section) of the prevailing charge (or, for services furnished on or after January 1, 1992, the fee schedule amount).”
provided under section 1395w–4 of this title) determined for such services performed by physicians who are not specialists.

(8) In subparagraph (A), the term ‘applicable percentage’ means—

(i) 75 percent in the case of services performed in a hospital, and

(ii) 85 percent in the case of other services.”

Subsec. (c)(3). Pub. L. 105–33, § 4511(b)(2)(C), (D), redesignated par. (3) as (2) and substituted ‘‘section 1395x(s)(2)(K)(i)’’ for ‘‘section 1395x(s)(2)(K)(ii)’’ of this title’’.

Pub. L. 105–33, § 4201(c)(1), substituted ‘‘critical access’’ for ‘‘rural primary care’’.


1994—Subsec. (a)(1)(D)(i). Pub. L. 103–432, § 156(a)(2)(B)(i), struck out ‘‘, or for tests 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 ‘‘assignment-related basis’’.

Subsec. (a)(1)(G). Pub. L. 103–432, § 156(a)(2)(B)(ii), struck out subpar. (G) which read as follows: ‘‘with respect to items and services (other than clinical diagnostic laboratory tests) 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), the amounts paid shall be 100 percent of the reasonable charges for such items and services.’’

Subsec. (a)(2)(A). Pub. L. 103–432, § 156(a)(2)(B)(iii), struck out ‘‘, or to items and services (other than clinical diagnostic laboratory tests) 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),’’ before ‘‘and to items and services in introductory provisions.’’

Pub. L. 103–432, § 147(f)(6)(C)(i), substituted ‘‘health services (other than a covered osteoporosis drug (as defined in section 1395x(k)(1) of this title))’’ for ‘‘health services’’ in introductory provisions.

Subsec. (a)(2)(D)(i). Pub. L. 103–432, § 156(a)(2)(B)(iv), substituted ‘‘assignment-related basis or’’ for ‘‘assignment-related basis,’’ and struck out ‘‘, or for tests 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),’’ before ‘‘and to items and services’’ in introductory provisions.


Subsec. (a)(3). Pub. L. 103–432, § 156(a)(2)(B)(v), struck out ‘‘, or for 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 ‘‘assignment-related basis’’.

Subsec. (b)(2). Pub. L. 103–432, § 147(f)(6)(D), inserted ‘‘(other than a covered osteoporosis drug (as defined in section 1395x(k)(1) of this title))’’ after ‘‘assignment-related basis’’.

Subsec. (b)(4). Pub. L. 103–432, § 156(a)(2)(B)(vi), redesignated par. (5) as (4) and struck out former par. (4) which read as follows: ‘‘such deductible shall not apply 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).’’

Subsec. (h)(5)(D). Pub. L. 103–432, § 129(e), substituted ‘‘(B) In subparagraph (A), the term ‘applicable percentage’ means—’’ for ‘‘assignment-related basis or’’ in subparagraph (A), redesignated par. (3) as (2) and substituted ‘‘section 1395x(s)(2)(K)(i)’’ for ‘‘section 1395x(s)(2)(K)(ii)’’ of this title’’.

Pub. L. 103–432, § 141(a)(2)(A), struck out ‘‘, and may be adjusted by the Secretary, when appropriate,’’ after ‘‘annually thereafter’’ in last sentence.

Subsec. (i)(2)(A). Subsec. (i)(2)(A), struck out ‘‘and to items and services furnished in connection with obtaining a second opinion required under section 1395x(s)(10)(A) of this title’’.


Subsec. (i)(3)(B)(ii). Pub. L. 103–432, § 141(c)(1), in subcls. (I) and (II) substituted ‘‘for portions of cost reporting periods for ‘for reporting periods’’ and ‘‘and ending on or before December 31, 1990’’ for ‘‘and on or before December 31, 1990’’.

Subsec. (i)(5)(B), (C). Pub. L. 103–432, § 123(b)(2)(A)(i), redesignated subpar. (C) as (B) and struck out former subpar. (B) which read as follows: ‘‘(B)(i) Payment for the services of a certified registered nurse anesthetist under this part may be made only on an assignment-related basis, and any such assignment agreed to by a certified registered nurse anesthetist shall be binding upon any other person presenting a claim or request for payment for such services.’’

(ii) Except for deductible and coinsurance amounts applicable under this section, any person who knowingly and willfully presents, or causes to be presented, to an individual enrolled under this part a bill or request for payment for services of a certified registered nurse anesthetist for which payment may be made under this part only on an assignment-related basis is subject to a civil money penalty of not to exceed $2,000 for each such bill or request. 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.’’


Pub. L. 103–432, § 147(d)(1), inserted ‘‘and for services described in subsection (a)(2)(E)(ii) of this section furnished on or after January 1, 1992’’ after ‘‘January 1, 1989’’ and ‘‘(or, in the case of services furnished on or after January 1, 1992, under section 1395w–4 of this title)’’ before period at end.

Subsec. (p). Pub. L. 103–432, § 123(b)(2)(A)(ii), struck out subsec. (p) which read as follows: ‘‘(p) In the case of services for which payment may be made under this part only pursuant to section 1395x(s)(2)(L) of this title, in the case of qualified psychologists services for which payment may be made under this part only pursuant to section 1395x(s)(2)(M) of this title, and in the case of clinical social worker services for which payment may be made under this part only pursuant to section 1395x(s)(2)(N) of this title, payment may only be made under this part for such services on an assignment-related basis. Except for deductible and coinsurance amounts applicable under this section, whoever knowingly and willfully presents, or causes to be presented, to an individual enrolled under this part a bill or request for payment for services described in the previous sentence, is subject to a civil money penalty of not to exceed $2,000 for each such bill or request. 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.’’

Subsec. (q)(1). Pub. L. 103–432, § 147(a), substituted ‘‘unique physician identification number’’ for ‘‘provider number’’ and struck out ‘‘and indicate whether or not the referring physician is an interested investor (within the meaning of section 1395nn(h)(5) of this title)’’ after ‘‘for the referring physician’’.
other person presenting a claim or request for payment
clinical nurse specialist shall be binding upon any
such assignment agreed to by a nurse practitioner or
made only on an assignment-related basis, and any
applicable under this section, any person who know-
graph (A) is subject to a civil money penalty of not to
quest for payment for services described in section
1395x(s)(2)(K)(iii) of this title in violation of subpara-
alty under the previous sentence in the same manner as
section 1320a–7a(a) of this title.’’
Subsec. (a)(1)(O). Pub. L. 101–508, § 415(b)(2)(A), which directed amendment of subpar. (K) by striking “and” at the end, could not be executed because of prior amend-
Subsec. (b). Pub. L. 101–508, § 4092, inserted “for calendar years before 1991 and $100 for 1991 and subsequent years” after “$75”.
Subsec. (h)(5)(A)(i)(III). Pub. L. 101–508, § 4154(e)(1)(C), substituted “receives requests for testing during the year in which the test is performed” for “submits bills or requests for payment in any year”.
Pub. L. 101–508, § 4154(e)(1)(B), which directed substitution of “laboratory (but not including a laboratory described in clause (II))” for “laboratory,” was executed by making the substitution for “laboratory” the second time appearing to reflect the probable intent of Congress.
Subsec. (h)(5)(A)(i)(I). Pub. L. 101–508, § 4154(c)(1)(A), substituted “testing, including a test performed in a physician’s office but excluding a test performed by a rural health clinic” for “testing performed by a laboratory other than a rural health clinic”.
Subsec. (h)(5)(D). Pub. L. 101–508, § 4154(c)(1)(B), substituted “testing, including a test performed in a physician’s office but excluding a test performed by a rural health clinic” for “testing performed by a laboratory, other than a rural health clinic”.

Other than a rural health clinic”.

“the update determined under section 1395w–4(d)(3) of this title for physician anesthesia services for that year.”
1990—Subsec. (a)(1)(H). Pub. L. 101–508, § 4118(h)(2)(D), struck out “, as the case may be” after “section 1395w–4 of this title”.
Subsec. (a)(1)(J). Pub. L. 101–508, § 4104(b)(1), struck out “or physician pathology services” after “1395mb(6) of this title” and “and section 1395m(f) of this title, respectively” after “1395mb(6) of this title”.
Subsec. (a)(1)(K). Pub. L. 101–508, § 4155(b)(2)(A), which directed amendment of subpar. (K) by striking “and” at the end, could not be executed because of prior amend-
Subsec. (s). Pub. L. 103–432, § 160(d)(1), redesignated subsec. (r) relating to other prepaid organizations, as (s).
Subsec. (i)(1). Pub. L. 101–508, § 4160(1), designated existing provisions as subpar. (A) and added subpars. (B) and (C).

Subsec. (i)(2). Pub. L. 101–508, § 4160(2), struck out at end “The fee schedule shall be adjusted annually (to become effective on January 1 of each calendar year) by the percentage increase in the MEI (as defined in section 1395ui(3) of this title) for that year.”


“In establishing the fee schedule under paragraph (1), the Secretary may utilize a system of time units, a system of base and time units, or any appropriate methodology. The Secretary may establish a nationwide fee schedule or adjust the fee schedule for geographic areas (as the Secretary may determine to be appropriate).”

Subsec. (k)(2). Pub. L. 101–508, § 4160(4), substituted “health professional shortage area” for “health manpower shortage area”.

Subsec. (m)(1)(B)(i)(I). Pub. L. 101–508, § 4151(c)(2), in specified or repealed by such sections are restored or revived as if such section had not been enacted, see 1988 Amendment notes below.

Subsec. (m). Pub. L. 101–597 substituted “health professional provisions” for “whichever of the following amounts is the smaller: “(A) $1375.00, or “(B) 62 1/2 percent of such expenses.”


Subsec. (q). Pub. L. 101–239, § 6113(a)(1), substituted “the amounts” for “the same service per period.”

Subsec. (r). Pub. L. 101–239, § 6113(a)(1), substituted “and” for “or” in last sentence and added par. (6).

Subsec. (s). Pub. L. 101–239, § 6113(a)(1), substituted “section 1395m(f) of this title, respectively” for “section 1395m(f) of this title, respectively”, and added subcls. (I) through (III).


Subsec. (v). Pub. L. 101–239, § 6003(g)(3)(D)(vii)(IV), inserted “‘or’ or ‘or’ hospital services” after “facility services” in introductory provisions.


Subsec. (h)(3). Pub. L. 100–647, § 4021(a), inserted at end “In establishing a fee to cover the transportation and personnel expenses for trained personnel to travel to the location of an individual to collect a sample, the Secretary shall provide a method for computing the fee based on the number of miles traveled and the personnel costs associated with the collection of each individual sample, but the Secretary shall only be required to apply such method in the case of tests furnished during the period beginning on April 1, 1989, and ending on December 31, 1990, by a laboratory that establishes to the satisfaction of the Secretary (based on data for the 12-month period ending June 30, 1988) that (i) the laboratory is dependent upon payments under this subchapter for at least 80 percent of its collected revenues for clinical diagnostic laboratory tests, (ii) at least 85 percent of its gross revenues for such tests are attributable to tests performed with respect to individuals who are homebound or who are residents in a nursing facility, and (iii) the laboratory did not collect such tests for residents in nursing facilities representing at least 20 percent of the number of such facilities in the State in which the laboratory is located.”


Subsec. (h)(5)(D). Pub. L. 100–360, § 411(h)(4)(E), substituted “a person may not bill for a clinical diagnostic laboratory test performed by a laboratory, other than a rural health clinic, other than on an assignment-related basis. If a person knowingly and willfully and on a repeated basis bills for a clinical diagnostic laboratory test in violation of the previous sentence for “If a person knowingly and willfully and on a repeated basis bills an individual enrolled under this part for charges for a clinical diagnostic laboratory test for which payment may only be made on an assignment-related basis under subparagraph (C)” and “paragraphs (2) and (3) of section 1395u(j) of this title in the same manner such paragraphs apply with respect to a physician for “section 1395u(j)(2)” of this title.”

Subsec. (i)(2)(A)(i)(I). Pub. L. 100–360, § 411(g)(2)(D), substituted “insertion” for “implantation” and inserted “or subsequent to” after “during.”


Subsec. (k)(3)(B). Pub. L. 100–360, § 411(h)(4)(B), inserted “plus applicable coinsurance” after “would have been paid.”


Subsec. (n)(1)(A). Pub. L. 100–360, § 411(g)(4)(C)(I), as added by Pub. L. 100–485, § 4008(a)(1), substituted “for services described in subsection (a)(2)(E)(i) of this section furnished under this part on or after October 1, 1988, and for services described in subsection (a)(2)(E)(ii) of this section furnished under this part on or after October 1, 1988,” for “beginning on or after October 1, 1988 under this part for services described in subsection (a)(2)(E)(i) of this section furnished on or after January 1, 1989, the fee schedule amount established” after “the prevailing charge.”

Subsec. (n)(1)(B)(i). Pub. L. 100–360, § 411(g)(4)(C)(III), amended subcls. (I) and (II) generally. Prior to amendment, subcls. (I) and (II) read as follows: “(I) The term ‘cost proportion’ means 65 percent for all or any part of cost reporting periods which occur in fiscal year 1989 and 50 percent for other cost reporting periods.”

“(II) The term ‘charge proportion’ means 35 percent for all or any part of cost reporting periods which occur in fiscal year 1989 and 50 percent for other cost reporting periods.”


Subsec. (a)(1)(F). Pub. L. 100–203, § 4055(a)(1), formerly § 4055(a)(1), as added and renumbered by Pub. L. 100–360, § 411(f)(12)(A), (14), struck out subpar. (F) which read as follows: “With respect to expenses incurred for services described in subsection (i)(4) of this section under the conditions specified in such subsection, the amounts paid shall be the reasonable charge for such services.”


nurse-midwife services under section 1395x(a)(2)(L) of this title.


Subsec. (b)(3). Pub. L. 100–203, § 4055(a)(2), formerly § 4055(a)(2)(D), as added and renumbered by Pub. L. 100–360, § 411(f)(12)(A), (14), redesignated par. (4) as (3) and struck out former par. (3) which read as follows: “such total amount shall not include expenses incurred for services the amount of payment for which is determined under subsection (a)(1)(F) of this section.”


Subsec. (b)(4)(A). Pub. L. 100–203, § 4085(b)(1)(C), substituted “on an assignment-related basis” for “on the basis of an assignment described in section 1395u(b)(3)(B)(i) of this title, under the procedure described in section 1395gg(f)(1) of this title.”

Subsec. (b)(4)(B). Pub. L. 100–203, § 4085(b)(1)(C)(vi), substituted “on an assignment-related basis” for “on the basis of an assignment described in section 1395u(b)(3)(B)(i) of this title, in accordance with section 1395u(b)(3)(B)(ii) of this title, under the procedure described in section 1395gg(f)(1) of this title.”


Subsec. (b)(5)(A). Pub. L. 100–203, § 4085(b)(1)(D)(i), inserted “Subject to the last sentence of this clause, ‘in’ for ‘In’.”

Pub. L. 100–203, § 4068(a)(1), substituted “‘Subject to the last sentence of this clause, in’ for ‘In’.”

Subsec. (b)(5)(B)(i). Pub. L. 100–203, § 4068(a)(2), inserted sentence at end relating to cost and ASC proportions in the case of an eye or ear and ear speciaity hospital.

Subsec. (b)(5)(B)(ii). Pub. L. 100–203, § 4068(a)(3), formerly § 4068(a)(3)(A), as added and renumbered by Pub. L. 100–360, § 411(f)(12)(A), (14), struck out par. (4) which read as follows: “In the case of services (including all pre- and post-operative services) described in paragraphs (1) and (2)(A) of section 1395x(s) of this title and furnished in connection with surgical procedures (specified pursuant to paragraph (1) of this subsection) in an ambulatory surgical center described in such paragraph, or a hospital outpatient department, payment for such services shall be determined in accordance with subsection (a)(1)(F) of this section if the physician accepts an assignment described in section 1395u(b)(3)(B)(ii) of this title with respect to payment for such services.”

Subsec. (b)(5)(B)(iii). Pub. L. 100–203, § 4068(a)(4), substituted “‘1985 and such other data as the Secretary determines necessary’ for ‘‘1985’.”

Pub. L. 100–203, § 4068(a)(5), substituted “‘1985 and such other data as the Secretary determines necessary’ for ‘‘1985’.”
"after the effective date of the reduction, the physician's actual charge is subject to a limit under section 1395x(s)(1)(D) of this title." for "(subject to subparagraph (B), the physician may charge the individual more than the limiting charge (as defined in subparagraph (B)) plus (for services furnished during the 12-month period beginning on the effective date of the reduction) of the amount by which the physician's actual charges for the service for the previous 12-month period exceeds the limiting charge.")

Pub. L. 100–203, § 4072(b), struck out subpar.

(10). Pub. L. 99–509, § 9343(a)(2), substituted "second sentence" for "next to last sentence", and inserted at end "In the case of outpatient occupational therapy services which are described in the second sentence of section 1395x(s)(1) of this title through the operation of section 1395x(g) of this title, with respect to expenses incurred in any calendar year, no more than $50 shall be considered as incurred expenses for purposes of subsections (a) and (b) of this section."

Pub. L. 99–509, § 9339(a)(1)(B), substituted "qualified hospital laboratory (as defined in subparagraph (D))" for "hospital laboratory".


Pub. L. 99–509, § 9339(a)(1)(B), substituted "qualified hospital laboratory (as defined in subparagraph (D))" for "hospital laboratory", struck out ", and ending on December 31, 1987", after "July 1, 1984", and struck out "For such tests furnished on or after January 1, 1988, the fee schedule under subparagraph (A) shall not apply with respect to diagnostic laboratory tests performed by a hospital laboratory for outpatients of such hospital." which constituted second sentence.

Pub. L. 99–509, § 9320(e)(1), substituted "qualified hospital laboratory (as defined in paragraph (1)D))" for "hospital laboratory".

Pub. L. 99–509, § 9339(a)(1)(A), substituted "hospital laboratory (as defined in subparagraph (D))" for "hospital laboratory".

Pub. L. 99–509, § 9339(b)(1), substituted "(i)" for "(i)".

Pub. L. 99–509, § 9339(a)(1)(A), substituted "qualified hospital laboratory (as defined in subparagraph (D))" for "hospital laboratory".

Pub. L. 99–509, § 9339(c)(1), inserted subpart. (A) designation after "provide for and establish", and added subpar. (D).

Pub. L. 99–509, § 9339(b)(2), struck out "(or, effective January 1, 1988, for the United States)" after "applicable region, State, or area".

Pub. L. 99–509, § 9339(a)(1)(A), substituted "qualified hospital laboratory (as defined in paragraph (1)D))" for "hospital laboratory".


Pub. L. 99–509, § 9320(e)(1), inserted subpart. (A) designation after "provide for and establish", and added subpar. (B).

Pub. L. 99–509, § 9339(b)(2), designated existing provisions as subpar. (A) and added subpar. (B).

Pub. L. 100–203, § 4085(i)(21)(D)(i), inserted provision relating to monetary penalties for whoever knowingly and willfully presents, under subsection (h)(4)(C), added subsec. (p) [originally added as subpar. (B)], redesignated and amended by Pub. L. 100–360, § 411(h)(7)(D), (F), inserted ''and in the case of outpatient occupational therapy services which are described in the second sentence of section 1395x(s)(1) of this title through the operation of section 1395x(g) of this title, with respect to expenses incurred in any calendar year, no more than $50 shall be considered as incurred expenses for purposes of subsections (a) and (b) of this section.''

Pub. L. 100–203, § 4085(i)(21)(D)(i), which directed that par. (3) be amended by striking "or under subsection (1)(2) or (1)(4) of this section", was executed by striking "or under subsection (1)(2) or (1)(5) of this section", to reflect the probable intent of Congress and an earlier amendment by Pub. L. 99–509, § 9343(a)(2), see below.


Pub. L. 99–509, § 9343(e)(2)(A), as amended by Pub. L. 100–203, § 4085(i)(21)(D)(i), which directed that par. (3) be amended by striking "or under subsection (1)(2) or (1)(4) of this section", was executed by striking "or under subsection (1)(2) or (1)(5) of this section", to reflect the probable intent of Congress and an earlier amendment by Pub. L. 99–509, § 9343(a)(2), see below.

Pub. L. 99–509, § 9339(a)(2), substituted "(1)(5)" for "(1)(4)".


Pub. L. 99–509, § 9339(b)(2), struck out "(or, effective January 1, 1988, for the United States)" after "applicable region, State, or area."
Subsec. (f). Pub. L. 98–369, §2350(b)(4), struck out subsec. (f) to part C of this subchapter and redesignated its provisions as section 1389 of the Social Security Act, which is classified to section 1395zz of this title.
Subsec. (h). Pub. L. 98–369, §2303(d), amended subsec. (h) generally, substituting provisions directing the Secretary to establish fee schedules for clinical diagnostic laboratory tests at a percentage of the charge level and nominal fees to cover costs in collecting samples and authorizing the Secretary to make adjustments in the fee schedule, setting forth the recipients of payments, and authorizing the Secretary to establish a negotiated payment rate for provision authorizing the Secretary to establish a negotiated rate of payment with the laboratory which would be considered the full charges described in this title.
Subsec. (i)(3). Pub. L. 98–369, §2303(d), substituted "subsection (a)(1)(F)" for "subsection (a)(1)(G)".
1982—Subsec. (a)(1)(B). Pub. L. 97–248, §112(a)(1), struck out subpar. (B) which related to payment of reasonable charges for preadmission diagnostic services furnished by a physician to individuals enrolled under this part which are furnished in the outpatient department of a hospital within seven days of such individual's admission to a hospital or another hospital or furnished in the physician's office within seven days of such individual's admission to a hospital as an inpatient.
Subsec. (a)(2)(B). Pub. L. 98–369, §2350(b)(4), struck out subpar. (B) which provided that with respect to items and services described in section 1395x(s)(10) of this title, the amount of benefits paid would be 100 percent of reasonable charges for such items and services for provision that with respect to items and services for provision that with respect to home health services and to items and services described in section 1395x(s)(10) of this title, the lesser of reasonable cost of such services as determined under section 1395x(v) of this title or customary charges with respect to such services, or if such services are furnished by a public provider of services free of charge or at nominal charges to the public, the amount determined in accordance with section 1395x(v) of this title.
Subsec. (a)(3). Pub. L. 98–369, §2332(b)(1), substituted "section 1395x(s)(10)(A) of this title" for "section 1395x(s)(10) of this title".
Subsec. (a)(5). Pub. L. 98–369, §2305(b), struck out par. (5) which related to payment of reasonable charges for preadmission diagnostic services described in section 1395x(s)(12) of this title and redesignated former par. (5) as (4) and redesignated former pars. (3) and (4) as (4) and (5), respectively.
Subsec. (b)(1). Pub. L. 98–369, §2332(b)(1), substituted "section 1395x(s)(10)(A) of this title" for "section 1395x(s)(10)(B) of this title".
Subsec. (a)(1)(C). Pub. L. 98–369, §2303(a), amended subpar. (D). Generally, prior to amendment, subpar. (D) read as follows: "with respect to diagnostic tests performed in a laboratory for which payment is made under this part to the laboratory, the amounts paid shall be equal to 100 percent of the negotiated rate for such tests (as determined pursuant to subsection (b) of this section),".
Subsec. (a)(1)(F). Pub. L. 98–369, §2305(a), redesignated subpar. (G) as (F), and struck out former subpar. (F) which related to payment of reasonable charges for preadmission diagnostic services furnished by a physician to individuals enrolled under this part which are furnished in the outpatient department of a hospital within seven days of such individual's admission to the same hospital or another hospital or furnished in the physician's office within seven days of such individual's admission to a hospital as an inpatient.
Subsec. (a)(2). Pub. L. 98–369, §2305(c), struck out "and in paragraph (5) of this subsection" after "of such section"
Subsec. (a)(2)(A). Pub. L. 98–369, §2308(b)(2), inserted "or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this provision),".
Pub. L. 98–369, §2321(b)(1), inserted in provision preceding cl. (1) ("other than durable medical equipment")
Pub. L. 98–369, §2332(b)(1), substituted "section 1395x(s)(10)(A) of this title" for "section 1395x(s)(10)(B) of this title".
Pub. L. 98–369, §2331(b)(2), inserted in provision preceding cl. (1) "items and" after "to other".
Pub. L. 98–369, §2303(b)(1), inserted "or (D)" after "subparagraph (C)".
Subsec. (a)(2)(B)(iv). Pub. L. 98–369, §2308(b)(2)(B), inserted "and" or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this clause),".
Subsec. (a)(3). Pub. L. 98–369, §2332(b)(1), substituted "section 1395x(s)(10)(A) of this title" for "section 1395x(s)(10) of this title".
Subsec. (a)(5). Pub. L. 98–369, §2305(b), struck out par. (5) which related to payment of reasonable charges for preadmission diagnostic services described in section 1395x(s)(12) of this title furnished to an individual by a physician in field of radiology or pathology who has an agreement with Secretary by which physician agrees to accept an assignment (as provided for in section 1395ul(b)(3)(B)(ii) of this title) for all physicians' services furnished by him to hospital inpatients enrolled under this part, the amounts paid would be equal to 100 percent of the reasonable charges for such services.
Subsec. (a)(1)(H). Pub. L. 97–248, §112(a)(2), (3), struck out subpar. (H) which provided that, with respect to items and services described in section 1395x(s)(10) of this title, the amount of benefits paid would be 100 percent of reasonable charges for such items and services.
Subsec. (a)(2)(A). Pub. L. 97–248, §110(c)(2), inserted "and except as may be provided in section 1395ww of this title".
Subsec. (b)(1). Pub. L. 97–248, §112(b), struck out subpar. (A) provision that total amount of expenses shall not include expenses incurred for radiological or pathological services furnished to an individual by a physician or an individual by a physician in field of radiology or pathology who has an agreement with Secretary by which physician agrees to accept an assignment (as provided for in section 1395ul(b)(3)(B)(ii) of this title) for all physicians' services furnished by him to hospital inpatients enrolled under this part, and redesignated subpar. (B) provisions as par. (1).
1981—Subsec. (a)(2)(A). Pub. L. 97–35, §2106(a), substituted provisions that with respect to home health services and to items and services described in section 1395x(s)(10) of this title, the lesser of reasonable cost of such services as determined under section 1395x(v) of this title or customary charges with respect to such services, or if such services are furnished by a public provider of services free of charge or at nominal charges to the public, the amount determined in accordance with section 1395ul(b)(2) of this title for provisions that with respect to home health services and to items and services described in section 1395x(s)(10) of this title, the reasonable cost of such services, as determined under section 1395x(v) of this title.
Subsec. (a)(2)(B). Pub. L. 97–35, §2106(a), substituted new formula in cls. (i) to (iii) with respect to other
services for provisions providing for reasonable costs of such services less the amount a provider may charge as described in section 1395cc(a)(2)(A) of this title and that in no case may payment for such other services exceed 80 percent of such costs.

Subsec. (b). Pub. L. 97–35, §§213A(a), 213A(d), redesignated pars. (2) to (4) as (1) to (3), and struck out former part (1) which provided that amount of deductible for such calendar year as so determined shall first be reduced by amount of any expenses incurred by such individual in last three months of preceding calendar year and such amount to be disregarded toward such individual's deductible under this section for such preceding year.

Pub. L. 97–35, §213A(a), substituted "by a deductible of $75" for "by a deductible of $60".

1980—Subsec. (a)(1)(B). Pub. L. 96–499, §493(a), inserted "who has in effect an agreement with the Secretary by which the physician agrees to accept an assignment (as provided for in section 1395u(b)(3)(B)(1) of this title) for all physicians' services furnished by him to hospital inpatients enrolled under this part" after "radiology or pathology services furnished by him to hospital inpatients enrolled under this part" after "radiology or pathology services furnished by him to hospital inpatients enrolled under this part".


Subsec. (b). Pub. L. 96–499, §493(c), inserted "as incurred for services furnished in last three months of preceding year, struck out former part (2) which provided that amount of any deduction imposed by section 1395x(f)(2)(A) of this title for outpatient hospital diagnostic services furnished in any calendar year is to be regarded as an incurred expense for such year; and added par. (2).

Pub. L. 96–499, §942, prescribed a formula for determining payment amounts for services described in subpars. (D) and (E) of section 1395k(a) of this title.

Subsec. (a)(3). Pub. L. 96–499, §942, authorized payment of reasonable cost of home health services and prescribed formulae for determining payment amounts for services other than home health services.


Subsec. (f)(2). Pub. L. 95–142 substituted provisions relating to waiver of coinsurance amount in purchase of used durable medical equipment, for provisions relating to reimbursement procedure established by the Secretary in cases of rental of durable medical equipment.


1972—Subsec. (a), Pub. L. 92–603, §226(c)(2), inserted reference to section 1395mm of this title in provisions preceding par. (1).

Subsec. (a)(1). Pub. L. 92–603, §§211(c)(4), 278(a), added subpars. (C) and (D).

Subsec. (a)(2). Pub. L. 92–603, §§233(b), 251(a)(3), 299K(a), substituted subpars. (A) and (B) for provisions relating to amount payable by reference to section 1395x(v)(A) of this title, added subpar. (C), and in provisions preceding subpar. (A), inserted "with respect to home health services, 100 percent, and with respect to other services," before "80 percent".

Subsec. (b). Pub. L. 92–603, §204(a), substituted "$50" for "$500".

Subsec. (c). Pub. L. 92–603, §254(d), designated existing provisions as pars. (1) and added par. (2).


Subsec. 1968—Subsec. (a)(1). Pub. L. 90–248, §131(a)(1), (2), designated existing provisions as subpar. (A) and added subpar. (B).

Pub. L. 90–248, §129(c)(7), substituted provisions relating to determinations by Secretary with respect to durable medical equipment authorized to be paid by Secretary, for provisions relating to purchase price of durable medical equipment, for provisions relating to waiver of coinsurance amount in purchase of used durable medical equipment, for provisions relating to reimbursement procedure established by the Secretary in cases of rental of durable medical equipment.


MATTER OF DATE OF 2010 AMENDMENTS

Pub. L. 111–148, title IV, §4102(c), Mar. 23, 2010, 124 Stat. 557, provided that: "The amendments made by this section [amending this section and section 1395q of this title] shall apply to services furnished on or after January 1, 2011."

P.L. 111–148, title IV, §4102(c), Mar. 23, 2010, 124 Stat. 558, provided that: "The amendments made by this section [amending this section and section 1395q of this title] shall apply to items and services furnished on or after January 1, 2011."

MATTER OF DATE OF 2008 AMENDMENTS

Pub. L. 110–275, title I, §101(c), July 15, 2008, 122 Stat. 2496, provided that: "The amendments made by this section [amending this section and sections 1395q and 1395y of this title] shall apply to services furnished on or after January 1, 2009."

Amendment by section 143(b)(2), (3), of Pub. L. 110–275 applicable to services furnished on or after January 1, 2008, see section 143(c) of Pub. L. 110–275, set out as a note under section 1395q of this title.

Effective Date of 2008 Amendment

Pub. L. 109–197, title V, §511(f), Feb. 8, 2006, 120 Stat. 44, provided that: “The amendments made by this section [amending this section and sections 1395w–4, 1395x, and 1395y of this title] shall apply to services furnished on or after January 1, 2007.”

Pub. L. 109–197, title V, §511(c), Feb. 8, 2006, 120 Stat. 44, provided that: “The amendments made by this section [amending this section and section 1396v of this title] shall apply to services furnished on or after January 1, 2007.”

Effective Date of 2003 Amendment
Amendment by section 237(a) of Pub. L. 108–173 applicable to services provided on or after Jan. 1, 2006, and contract years beginning on or after such date, see section 237(e) of Pub. L. 108–173, set out as a note under section 1320a–7b of this title.


“(1) in the case of screening mammography, to services furnished on or after the date of the enactment of this Act [Dec. 8, 2003]; and

“(2) in the case of diagnostic mammography, to services furnished on or after January 1, 2005.”


Pub. L. 108–173, title VI, §627(c), Dec. 8, 2003, 117 Stat. 2321, provided that: “The amendments made by this section [amending this section and sections 1395m and 1395y of this title] shall apply to items furnished on or after January 1, 2005.”


Effective Date of 2000 Amendment
Pub. L. 106–554, §1(a)(6) [title I, §105(e)], Dec. 21, 2000, 114 Stat. 2763, 2763A–472, provided that: “The amendments made by this section [amending this section and sections 1395u and 1395x of this title] shall apply to services furnished on or after December 31, 1999.”

Pub. L. 106–554, §1(a)(6) [title I, §111(a)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–473, provided that: “The amendment made by paragraph (1) [amending this section] shall apply with respect to services furnished on or after April 1, 2001.”

Pub. L. 106–554, §1(a)(6) [title II, §201(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–481, provided that: “The amendment made by subsection (b) [amending section 1395m of this title] shall apply to services furnished on or after the date of the enactment of this Act [July 15, 2008].”

Pub. L. 106–554, §1(a)(6) [title II, §201(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–482, provided that: “The amendments made by this section [amending section 1395m of this title] shall apply to services furnished on or after January 1, 2001.”

Pub. L. 106–554, §1(a)(6) [title II, §202(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–483, provided that: “The amendments made by this section [amending section 1395m of this title] shall apply to services furnished on or after the date of the enactment of this Act [Dec. 21, 2000].”

Pub. L. 106–554, §1(a)(6) [title II, §223(e)], Dec. 21, 2000, 114 Stat. 2763, 2763A–490, provided that: “The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after July 1, 2001.”


Pub. L. 106–554, §1(a)(6) [title IV, §402(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–504, provided that: “The amendments made by this section [amending section 1395m of this title] shall apply to payment for services furnished on or after October 1, 2001.”

Pub. L. 106–554, §1(a)(6) [title IV, §403(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–505, provided that: “The amendments made by this section [amending section 1395m of this title] shall apply to services furnished on or after January 1, 2001.”

Pub. L. 106–554, §1(a)(6) [title IV, §403(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–506, provided that: “The amendments made by subsection (a) [amending this section] shall take effect as if included in the enactment of BBA [Pub. L. 106–113, §1000(a)(6)].”

Pub. L. 106–554, §1(a)(6) [title IV, §405(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–507, provided that: “The amendments made by this section [amending section 1395m of this title] shall apply to services furnished on or after July 1, 2001.”

Effective Date of 1999 Amendment
Pub. L. 106–113, div. B, §1000(a)(6) [title II, §201(h)(2)], Nov. 29, 1999, 113 Stat. 1536, 1501A–340, provided that: “The Secretary of Health and Human Services shall first conduct the annual review under the amendment made by paragraph (1)(A) [amending this section] in 2001 for application in 2002 and the amendment made by paragraph (1)(B) [amending this section] takes effect on the date of the enactment of this Act [Nov. 29, 1999].”

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §201(m)], Nov. 29, 1999, 113 Stat. 1536, 1501A–341, provided that: “Except as provided in this section, the amendments made by this section [amending this section and sections 1395m and 1395x of this title] shall take effect as if included in the enactment of BBA [the Balanced Budget Act of 1997, Pub. L. 105–33].”

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §202(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–344, provided that: “The amendments made by this section [amending this section] shall be effective as if included in the enact-

Section 106–113, div. B, §1000(a)(6) [title II, §204(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A–345, provided that:

"The amendments made by this section [amending this section] apply as if included in the enactment of BBA [the Balanced Budget Act of 1997, Pub. L. 105–33] and shall only apply to procedures and payments under section 1395f of this title for services furnished on or after Oct. 1, 1997, under section 1395f of this title.


The amendment made by paragraph (1) [amending this section] shall apply to services furnished on or after the date of enactment of this Act [Nov. 29, 1999]."

**Effective Date of 1997 Amendment**

Section 4002(c)(1)(B) of Pub. L. 105–33 provided that:

"The amendment made by subparagraph (A) [amending this section] applies to new contracts entered into after the date of enactment of this Act [Aug. 5, 1997] and, with respect to contracts in effect as of such date, shall apply to payment for services furnished after December 31, 1998."

Section 410(d) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section and section 1395m of this title] shall apply to items and services furnished on or after January 1, 1998." Section 410(e) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section and sections 1395w–4, 1395x, and 1395y of this title] shall apply to items and services furnished on or after January 1, 1998." Section 410(c)(1) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section] apply to services furnished on or after January 1, 1999." Section 410(c)(2) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section] apply to services furnished on or after January 1, 1995." Section 410(c)(3) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section] apply to services furnished on or after January 1, 1995." Section 410(c)(4) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section and section 1395a of this title] shall apply to services furnished on or after October 1, 1997." Section 410(c)(5) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section and section 1395a of this title] shall take effect as if included in the enactment of OBRA–1990 [Pub. L. 101–508]."

Amendment by section 420(c)(1) of Pub. L. 105–33 applicable to services furnished on or after Oct. 1, 1997, see section 420(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Section 420(d)(1) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section and sections 1395a of this title] shall apply to items and services furnished on or after January 1, 1998, including portions of cost reporting periods occurring on or after such date, except that section 1384(k) of the Social Security Act [section 1395m(k) of this title] (as added by subsection (a)(2)) shall not apply to services described in section 1395a(b)(8) of such Act (section 1395m(k) of this title) (as added by subsection (a)(2)) shall not apply to services described in section 1395a(b)(8) of such Act (section 1395m(k) of this title) (as added by subsection (a)(2)) shall not apply to services described in section 1395a(b)(8) of such Act (section 1395m(k) of this title) (as added by subsection (a)(2)) shall not apply to services described in section 1395a(b)(8) of such Act.

Section 420(c)(2) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section and sections 1395a of this title] shall apply to services furnished on or after January 1, 1998." Section 420(c)(3) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section and sections 1395a of this title] shall apply with respect to services furnished and supplies provided on or after Jan. 1, 1998, see section 451(e) of Pub. L. 105–33, set out as a note under section 1395k of this title.

Section 451(d)(2) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section and sections 1395a and 1395x of this title] shall apply with respect to services furnished and supplies provided on and after January 1, 1998.

Section 452(c) of Pub. L. 105–33 provided that: ‘‘The amendments made by this section [amending this section] apply to services furnished during portions of cost reporting periods occurring on or after October 1, 1997.’’

Section 4523(d)(1)(A)(ii) of Pub. L. 105–33 provided that: ‘‘The amendments made by this subsection [amending this section] shall apply to services furnished on or after January 1, 1999.’’

Section 453(b)(3) of Pub. L. 105–33 provided that: ‘‘The amendments made by this subsection [amending this section and section 1395m of this title] shall apply to services furnished on or after January 1, 1998, including portions of cost reporting periods occurring on or after such date, except that section 1384(k) of the Social Security Act [section 1395m(k) of this title] (as added by subsection (a)(2)) shall not apply to services described in section 1395a(b)(8) of such Act (section 1395m(k) of this title) (as added by subsection (a)(2)) shall not apply to services described in section 1395a(b)(8) of such Act (section 1395m(k) of this title) (as added by subsection (a)(2)) shall not apply to services described in section 1395a(b)(8) of such Act.

(2) The amendments made by subsections (a)(3) and (c) [amending this section and section 1395m of this title] apply to services furnished on or after January 1, 1999.

(3) The amendments made by subsection (d)(1) [amending this section] apply to expenses incurred on or after January 1, 1999.

Section 455(d) of Pub. L. 105–33 provided that: ‘‘The amendments made by this subsection [amending this section and section 1395m of this title] shall apply to drugs and biologicals furnished on or after January 1, 1996.’’

Amendment by section 4603(c)(2)(A) 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.

**Effective Date of 1994 Amendment**

Section 123(c)(1), (2) of Pub. L. 103–423 provided that:

"(1) ENFORCEMENT; MISCELLANEOUS AND TECHNICAL AMENDMENTS.—The amendments made by subsections (a) and (e) [amending this section and section 1395w–4 of this title] shall apply to services furnished on or after the date of the enactment of this Act [Oct. 31, 1994]; except that the amendments made by subsection (a) [amending section 1395w–4 of this title] shall not apply to services of a nonparticipating supplier or other person furnished before January 1, 1995.

"(2) PRACTITIONERS.—The amendments made by subsection (b) [amending this section and section 1395u of this title] shall apply to services furnished on or after January 1, 1995."

Section 141(c)(2) of Pub. L. 103–423 provided that: ‘‘The amendments made by paragraph (1) [amending this section] shall apply to payments made on or after Oct. 1, 1999.’’

Amendment by section 147(a), (e)(2), (3), (b)(6)(C), (D) of Pub. L. 103–423 effective as if included in the enactment of Pub. L. 101–508, see section 147(g) of Pub. L. 103–423, set out as a note under section 1320a–3a of this title.

Amendment by section 147(d)(1), (2) of Pub. L. 103–423 provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 101–239. Amendment by section 156(a)(2)(B) of Pub. L. 103–423 applicable to services furnished on or after Oct. 31, 1994, see section 156(a)(3) of Pub. L. 103–423, set out as a note under section 1320c–3 of this title.

**Effective Date of 1993 Amendment**

Section 13532(b) of Pub. L. 103–66 provided that: ‘‘The amendments made by subsection (a) [amending this
section] shall apply to portions of cost reporting periods beginning on or after January 1, 1994.

Section 1354(h)(b)(3) of Pub. L. 101–66 provided that: "The amendments made by subsection (a) [amending this section and section 1395m of this title] shall apply to items furnished on or after January 1, 1994."

Section 1355(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."

Effective Date of 1990 Amendment

Section 410(d) of Pub. L. 101–508 provided that: "The amendments made by this section [amending this section and sections 1395m and 1395w–4 of this title] shall apply to services furnished on or after January 1, 1991.

Amendment by section 4153(a)(2)(B), (C) of Pub. L. 101–508 applicable to items furnished on or after Jan. 1, 1991, see section 4153(a)(3) of Pub. L. 101–508, set out as a note under section 1395k of this title.

Section 4154(b)(2) of Pub. L. 101–508 provided that: "The amendments made by paragraph (1) [amending this section] shall apply to tests furnished on or after January 1, 1991.

Amendment by section 4154(c)(2) of Pub. L. 101–508 provided that: "The amendment made by paragraph (1)(A) [amending this section] shall take effect as if included in the enactment of the Omnibus Budget Reconciliation Act of 1986 [Pub. L. 99–272], and the amendment made by paragraph (1)(B) [amending this section] shall take effect as if included in the enactment of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203]."


Amendment by section 4155(b)(2), (3) 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 13956 of this title.


Section 4164(e) of Pub. L. 101–508, as amended by Pub. L. 103–432, title I, §147(f)(5)(B), Oct. 31, 1994, 108 Stat. 4431, provided that: "Except as provided in subsection (d) of this section, the amendments made by this section [amending this section and sections 1395m, 1395w–3, 1395y, 1395z, 1395aa, and 1395bb of this title] shall apply to screening mammography performed on or after January 1, 1990.

Amendment by section 4206(e)(2) of Pub. L. 101–508 provided that: "The amendments made by subsection (b) [amending this section and section 1395m of this title] shall apply to contracts under section 1876 of the Social Security Act [section 1395mm of this title] and payments under section 1833(a)(1)(A) of such Act [subsection (a)(1)(A) of this section] as of first day of the first month beginning more than 1 year after the date of the enactment of this Act [Nov. 5, 1990]."

Effective Date of 1988 Amendments

Section 6102(c) of Pub. L. 101–239 provided that: "Except as otherwise provided in this section, this section, and the amendments made by this section [enacting this section and sections 1395m, 1395w, and 1395r of this title, and enacting provisions set out as notes under this section and sections 1395w and 1395m of this title], shall take effect on the date of enactment of this Act (Dec. 19, 1989).

Section 6111(b)(2) of Pub. L. 101–239, as amended by Pub. L. 101–606, title IV, §4154(e)(4), Nov. 5, 1990, 104 Stat. 1388–86, provided that: "The amendment made by paragraph (1) [amending this section] shall apply with respect to clinical diagnostic laboratory tests performed on or after May 1, 1990.

Section 6113(e) of Pub. L. 101–239 provided that: "The amendments made by this section [amending this section and section 1395x of this title], and the provisions of subsection (c) [set out below], shall apply to services furnished on or after July 1, 1990, and the amendments made by subsection (d) [amending this section] shall apply to expenses incurred in a year beginning with 1990.

Section 6131(c) of Pub. L. 101–239 provided that: "(1) The amendments made by this section [amending this section and section 1395x of this title] shall apply with respect to therapeutic shoes and inserts furnished on or after July 1, 1989.

(2) In applying the amendments made by this section, the increase under subparagraph (A) of section 1833(o)(2) of the Social Security Act [subsec. (o)(2)(C) of this section] shall apply to the dollar amounts specified under subparagraph (A) of such section (as amended by this section) in the same manner as the increase would have applied to the dollar amounts specified under subparagraph (A) of such section (as in effect before the date of the enactment of this Act [Dec. 19, 1989])."

Amendment by section 6133(b) of Pub. L. 101–239 provided that: "The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1990.

Amendment by section 6202(b) of Pub. L. 101–239 effective with respect to referrals made on or after Jan. 1, 1992, see section 6204(c) 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 1330a–7a of this title.

Amendment by section 202(a) of Pub. L. 101–234 effective Jan. 1, 1990, see section 202(b) of Pub. L. 101–234, set out as a note under section 401 of this title.

Effective Date of 1989 Amendments

Section 6202(b) of Pub. L. 100–647 provided that: "The amendment made by subsection (a) [amending this section] shall become effective as if included in the amendment made by section 9320(e)(2) of the Omnibus Budget Reconciliation Act of 1986 [Pub. L. 99–509]."

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 808(g) of Pub. L. 100–485, set out as a note under section 704 of this title.

Amendment by section 202(b)(1)–(3) 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 1396u of this title.

Amendment by section 203(c)(1)(A)–(E) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100–360, set out as a note under section 1395m of this title.

Amendment by section 204(d)(1) 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(c) 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(c)(2)(D), (8)(B)(i),
(C), (12)(A), (14), (g)(1)(E), (2)(D), (E), (3)(A)–(F), (4)(C), (5), (h)(1)(A), (3)(B), (4)(B), (C), (7)(C), (D), (F), (i)(3), (4)(D)–(C)(ii), (iv), and (vi) of Pub. L. 100–360, as it re-
lates to the amendment made by the Omnibus Budget Reconcili-
ation Act of 1987, see 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 OHLA: Effective Date note under section 106 of Title 1, General Provisions.

**Effective Date of 1987 Amendment**

Section 404(c) of Pub. L. 100–203 provided that: 
"The amendments made by this [sic] subsection (a) [amending this section] shall apply with respect to services furnished in a rural area (as defined in section 1866(d)(2)(D) of the Social Security Act [section 1955w(d)(2)(D) of this title]) on or after January 1, 1989, and to other services furnished on or after January 1, 1991."

Amendment by section 404(c)(2)(A) of Pub. L. 100–203 applicable to items and services furnished on or after Apr. 1, 1989, see section 404(c) of Pub. L. 100–203, set out as a note under section 1395u of this title.

Amendment by section 404(a)(1) of Pub. L. 100–203 applicable to services performed on or after Apr. 1, 1989, see section 404(a)(2) of Pub. L. 100–203, as amended, set out as a note under section 1395m of this title.

Section 405(b), formerly §405(b), of Pub. L. 100–203, as added and renumbered by Pub. L. 100–203, title IV, §411(f)(12)(A), (14), July 1, 1988, 102 Stat. 787, provided that: "The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after April 1, 1988."

Amendment by section 406(c)(3) 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 406(c) of Pub. L. 100–203, as amended, set out as a note under section 1395u of this title.

Section 406(c) of Pub. L. 100–203 provided that: "The amendments made by this section [amending this section and section 1395u of this title] shall apply to items and services furnished on or after July 1, 1988."

Section 406(b)(3) of Pub. L. 100–203 provided that: "The amendments made by paragraphs (1) and (2) [amending this section] shall apply with respect to services furnished on or after April 1, 1988."

Section 406(c)(2) of Pub. L. 100–203, as added by Pub. L. 100–360, title IV, §411(g)(3)(F), July 1, 1988, 102 Stat. 781, provided that: "The amendment made by paragraph (1) [amending this section] shall apply with respect to diagnostic laboratory tests furnished on or after April 1, 1988."

Section 406(c) of Pub. L. 100–203 provided that: "The amendments made by subsection (a) [amending this section] shall apply with respect to outpatient hospital services furnished on or after October 1, 1988, and other diagnostic procedures performed on or after October 1, 1988."

Section 406(c) of Pub. L. 100–203 provided that: "The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after April 1, 1988."

Section 406(c) of Pub. L. 100–203 provided that: "The amendments made by subsection (a) [amending this section] shall be effective as if included in the amendment made by section 9320(e)(2) of the Omnibus Budget Reconciliation Act of 1986 [Pub. L. 99–509]."

Section 408(c)(3) of Pub. L. 100–203, as added by Pub. L. 100–360, title IV, §411(l)(3), July 1, 1988, 102 Stat. 786, provided that: "The amendments made by this subsection [amending this section and section 1395u of this title] shall apply to services furnished after December 31, 1988."

Section 406(b)(2) of Pub. L. 100–203 provided that: "The amendment made by paragraph (1) [amending this section] shall apply to procedures performed on or after January 1, 1988."

Section 4085(b)(21) of Pub. L. 100–203 provided that the amendment to section 9343 of Pub. L. 99–509 by section 4085(b)(21)(D) of Pub. L. 100–203, amending this section and provisions set out as an Effective Date of 1986 Amendments note below, is effective as if included in the enactment of Pub. L. 99–509.

**Effective Date of 1986 Amendments**

Amendment by section 9320(e)(1), (2) 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 1395u of this title.

Amendment by section 9320(b) 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 1395u of this title.

Amendment by section 9320(c)(2) of Pub. L. 99–509 provided that: "The amendments made by this subsection [amending this section] apply to clinical diagnostic laboratory tests performed on or after January 1, 1987."

Section 9337(b) of Pub. L. 99–509 provided that: "The amendment made by paragraph (1) [amending this section] shall apply to samples collected on or after April 1, 1987."


"(2) The amendments made by subsections (b)(1) and (c) [amending this section and sections 1395y and 1395cc of this title] shall apply to services furnished after June 30, 1987.

"(3) The Secretary of Health and Human Services shall first provide, under the amendment made by subsection (b)(2) [amending this section], for the review and update of procedure lists within 6 months after the date of the enactment of this Act [Oct. 21, 1986]."

"(4) The amendments made by subsection (d) [amending section 1320c–3 of this title] shall apply to contracts entered into or renewed after January 1, 1987."

Section 9303(a)(2) of Pub. L. 99–272 provided that: "The amendments made by subsection (a) [amending this section] shall apply to clinical diagnostic laboratory tests performed on or after July 1, 1986."
“(B) The amendment made by paragraph (3) [amending this section] shall apply to clinical diagnostic laboratory tests performed on or after January 1, 1987.”

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 1396f of this title.

Section 2303(j) of Pub. L. 98–369 provided that:
“(1) Except as provided in paragraphs (2) and (3), the amendments made by this section [amending this section and sections 1395u, 1396cc, 1396a, and 1396b of this title and enacting provisions set out as notes under this section and section 1395a of this title] shall apply to clinical diagnostic laboratory tests furnished on or after July 1, 1984.

“(2) The amendments made by subsection (g)(2) [amending section 1396b of this title] shall apply to payments for calendar quarters beginning on or after October 1, 1984.

“(3) The amendments made by this section shall not apply to clinical diagnostic laboratory tests furnished to inpatients of a provider operating under a waiver granted pursuant to 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 1396y of this title]. Payments for such services shall be made under part B of title XVIII of the Social Security Act [this part] at 80 percent (or 100 percent in the case of such tests for which payment is made on the basis of an assignment described in section 1842(b)(3)(B)(i) of the Social Security Act [section 1395u(b)(3)(B)(i) of this title] or under the procedure described in section 1870(f)(1) of such Act [section 1395gg(f)(1) of this title]) of the reasonable charge for such service. The deductible under section 1833(b) of such Act [subsection (b) of such section] shall not apply to such tests if payment is made on the basis of such an assignment or procedure.”

Section 2303(e) of Pub. L. 98–369 provided that: “The amendments made by this section [amending this section and enacting provisions set out below] shall apply to services performed after the date of the enactment of this Act [July 18, 1984].”

Amendment by section 2321(b), (d)(4)(A) of Pub. L. 98–369 applicable to items and services furnished on or after July 18, 1984, see section 2321(g) of Pub. L. 98–369, set out as a note under section 1395f of this title.

Section 2323(d) of Pub. L. 98–369 provided that: “The amendments made by this section [amending this section and sections 1385x, 1395cc, and 1386r of this title and enacting provisions set out below] apply to services furnished on or after September 1, 1984.”

Amendment by section 2354(b)(5), (7) of Pub. L. 98–369 effective July 18, 1984, but not to be construed as changing the effecting 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 1982 Amendment
Section 112(c) of Pub. L. 97–248 provided that: “The amendments made by this section [amending this section] shall apply with respect to items and services furnished on or after October 1, 1982.”

Amendment by section 117(a)(2) of Pub. L. 97–248 applicable to final determinations made on or after Sept. 3, 1982, see section 117(b) of Pub. L. 97–248, set out as a note under section 1395g of this title.

Amendment by section 148(d) 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 2106(c) of Pub. L. 97–35 provided that: “The amendment made by subsection (a) [amending this section] is effective as of December 5, 1980, and the amendment made by subsection (b)(2) [amending section 1395g(b) of this title], is effective as of April 1, 1981.”

Section 2133(b) of Pub. L. 97–35 provided that: “The amendments made by subsection (a) [amending this section] first apply to the deductible for calendar year 1982 with respect to expenses incurred on or after October 1, 1981.”

Section 2134(b) of Pub. L. 97–35 provided that: “The amendment made by subsection (a) [amending this section] shall take effect on January 1, 1982, and shall apply to the deductible for calendar years beginning with 1982.”

Effective Date of 1980 Amendments
Section 2 of Pub. L. 96–611 provided that: “The amendments made by this Act [probably should be the amendments made by section 1 of this Act, which amended this section and sections 1396x, 1396y, 1396aa, and 1396cc of this title] shall take effect on, and apply to services furnished on or after, July 1, 1981.”

Amendment by section 938(h) of Pub. L. 96–499, effective with respect to services furnished on or after July 1, 1981, see section 938(s)(1) of Pub. L. 96–499, set out as a note under section 1395x of this title.

Section 938(b) of Pub. L. 96–499 provided that: “The amendment made by subsection (a) [amending this section] shall apply to services furnished for the sixth calendar month beginning after the date of the enactment of this Act [Dec. 5, 1980].”

Effective Date of 1978 Amendment
Amendment by Pub. L. 95–292 effective with respect to services, supplies, or 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
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 204(c) of Pub. L. 95–210, set out as a note under section 1395k of this title.

Section 16(b) of Pub. L. 95–142 provided that: “The amendment made by subsection (a) [amending this section] shall apply with respect to durable medical equipment purchased or rented on or after October 1, 1977.”

Effective Date of 1972 Amendment
Section 204(c) of Pub. L. 92–603 provided that: “The amendments made by this section [amending this section and section 1395n of this title] shall be effective with respect to calendar years after 1972 (except that, for purposes of applying clause (1) of the first sentence of section 1833(b) of the Social Security Act [subsection (b) of this section], such amendments shall be deemed to have taken effect on January 1, 1971).”

Amendment by section 211(c)(4) 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 1395k of this title.

Amendment by section 226(c)(2) 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 1395nn of this title.

Amendment by section 251(a)(2), (3) of Pub. L. 92–603 applicable with respect to services furnished on or after July 1, 1973, see section 251(d)(1) of Pub. L. 92–603, set out as a note under section 1395f of this title.

Section 299(k)(b) of Pub. L. 92–603 provided that: "The amendment made by subsection (a) [amending this section] shall apply to services furnished by home health agencies in accounting periods beginning after December 31, 1972."

**Effective Date of 1968 Amendment**

Amendment by section 129(c)(7), (8) of Pub. L. 90–248 applicable with respect to services furnished after Mar. 31, 1968, see section 129(d) of Pub. L. 90–248, set out as a note under section 1395d of this title.

Section 131(c) 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."

Section 132(c) of Pub. L. 90–248 provided that: "The amendments made by this section [amending this section and section 1395x of this title] shall apply only with respect to items purchased after December 31, 1967."

Amendment by section 135(c) 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 135(d) of Pub. L. 90–248, set out as a note under section 1395e of this title.

**Construction of 2008 Amendment**

Pub. L. 110–275, title I, §101(a)(4), July 15, 2008, 122 Stat. 2967, provided that: "Nothing in the provisions of, or amendments made by, this subsection [amending this section and sections 1395x and 1395y of this title] shall be construed to provide coverage under title XVIII of the Social Security Act [this subchapter] for teaching certified registered nurse anesthetists that—

1. is consistent with the adjustments made by the special rule for teaching anesthesiologists under section 1848(a)(6) of the Social Security Act (42 U.S.C. 1395w–4(a)(6)), as added by subsection (a); and

2. is consistent with comparable adjustments and limitations to the extent that comparable adjustments and limitations apply to teaching certification in anesthesiology.

**TREATMENT OF CERTAIN COMPLEX DIAGNOSTIC LABORATORY TESTS**


"(a) Demonstration Project.—

(1) In General.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall conduct a demonstration project under part B [of] title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) under which separate payment would not otherwise be made under such title (including preparing and submitting a report to Congress on the project. Such report shall include—

1. an assessment of the impact of the demonstration project on access to care, quality of care, health outcomes, and expenditures under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) (including any savings under such title); and

2. such recommendations as the Secretary determines appropriate.

(b) Implementation Funding.—For purposes of administering this section (including preparing and submitting the report under subsection (d)), the Secretary shall provide for the transfer from the Federal Supplemental [probably should be "Supplementary"] Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395c) of amounts transferred under the preceding sentence shall remain available until expended."

**Treatment of Certified Registered Nurse Anesthetists**

Pub. L. 110–275, title I, §139(b), July 15, 2008, 122 Stat. 291, provided that: "With respect to items and services furnished on or after January 1, 2010, the Secretary of Health and Human Services shall make appropriate adjustments to payments under the Medicare program under title XVIII of the Social Security Act (this subchapter) for teaching certified registered nurse anesthetists to implement a policy with respect to teaching certification in anesthesiology that—

1. is consistent with the adjustments made by the special rule for teaching anesthesia physicians under section 1848(a)(6) of the Social Security Act (42 U.S.C. 1395w–4(a)(6)), as added by subsection (a); and
“(2) maintains the existing payment differences between teaching anesthesiologists and teaching certified registered nurse anesthetists.”

IMPLEMENTATION OF 2006 AMENDMENT

Pub. L. 109–432, div. B, title I, §107(b)(2), Dec. 20, 2006, 120 Stat. 2961, provided that: “The Secretary of Health and Human Services may implement the amendments made by paragraph (1) [amending this section] by program instruction or otherwise. There shall be no administrative or judicial review under section 1869 or section 1878 of the Social Security Act (42 U.S.C. 1395f and 1395gg) or otherwise of the process (including the establishment of the process) under section 1833(g)(5) of such Act [subsec. (g)(5) of this section], as added by paragraph (1).”

IMPLEMENTATION OF CLINICALLY APPROPRIATE CODE EDITS IN ORDER TO IDENTIFY AND ELIMINATE IMPROPER PAYMENTS FOR THERAPY SERVICES

Pub. L. 109–171, title V, §5107(b), Feb. 8, 2006, 120 Stat. 457, provided that: “By not later than July 1, 2006, the Secretary of Health and Human Services shall implement clinically appropriate code edits with respect to payments under part B of title XVIII of the Social Security Act [this part] that is furnished during a cost reporting period beginning on July 1, 2004, and ending on June 30, 2006, or during the 2-year period beginning on July 1, 2010. “(b) APPLICATION.—A cost reporting period described in this subsection is a cost reporting period beginning during the period beginning on July 1, 2004, and ending on June 30, 2006, or during the 2-year period beginning on July 1, 2010. “(c) PROVISION AS PART OF OUTPATIENT HOSPITAL SERVICES.—For purposes of subsection (a), in determining whether clinical diagnostic laboratory services are furnished as part of outpatient services of a hospital, the Secretary [of Health and Human Services] shall apply the same rules that are used to determine whether clinical diagnostic laboratory services are furnished as an outpatient critical access hospital service under section 1834(d)(4) of the Social Security Act (42 U.S.C. 1395m(g)(4)).”

GAO REPORT ON PAYMENTS FOR BRACHYTHERAPY DEVICES

Pub. L. 108–173, title VI, §621(b)(3), Dec. 8, 2003, 117 Stat. 2311, provided that: “The Comptroller General of the United States shall conduct a study to determine appropriate payment amounts under section 1833(c)(16)(C) of the Social Security Act [subsec. (t)(16)(C) of this section], as added by paragraph (1), for devices of brachytherapy. Not later than January 1, 2005, the Comptroller General shall submit to Congress and the Secretary [of Health and Human Services] a report on the study conducted under this paragraph, and shall include specific recommendations for appropriate payments for such devices.”

MORATORIUM ON PHYSICAL THERAPY SERVICES CARRIED IN 2003


GAO REPORT ON PAYMENTS FOR INHALATION THERAPY


“(1) STUDY.—The Comptroller General of the United States shall conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the Medicare program.

“(2) REPORT.—Not later than 1 year after the date of enactment of this Act (Dec. 8, 2003), the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).”

TREATMENT OF CERTAIN CLINICAL DIAGNOSTIC LABORATORY TESTS FURNISHED TO HOSPITAL OUTPATIENTS IN CERTAIN RURAL AREAS


“(a) IN GENERAL.—Notwithstanding subsections (a), (b), and (h) of section 1833 of the Social Security Act (42 U.S.C. 1395g) and section 1844(d)(1) of such Act (42 U.S.C. 1395mm(d)(1)), in the case of any clinical diagnostic laboratory test covered under part B of title XVIII of such Act [this part] that is furnished during a cost reporting period described in subsection (b) by a hospital with fewer than 50 beds that is located in a qualified rural area (identified under paragraph (12)(B)(iii) of section 1834(l) of the Social Security Act (42 U.S.C. 1395l(m)), as added by section 414(c)) as part of outpatient services of the hospital, the amount of payment for such test shall be 100 percent of the reasonable costs of the hospital in furnishing such test.

“(b) APPLICATION.—A cost reporting period described in this subsection is a cost reporting period beginning during the period beginning on July 1, 2004, and ending on June 30, 2008, or during the 2-year period beginning on July 1, 2010.

“(c) PROVISION AS PART OF OUTPATIENT HOSPITAL SERVICES.—For purposes of subsection (a), in determining whether clinical diagnostic laboratory services are furnished as part of outpatient services of a hospital, the Secretary [of Health and Human Services] shall apply the same rules that are used to determine whether clinical diagnostic laboratory services are furnished as an outpatient critical access hospital service under section 1834(d)(4) of the Social Security Act (42 U.S.C. 1395m(g)(4)).”

EARLY REPORTING AND PSYCHIATRIC TREATMENT DEVICES

Pub. L. 109–171, title V, §5107(b), Feb. 8, 2006, 120 Stat. 457, provided that: “By not later than January 1, 2005, the Comptroller General shall submit to Congress and the Secretary [of Health and Human Services] a report on the study conducted under this paragraph, and shall include specific recommendations for appropriate payments for such devices.”

PROMPT SUBMISSION OF OVERDUE REPORTS ON PAYMENT AND UTILIZATION OF OUTPATIENT THERAPY SERVICES

outpatient therapy) and under section 221(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Reconciliation Act of 1999 (Appendix F, 113 Stat. 1301A–352), as enacted into law by section 100(a)(6) of Public Law 106–113 [set out as a note under this section] (relating to utilization patterns for outpatient therapy)."

GAO STUDY OF AMBULATORY SURGICAL CENTER PAYMENTS


"(1) STUDY.—
"(A) In general.—The Comptroller General of the United States shall conduct a study that compares the relative costs of procedures furnished in ambulatory surgical centers with the relative costs of procedures furnished in hospital outpatient departments under section 1833(t) of the Social Security Act (42 U.S.C. 1395x(t)). The study shall also examine how accurate the ambulatory surgical centers' cost categories reflect procedures furnished in ambulatory surgical centers.

"(B) Consideration of ASC data.—In conducting the study under paragraph (1), the Comptroller General shall consider data submitted by ambulatory surgical centers regarding the matters described in clauses (i) through (iii) of paragraph (2)(B).

"(2) REPORT AND RECOMMENDATIONS.—
"(A) REPORT.—Not later than January 1, 2005, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

"(B) RECOMMENDATIONS.—The report submitted under subparagraph (A) shall include recommendations on the following matters:

"(i) The appropriateness of using the groups of codes and relative weights established under the outpatient prospective payment system as the basis of payment for ambulatory surgical centers.

"(ii) If the relative weights under such hospital outpatient prospective payment system are appropriate for such purpose—

"(I) whether the payment rates for ambulatory surgical centers should be based on a uniform percentage of the payment rates or weights under such outpatient system; or

"(II) whether the payment rates for ambulatory surgical centers should vary, or the weights should be revised, based on specific procedures or types of services (such as ophthalmology and pain management services).

"(iii) Whether a geographic adjustment should be used for payment of services furnished in ambulatory surgical centers, and if so, the labor and nonlabor shares of such payment.

DEMONSTRATION PROJECT FOR COVERAGE OF CERTAIN PRESCRIPTION DRUGS AND BIOLOGICALS


"(a) DEMONSTRATION PROJECT.—The Secretary of Health and Human Services shall conduct a demonstration project under part B of title XVIII of the Social Security Act [this part] under which payment is made for drugs or biologicals that are prescribed as replacements for drugs and biologicals described in section 1395w–2(a) or 1361(q)(2)(A) of such Act (42 U.S.C. 1395w–2(a), 1361(q)(2)(A)), or both, for which payment is made under such part. Such project shall provide for cost-sharing with respect to such replacement drugs or biologicals in the same manner as cost-sharing applies with respect to part D [part D of this subchapter] drugs under standard prescription drug coverage (as defined in section 1860D–2(b) of the Social Security Act [section 1395w–162(b) of this title], as added by section 101(a)).

"(b) DEMONSTRATION PROJECT SITES.—The project established under this section shall be conducted in sites selected by the Secretary.

"(c) DURATION.—The Secretary shall conduct the demonstration project for the 2-year period beginning on the date that is 90 days after the date of the enactment of this Act [Dec. 8, 2003], but in no case may the project extend beyond December 31, 2005.

"(d) LIMITATION.—Under the demonstration project over the duration of the project, the Secretary may not provide—

"(1) coverage for more than 50,000 patients; and

"(2) more than $500,000,000 in funding.

"(e) REPORT.—Not later than July 1, 2006, the Secretary shall submit to Congress a report on the project. The report shall include an evaluation of patient access to care and patient outcomes under the project, as well as an analysis of the cost effectiveness of the project, including an evaluation of the costs savings (if any) to the Medicare program attributable to physicians' services and hospital outpatient departments services for administration of the biological."

PAYMENT FOR PANCREATIC ISLET CELL INVESTIGATIONAL TRANSPLANTS FOR MEDICARE BENEFICIARIES IN CLINICAL TRIALS


"(a) CLINICAL TRIAL.—

"(1) IN GENERAL.—The Secretary of Health and Human Services, acting through the National Institute of Diabetes and Digestive and Kidney Disorders, shall conduct a clinical investigation of pancreatic islet cell transplantation which includes Medicare beneficiaries.

"(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary such sums as may be necessary to conduct the clinical investigation under paragraph (1).

"(2) MEDICARE PAYMENT.—Not earlier than October 1, 2004, the Secretary shall pay for the routine costs as well as transplantation and appropriate related items and services (as described in subsection (c)) in the case of a clinical trial described in subsection (a) as if such transplantation were covered under part B of such part [this subchapter] and as would be paid under part A or part B of such title [part A of this subchapter or this part] for such beneficiary.

"(3) SCOPE OF PAYMENT.—For purposes of subsection (b):"

"(1) The term 'routine costs' means reasonable and necessary routine patient care costs (as defined in the Medicare Program Payment Policy Manual, section 30–1), including immunosuppressive drugs and other followup care.

"(2) The term 'transplantation and appropriate related items and services' means items and services related to the acquisition and delivery of the pancreatic islet cell transplantation, notwithstanding any national noncoverage determination contained in the Centers for Medicare & Medicaid Services Coverage Issues Manual.

"(3) The term 'medicare beneficiary' means an individual who is entitled to benefits under part A of title XVIII of the Social Security Act [this part of this subchapter], or enrolled under part B of such title [this part, or both).

"(a) DEMONSTRATION PROJECT.—The provisions of this section shall not be construed—

"(1) to permit payment for partial pancreatic tissue or islet cell transplantation under title XVIII of the Social Security Act [this subchapter] other than payment as described in subsection (b); or

"(2) as authorizing or requiring coverage or payment.

"(A) benefits under part A of such title [part A of this subchapter] to a beneficiary not entitled to such part A; or

"(B) benefits under part B of such title [this part] to a beneficiary not enrolled in such part B;"

GAO STUDY OF REDUCTION IN MEDICARE PREMIUM LEVELS RESULTING FROM REDUCTIONS IN COINSURANCE

Pub. L. 106–554, § 1(a)(6) [title I, § 111(c)], Dec. 21, 2000, 114 Stat. 2783, 2783A–473, provided that: "The Comptrol-
ler General of the United States shall work, in concert with the National Association of Insurance Commissioners, to evaluate the extent to which the premium levels for medicare supplemental policies reflect the reductions in coinsurance resulting from the amendment made by subsection (a) [amending this section]. Not later than April 1, 2004, the Comptroller General shall submit to Congress a report on such evaluation and the extent to which the reductions in beneficiary coinsurance required by law have resulted in actual savings to medicare beneficiaries.”

MEDPAC STUDY ON LOW-VOLUME, ISOLATED RURAL HEALTH CARE PROVIDERS

Pub. L. 106–554, §1(a)(6) [title IV, §421(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–516, provided that:

“(1) STUDY.—The Secretary of Health and Human Services shall conduct a study of the effect of low patient and procedure volume on the financial status of low-volume, isolated rural health care providers participating in the medicare program under title XVIII of the Social Security Act [this subchapter].

“(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) indicating—

“(1) whether low-volume, isolated rural health care providers are having, or may have, significantly decreased medicare margins or other financial difficulties resulting from any of the payment methodologies described in subsection (c);

“(2) whether the status as a low-volume, isolated rural health care provider should be designated under the medicare program and any criteria that should be used to qualify for such a status; and

“(3) any changes in the payment methodologies described in subsection (c) that are necessary to provide appropriate reimbursement under the medicare program to low-volume, isolated rural health care providers (as designated pursuant to paragraph (2)).

“(c) PAYMENT METHODOLOGIES DESCRIBED.—The payment methodologies described in this subsection are the following:

“(1) The prospective payment system for hospital outpatient department services under section 1833(t) of the Social Security Act (42 U.S.C. 1395fff).

“(2) The fee schedule for ambulance services under section 1834(m) of such Act (42 U.S.C. 1395mm).

“(3) The prospective payment system for inpatient hospital services under section 1886 of such Act (42 U.S.C. 1395ww).

“(4) The prospective payment system for routine service costs of skilled nursing facilities under section 1864(e) of such Act (42 U.S.C. 1395yy).

“(5) The prospective payment system for home health services under section 1855 of such Act (42 U.S.C. 1395ff).

SPECIAL RULE FOR PAYMENT FOR 2001

Pub. L. 106–554, §1(a)(6) [title IV, §401(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–503, provided that: “Notwithstanding the amendment made by subsection (a) [amending this section], for purposes of making payments under section 1833(t) of the Social Security Act (42 U.S.C. 1395fff) for covered OPD services furnished during 2001, the medicare OPD fee schedule amount under such section—

“(1) for services furnished on or after January 1, 2001, and before April 1, 2001, shall be the medicare OPD fee schedule amount for 2001 as 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 fee schedule amount (as determined taking into account the amendment made by subsection (a)), increased by a transitional percentage allowance equal to 0.32 percent (to account for the timing of implementation of the full market basket update).”

TRANSITION PROVISIONS APPLICABLE TO SUBSECTION (1)(6)(B)

Pub. L. 106–554, §1(a)(6) [title IV, §402(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–506, provided that:

“(1) IN GENERAL.—In the case of a medical device provided as part of a service (or group of services) furnished during the period before initial categories are implemented under subparagraph (B)(i) of section 1833(t)(6) of the Social Security Act (subsec. (t)(6)(B)(i) of this section) (as amended by subsection (a)), payment shall be made for such device under such section in accordance with the provisions in effect before the date of the enactment of this Act [Dec. 21, 2000]. In addition, beginning on the date that is 30 days after the date of the enactment of this Act, payment shall be made for such a device that is not included in a program memorandum described in such subparagraph if the Secretary of Health and Human Services determines that the device (including a device that would have been included in such program memoranda but not for the requirement of subparagraph (A)(iv)(D) of that section) is likely to be described by such an initial category.

“(2) APPLICATION OF CURRENT PROCESS.—Notwithstanding any other provision of law, the Secretary shall continue to accept applications with respect to medical devices under the process established pursuant to paragraph (6) of section 1833(t) of the Social Security Act [subsec. (t)(6) of this section] (as in effect on the day before the date of the enactment of this Act [Dec. 21, 2000]) through December 1, 2000, and any device—

“(A) with respect to which an application was submitted (pursuant to such process) on or before such date; and

“(B) that meets the requirements of clause (ii) or (iv) of subparagraph (A) (as determined pursuant to such process), shall be treated as a device with respect to which an initial category is required to be established under subparagraph (A)(iv)(D) of such paragraph (as amended by subsection (a)(2))).”

STUDY ON STANDARDS FOR SUPERVISION OF PHYSICAL THERAPY ASSISTANTS

Pub. L. 106–554, §1(a)(6) [title IV, §421(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–516, provided that:

“(1) STUDY.—The Secretary of Health and Human Services shall conduct a study of the implications—

“(A) of eliminating the ‘in the room’ supervision requirement for medicare payment for services of physical therapy assistants who are supervised by physical therapists; and

“(B) of such requirement on the cap imposed under section 1833(g) of the Social Security Act (42 U.S.C. 1395gg) on physical therapy services.

“(2) REPORT.—Not later than 18 months after the date of the enactment of this Act [Dec. 21, 2000], the Secretary shall submit to Congress a report on the study conducted under paragraph (1).”

DELAY IN IMPLEMENTATION OF PROSPECTIVE PAYMENT SYSTEM FOR AMBULATORY SURGICAL CENTERS


MEDPAC STUDY AND REPORT ON MEDICARE REIMBURSEMENT FOR SERVICES PROVIDED BY CERTAIN PROVIDERS

Pub. L. 106–554, §1(a)(6) [title IV, §434], Dec. 21, 2000, 114 Stat. 2763, 2763A–526, provided that:

“(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study on the appropriateness of the current payment rates under the medicare program under title XVIII of the Social Security Act [this subchapter] for services provided by a—
“(1) certified nurse-midwife (as defined in subsection (gg)(2) of section 1861 of such Act (42 U.S.C. 1395x));
(2) physician assistant (as defined in subsection (aa)(5)(A) of such section);
(3) nurse practitioner (as defined in such subsection); and
(4) clinical nurse specialist (as defined in subsection (aa)(5)(B) of such section).
The study shall separately examine the appropriateness of such payment rates for orthopedic physician assistant and clinical nurse specialist, taking into consideration the requirements for accreditation, training, and education.

“(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.’’

MEDPAC STUDY ON ACCESS TO OUTPATIENT PAIN MANAGEMENT SERVICES
Pub. L. 106-554, §1(a)(6) [title IV, §438], Dec. 21, 2000, 114 Stat. 2783, 2783A-528, provided that:

‘‘(a) Study.—The Medicare Payment Advisory Commission shall conduct a study on the barriers to coverage and payment for outpatient interventional pain medicine procedures under the medicare program under title XVIII of the Social Security Act [this subchapter]. Such study shall examine—

‘‘(1) the specific barriers imposed under the medicare program on the provision of pain management procedures in hospital outpatient departments, ambulatory surgery centers, and physicians’ offices; and

‘‘(2) the consistency of medicare payment policies for pain management procedures in those different settings.

‘‘(b) 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.’’

ESTABLISHMENT OF CODING AND PAYMENT PROCEDURES FOR NEW CLINICAL DIAGNOSTIC LABORATORY TESTS AND OTHER ITEMS ON A FEE SCHEDULE
Pub. L. 106-554, §1(a)(6) [title V, §531(b)], Dec. 21, 2000, 114 Stat. 2783, 2783A-547, provided that: ‘‘Not later than 1 year after the date of the enactment of this Act (Dec. 21, 2000), the Secretary of Health and Human Services shall establish procedures for coding and payment determination for the following categories of new clinical diagnostic laboratory tests and new durable medical equipment under part B of title XVIII of the Social Security Act [this part] that permit public consultation in a manner consistent with the procedures established for implementing coding modifications for ICD-9-CM.’’

REPORT ON PROCEDURES USED FOR ADVANCED, IMPROVED TECHNOLOGIES
Pub. L. 106-554, §1(a)(6) [title V, §551(c)], Dec. 21, 2000, 114 Stat. 2783, 2783A-547, provided that: ‘‘Not later than 1 year after the date of the enactment of this Act (Dec. 21, 2000), the Secretary of Health and Human Services shall submit to Congress a report that identifies the specific procedures used by the Secretary under part B of title XVIII of the Social Security Act [this part] to adjust payments for clinical diagnostic laboratory tests and durable medical equipment which are classified to existing codes where, because of an advance in technology with respect to the test or equipment, there has been a significant increase or decrease in the resources used in the test or in the manufacture of the equipment, and there has been a significant improvement in the performance of the test or equipment. The report shall include such recommendations for changes in law as may be necessary to assure fair and appropriate payment levels under such parts for such improved tests and equipment as reflects increased costs necessary to produce improved results.’’

CONGRESSIONAL INTENTION REGARDING BASE AMOUNTS IN APPL YING HOPD PPS
Pub. L. 106-113, div. B, §1000(a)(6) [title II, §231], Nov. 29, 1999, 113 Stat. 1596, 1501A-341, provided that: ‘‘With respect to determining the amount of copayments described in paragraph (3)(A)(ii) of section 1836 of the Social Security Act [subsec. (t) of this section], as added by section 423(a) of BBA [the Balanced Budget Act of 1997, Pub. L. 105-33], Congress finds that such amount should be determined without regard to such section, in a budget neutral manner with respect to aggregate payments to hospitals, and that the Secretary of Health and Human Services has the authority to determine such amount without regard to such section.’’

STUDY AND REPORT TO CONGRESS REGARDING SPECIAL TREATMENT OF RURAL AND CANCER HOSPITALS IN PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

‘‘(1) In general.—The Medicare Payment Advisory Commission (referred to in this section as ‘MedPAC’) shall conduct a study to determine the appropriate amounts and the appropriate methods of providing payments to hospitals described in paragraph (2) for covered OPD services (as defined in paragraph (1)(B) of section 1833(t) of the Social Security Act (42 U.S.C. 1395f(t))) based on the prospective payment system established by the Secretary in accordance with such section.

‘‘(2) Hospitals described.—The hospitals described in this paragraph are the following:

‘‘(A) A medicare-dependent, small rural hospital (as defined in section 1886(d)(5)(G)(iv) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(G)(iv)),

‘‘(B) A sole community hospital (as defined in section 1886(d)(5)(D)(iii) of such Act (42 U.S.C. 1395ww(d)(5)(D)(iii)),

‘‘(C) Rural health clinics (as defined in section 1861(aa)(2) of such Act (42 U.S.C. 1395x(aa)(2)),

‘‘(D) Rural referral centers (as so classified under section 1886(d)(5)(C) of such Act (42 U.S.C. 1395ww(d)(5)(C)),

‘‘(E) Any other rural hospital with not more than 100 beds.

‘‘(F) Any other rural hospital that the Secretary determines appropriate.

‘‘(G) A hospital described in section 1886(d)(1)(B)(v) of such Act (42 U.S.C. 1395ww(d)(1)(B)(v));

‘‘(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 the Secretary of Health and Human Services and 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.

‘‘(c) Comments.—Not later than 60 days after the date on which MedPAC submits the report under subsection (b) to the Secretary of Health and Human Services, the Secretary shall submit comments on such report to Congress.’’

GAO STUDY ON RESOURCES REQUIRED TO PROVIDE SAFE AND EFFECTIVE OUTPATIENT CANCER THERAPY
Pub. L. 106-115, div. B, §1000(a)(6) [title II, §213], Nov. 29, 1999, 113 Stat. 1596, 1501A-350, provided that: ‘‘(a) Study.—The Comptroller General of the United States shall conduct a nationwide study to determine the physician and non-physician clinical resources necessary to provide safe outpatient cancer therapy services and the appropriate payment rates for such services under the medicare program. In making such determination, the Comptroller General shall—

(1) determine the adequacy of practice expense relative value units associated with the utilization of those clinical resources;
“(2) determine the adequacy of work units in the practice expense formula; and

“(3) assess various standards to assure the provision of safe outpatient cancer therapy services.

“(b) REPORT TO CONGRESS.—The Comptroller General shall submit to Congress a report on the study conducted under subsection (a). The report shall include recommendations regarding practice expense adjustments to the payment methodology under part B of title XVIII of the Social Security Act [this part], including the development and inclusion of adequate work units to assure the adequacy of payment amounts for safe outpatient cancer therapy services. The study shall also include an estimate of the cost of implementing such recommendations.”

FOCUSED MEDICAL REVIEWS OF CLAIMS DURING MORATORIUM PERIOD

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §221(a)(2)], Nov. 29, 1999, 113 Stat. 1536, 1501A–351, as amended by Pub. L. 106–554, §1(a)(6) [title IV, §421(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–516, provided that: “During years in which paragraph (4) of section 1833(g) of the Social Security Act (42 U.S.C. 1395gg) applies, the Secretary of Health and Human Services shall conduct focused medical reviews of claims for reimbursement for services described in paragraph (5) or (6) of such section, with an emphasis on such claims for services that are provided to residents of skilled nursing facilities.”

STUDY AND REPORT ON UTILIZATION


“(1) STUDY.—

“(A) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study which compares—

“(i) utilization patterns (including nationwide patterns, and patterns by region, type of setting, and diagnosis or condition) of outpatient physical therapy services, outpatient occupational therapy services, and speech-language pathology services that are covered under the medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395) [this subchapter] and provided on or after January 1, 2000, with

“(ii) such patterns for such services that were provided in 1998 and 1999.

“(B) REVIEW OF CLAIMS.—In conducting the study under this subsection the Secretary of Health and Human Services shall review a statistically significant number of claims for reimbursement for the services described in subparagraph (A).

“(C) REPORT.—Not later than June 30, 2001, the Secretary of Health and Human Services shall submit a report to Congress on the study conducted under paragraph (1), together with any recommendations for legislation that the Secretary determines to be appropriate as a result of such study.”

PHASE-IN OF PPS FOR AMBULATORY SURGICAL CENTERS

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §226], Nov. 29, 1999, 113 Stat. 1536, 1501A–354, as amended by Pub. L. 106–554, §1(a)(6) [title IV, §424(b), (c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–518, 2763A–519, provided that: “If the Secretary of Health and Human Services implements a revised prospective payment system for services of ambulatory surgical facilities under section 1833(i) of the Social Security Act (42 U.S.C. 1395gg), prior to incorporating data from the 1999 medicare cost survey or a subsequent cost survey, such system shall be implemented in a manner so that—

“(1) in the first year of its implementation, only a proportion (specified by the Secretary and not to exceed one-fourth) of the payment for such services shall be made in accordance with such system and the remainder shall be made in accordance with current regulations; and

“(2) in each of the following 2 years a proportion (specified by the Secretary and not to exceed one-half and three-fourths, respectively) of the payment for such services shall be made under such system and the remainder shall be made in accordance with current regulations.

By not later than January 1, 2003, the Secretary shall incorporate data from a 1999 medicare cost survey or a subsequent cost survey for purposes of implementing or revising such system.”

MEFPAC STUDY ON POSTSURGICAL RECOVERY CARE CENTER SERVICES


“(1) IN GENERAL.—The Medicare Payment Advisory Commission shall conduct a study on the cost-effectiveness and efficacy of covering under the medicare program under title XVIII of the Social Security Act (this subchapter) services of a post-surgical recovery care center (that provides an intermediate level of recovery care following surgery). In conducting such study, the Commission shall consider data on these centers gathered in demonstration projects.

“(2) REPORT.—Not later than 1 year 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 in the report recommendations on the feasibility, costs, and savings of covering such services under the medicare program.”

MEDICARE REIMBURSEMENT FOR TELEHEALTH SERVICES


“(a) IN GENERAL.—For services furnished on and after January 1, 1999, and before October 1, 2001, the Secretary of Health and Human Services shall make payments from the Federal Supplementary Medical Insurance Trust Fund under part B of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) in accordance with the methodology described in subsection (b) for professional consultation via telecommunications systems with a physician (as defined in section 1861(r) of such Act (42 U.S.C. 1395rr)) or a practitioner (described in section 1842(b)(18)(C) of such Act (42 U.S.C. 1395u(b)(18)(C))) furnishing a service for which payment may be made under such part to a beneficiary under the medicare program residing in a county in a rural area (as defined in section 1866(d)(2)(D) of such Act (42 U.S.C. 1395ww(d)(2)(D))) that is designated as a health professional shortage area under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)), notwithstanding that the individual physician or practitioner providing the professional consultation is not at the same location as the physician or practitioner furnishing the service to that beneficiary.

“(b) METHODOLOGY FOR DETERMINING AMOUNT OF PAYMENTS.—Taking into account the findings of the report required under section 192 of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104–191; 110 Stat. 1988), the findings of the report required under paragraph (c), and any other findings related to the clinical efficacy and cost-effectiveness of telehealth applications, the Secretary shall establish a methodology for determining the amount of payments made under subsection (a) within the following parameters:

“(1) The payment shall [be] shared between the referring physician or practitioner and the consulting physician or practitioner. The amount of such payment shall not be greater than the current fee schedule of the consulting physician or practitioner for the health care services provided.

“(2) The payment shall not include any reimbursement for any telephone line charges or any facility charges, and a beneficiary may not be billed for any such charges or fees.

“(3) The payment shall be made subject to the coinsurance and deductible requirements under subsections (a)(1) and (b) of section 1833 of the Social Security Act (42 U.S.C. 1395).
“(4) The payment differential of section 1845(a)(3) of such Act (42 U.S.C. 1395w–4(a)(3)) shall apply to services furnished by non-participating physicians. The provisions of section 1848(g) of such Act (42 U.S.C. 1395w–4(g)) and section 1842(b)(18) of such Act (42 U.S.C. 1395w–4(d)).

(c) SUPPLEMENTAL REPORT.—Not later than January 1, 1999, the Secretary shall submit a report to Congress that shall contain a detailed analysis of—

“(1) how telemedicine and telehealth systems are expanding access to health care services;

“(2) the clinical efficacy and cost-effectiveness of telemedicine and telehealth applications;

“(3) the quality of telemedicine and telehealth services delivered; and

“(4) the reasonable cost of telecommunications charges incurred in practicing telemedicine and telehealth in rural, frontier, and underserved areas.

“(d) EXPANSION OF TELEHEALTH SERVICES FOR CERTAIN MEDICARE BENEFICIARIES.—

“(1) IN GENERAL.—Not later than January 1, 1999, the Secretary shall submit a report to Congress that examines the possibility of making payments from the Federal Supplementary Medical Insurance Trust Fund under part B of title XVIII of the Social Security Act (42 U.S.C. 1395) for professional consultation via telecommunications systems with such a physician or practitioner furnishing a service for which payment may be made under such part to a beneficiary described in paragraph (2), notwithstanding that the individual physician or practitioner providing the professional consultation is not at the same location as the physician or practitioner furnishing the service to that beneficiary.

“(2) BENEFICIARY DESCRIBED.—A beneficiary described in this paragraph is a beneficiary under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) who does not reside in a rural area (as so defined) that is designated as a health professional shortage area under section 332(a)(1) of the Public Health Service Act (42 U.S.C. 254e(a)(1)A), who is homebound or nursing homebound, and for whom being transferred for health care services imposes a serious hardship.

“REPORT.—The report described in paragraph (1) shall contain a detailed statement of the potential costs and savings to the Medicare program of making the payments described in that paragraph using various reimbursement schemes.

REPORT ON COVERAGE OF OUTPATIENT OCCUPATIONAL THERAPY SERVICES


(c) SUPPLEMENTAL REPORT.—Not later than January 1, 1999, the Secretary shall submit a report to Congress that shall contain a detailed analysis of—

“(1) how telemedicine and telehealth systems are expanding access to health care services;

“(2) the clinical efficacy and cost-effectiveness of telemedicine and telehealth applications;

“(3) the quality of telemedicine and telehealth services delivered; and

“(4) the reasonable cost of telecommunications charges incurred in practicing telemedicine and telehealth in rural, frontier, and underserved areas.

“(d) EXPANSION OF TELEHEALTH SERVICES FOR CERTAIN MEDICARE BENEFICIARIES.—

“(1) IN GENERAL.—Not later than January 1, 1999, the Secretary shall submit a report to Congress that examines the possibility of making payments from the Federal Supplementary Medical Insurance Trust Fund under part B of title XVIII of the Social Security Act (42 U.S.C. 1395) for professional consultation via telecommunications systems with such a physician or practitioner furnishing a service for which payment may be made under such part to a beneficiary described in paragraph (2), notwithstanding that the individual physician or practitioner providing the professional consultation is not at the same location as the physician or practitioner furnishing the service to that beneficiary.

“(2) BENEFICIARY DESCRIBED.—A beneficiary described in this paragraph is a beneficiary under the Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) who does not reside in a rural area (as so defined) that is designated as a health professional shortage area under section 332(a)(1) of the Public Health Service Act (42 U.S.C. 254e(a)(1)A), who is homebound or nursing homebound, and for whom being transferred for health care services imposes a serious hardship.

“REPORT.—The report described in paragraph (1) shall contain a detailed statement of the potential costs and savings to the Medicare program of making the payments described in that paragraph using various reimbursement schemes.

REPORT ON COVERAGE OF OUTPATIENT OCCUPATIONAL THERAPY SERVICES


Study and Report on Clinical Laboratory Tests

Section 4553(c) of Pub. L. 105–33 provided that:

“(1) IN GENERAL.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct a study of payments under part B of title XVIII of the Social Security Act (this part) for clinical laboratory tests. The study shall include a review of the adequacy of the current methodology and recommendations regarding alternative payment systems. The study shall also analyze and discuss the relationship between such payment systems and access to high quality laboratory tests for Medicare beneficiaries, including availability and access to new testing methodologies.

“(2) REPORT TO CONGRESS.—The Secretary shall, not later than 2 years after the date of enactment of this section [Aug. 5, 1997], report to the Committees on Ways and Means and Commerce of the House of Representatives and the Committee on Finance of the Senate on the study described in paragraph (1), including any recommendations for legislation.

ADJUSTMENTS TO PAYMENT AMOUNTS FOR NEW TECHNOLOGY INTRAOCULAR LENSES

Section 141(b) of Pub. L. 103–432 provided that:

“(1) ESTABLISHMENT OF PROCESS FOR REVIEW OF AMOUNTS.—Not later than 1 year after the date of enactment of this Act [Oct. 31, 1994], the Secretary of Health and Human Services (in this subsection referred to as the ‘Secretary’) shall develop and implement a process under which interested parties may request review by the Secretary of the appropriateness of the reimbursement amount provided under section 1833(g)(2)(A)(i) of the Social Security Act [subsec. (1)(2)(A)(ii) of this section] with respect to a class of new technology intracocular lenses. For purposes of the preceding sentence, an intracocular lens may not be treated as a new technology lens unless it has been approved by the Food and Drug Administration.

“(2) FACTORS CONSIDERED.—In determining whether to provide an adjustment of payment with respect to a particular lens under paragraph (1), the Secretary shall take into account whether use of the lens is likely to result in reduced risk of intraocular complications or trauma, accelerated postoperative recovery, reduced induced astigmatism, improved postoperative visual acuity, more stable postoperative vision, or other comparable clinical advantages.

“(3) NOTICE AND COMMENT.—The Secretary shall publish notice in the Federal Register from time to time (but no less often than once each year) of a list of the requests that the Secretary has received for review under this subsection, and shall provide for a 30-day comment period on the lenses that are the subjects of the requests contained in such notice. The Secretary shall publish a notice of the Secretary’s determinations with respect to intraocular lenses listed in the notice within 90 days after the close of the comment period.

“(4) EFFECTIVE DATE OF ADJUSTMENT.—Any adjustment of a payment amount (or payment limit) made under this subsection shall become effective not later than 30 days after the date on which the notice with respect to the adjustment is published under paragraph (3).

STUDY OF MEDICARE COVERAGE OF PATIENT CARE COSTS ASSOCIATED WITH CLINICAL TRIALS OF NEW CANCER THERAPIES

Section 142 of Pub. L. 103–432 directed Secretary of Health and Human Services to conduct a study, and to
submit a report to Congress not later than 2 years after Oct. 31, 1994, of effects of expressly covering under medicare program patient care costs for beneficiaries enrolled in clinical trials of new cancer therapies, where protocol for the trial has been approved by the National Cancer Institute or met similar scientific and ethical standards, including approval by an institutional review board.

STUDY OF ANNUAL CAP ON AMOUNT OF MEDICARE PAYMENT FOR OUTPATIENT PHYSICAL THERAPY AND OCCUPATIONAL THERAPY SERVICES

Section 143 of Pub. L. 101–432 directed Secretary of Health and Human Services to submit to Congress, not later than Jan. 1, 1996, study and report on appropriate-ness of continuing annual limitation on amount of payment for outpatient services of independently practicing physical and occupational therapists under medicare program, which was to include such recommenda-tions for changes in such annual limitation as Secretary found appropriate.

AMBULATORY SURGICAL CENTER SERVICES: INFLATION UPDATE

Section 13331 of Pub. L. 101–66 provided that: "The Secretary of Health and Human Services shall not pro-vide for any inflation update in the payment amounts under subparagraphs (A) and (B) of section 1833(1) of the Social Security Act [subsec. (1)(2)(A)(ii) of this section], the amount of payment de-termined under such section for an intraocular lens in-serted during or subsequent to cataract surgery fur-nished to an individual in an ambulatory surgical cen-ter on or after January 1, 1991, and before January 1, 1999, shall be equal to $150.''

FREEZE IN ALLOWANCE FOR INTRAOCULAR LENSES

Section 13333 of Pub. L. 101–66 provided that: "Not-withstanding section 1833(1)(2)(A)(iii) of the Social Security Act [subsec. (1)(2)(A)(ii) of this section], the amount of payment de-termined under such section for an intraocular lens inserted subsequent to or during cataract surgery in an ambulatory surgical center on or after January 1, 1994, and before January 1, 1999, shall be equal to $150.''

FREEZE IN ALLOWANCE FOR INTRAOCULAR LENSES

Section 4151(c)(3) of Pub. L. 101–508, as amended by Pub. L. 103–422, title I, §141(d), Oct. 31, 1994, 108 Stat. 4429, provided that: "Notwithstanding section 1833(1)(2)(A)(iii) of the Social Security Act [subsec. (1)(2)(A)(ii) of this section], the amount of payment de-termined under such section for an intraocular lens inserted during or subsequent to cataract surgery fur-nished to an individual in an ambulatory surgical cen-ter on or after the date of the enactment of this Act [Nov. 5, 1990] and on or before December 31, 1992, shall be equal to $200.''

REduction in Payments Under Part B During Final Two Months of 1990

Section 4158 of Pub. L. 101–508 provided that:
"(a) IN GENERAL.—Notwithstanding any other provi-sion of law (including any other provision of this Act, other than subsection (b)(4)), payments under part B of title XVIII of the Social Security Act [this part] for items and services furnished during the period begin-ning on November 1, 1990, and ending on December 31, 1990, shall be reduced by 2 percent, in accordance with subsection (b).

"(b) SPECIAL RULES FOR APPLICATION OF REDUCTION.—
"(1) PAYMENT ON THE BASIS OF COST REPORTING PERIODS.—In the case in which payment for services of a provider of services is made under part B of such title on a basis relating to the reasonable cost incurred for the services during a cost reporting period of the pro-vider, the reduction made under subsection (a) shall be applied to payment for costs for such services in-urred at any time during each cost reporting period of the provider any part of which occurs during the period described in such subsection, but only in the same proportion as the fraction of the cost reporting period that occurs during such period."

"(2) NO INCREASE IN BENEFICIARY CHARGES IN ASSIGNMENT-RELATED CASES.—If a reduction in payment amounts is made under subsection (a) for items or services under part B of such title is made on an assignment-related basis (as defined in section 1842(i)(1) of the Social Security Act [section 1395n(i)(1) of this title]), the person furnishing the items or services shall be considered to have accepted payment of the reasonable charge for the items or services, less any reduction in payment amount made under subsection (a), as payment in full."

"(3) TREATMENT OF PAYMENTS TO HEALTH MAINTENANCE ORGANIZATIONS.—Subsection (a) shall not apply to payments under risk-sharing contracts under sec-tion 1877 of the Social Security Act [section 1395mm of this title] or under similar contracts under section 402 of the Social Security Amendments of 1967 [Pub. L. 90–248, enacting section 1395b–1 of this title and amending section 1395l of this title] or section 221 of the Social Security Amendments of 1972 [Pub. L. 92–603, amending sections 1395b–1 and 1395l of this title and enacting provisions set out as a note under section 1395b–1 of this title]."

EFFECT ON STATE LAW

Conscientious objections of health care provider under state law unaffected by enactment of subsections (a)(1) and (b) of section 1833(1) of the Social Security Act [Pub. L. 101–508, set out as a note under section 1395cc of this title].

DEVELOPMENT OF CRITERIA REGARDING CONSULTATION WITH A PHYSICIAN

Section 613(c) of Pub. L. 101–239, as amended by Pub. L. 103–422, title I, §147(b), Oct. 31, 1994, 108 Stat. 4429, provided that: "The Secretary of Health and Human Services shall, taking into consideration concerns for patient confidentiality, develop criteria with respect to payment for qualified psychologist services and clinical social work services for which payment may be made directly to the psychologist or clinical social worker under part B of title XVIII of the Social Security Act [this part] under which such a psychologist or clinical social worker must agree to consult with a patient’s at-tending physician in accordance with such criteria."

Section 147(b) of Pub. L. 103–422 provided that the amendment made by that section to section 613(c) of Pub. L. 101–239, set out above, is effective with respect to services furnished on or after Jan. 1, 1991.

STUDY OF REIMBURSEMENT FOR AMBULANCE SERVICES

Section 6136 of Pub. L. 101–239 directed Secretary of Health and Human Services to conduct a study to de-termine adequacy and appropriateness of payment amounts under this subchapter for ambulance services and, not later than one year after Dec. 19, 1990, submit a report to Congress on results of the study, with re-port to include such recommendations for changes in medicare payment policy with respect to ambulance services as may be needed to ensure access by medicare beneficiaries to quality ambulance services in metropoli-tan and rural areas.

PRO PAC STUDY OF PAYMENTS FOR SERVICES IN HOSPITAL OUTPATIENT DEPARTMENTS

Section 6137 of Pub. L. 101–239, directed Prospective Payment Assessment Commission to conduct a study on payment under this subchapter for hospital out-patient services and, not later than July 1, 1990, and not later than Mar. 1, 1991, to submit reports to Con-gress on specified portions of the study, with the re-port to include such recommendations as the Commis-sion deemed appropriate, prior to repeal by Pub. L. 103–422, title I, §147(c)(1), Oct. 31, 1994, 108 Stat. 4429.

BUDGET NEUTRALITY

Section 8212(b) of Pub. L. 100–647 provided that: "The Secretary of Health and Human Services shall adjust the fees for transportation and personnel established..."
under section 1833(h)(3)(B) of the Social Security Act [subsec. (h)(3)(B) of this section] for tests not covered under the amendment made by subsection (a) (amending this section) in such manner that the total cost of fees under such section is the same as would have been the case without such amendment.'

ADJUSTMENT OF CONTRACTS WITH PREPAID HEALTH PLANS

For requirement that Secretary of Health and Human Services modify contracts under subsection (a)(1)(A) of this section to take into account amendments made by Pub. L. 100–360 and that such organizations make appropriate adjustments in their agreements with Medicare beneficiaries to take into account such amendments, see section 222 of Pub. L. 100–360, set out as a note under section 1395mm of this title.

STUDY AND REPORT TO CONGRESS RESPECTING INCENTIVE PAYMENTS FOR PHYSICIANS' SERVICES FURNISHED IN UNDERSERVED AREAS

Section 404(b) of Pub. L. 100–203 directed Secretary of Health and Human Services to study and report to Congress, by not later than Jan. 1, 1990, on feasibility of making additional payments described in section 1395mm of this title with respect to physician services performed in health manpower shortage areas located in urban areas, prior to repeal by Pub. L. 101–508, title IV, §4118(g)(1), Nov. 5, 1990, 104 Stat. 1388–70.

FEE SCHEDULES FOR PHYSICIAN PATHOLOGY SERVICES

Section 4050 of Pub. L. 100–203 directed Secretary of Health and Human Services to develop a relative value scale and fee schedules with updating index for payment of physician pathology services under this part, and to report to committees of Congress not later than Apr. 1, 1989, on the scale, schedules, and index, prior to repeal by Pub. L. 101–508, title IV, §4118(g)(3)(A), Nov. 5, 1990, 104 Stat. 1388–59.

APPLYING COPAYMENT AND DEDUCTIBLE TO CERTAIN OUTPATIENT PHYSICIANS' SERVICES

Section 4054 of Pub. L. 100–203, relating to copayment under part B of title XVIII of the Social Security Act (this part) for physicians' services specified in subsec. (i) of this section and furnished on or after Apr. 1, 1988, in an ambulatory surgical center or hospital outpatient department on an assignment-related basis, was negated in the amendment of section 4054 by Pub. L. 100–360, title IV, §4117(f)(2), July 1, 1988, 102 Stat. 781.

OTHER PHYSICIAN PAYMENT STUDIES

Section 4056(c), formerly §4055(c), of Pub. L. 100–203, as renumbered by Pub. L. 100–360, title IV, §4111(f)(14), July 1, 1988, 102 Stat. 781, provided directed Secretary to (1) conduct a study of changes in the payment system for physicians' services, under part B, that would be required for the implementation of a national fee schedule for such services furnished on or after Jan. 1, 1990, and report to Congress on such study by not later than July 1, 1989, (2) conduct a study of issues relating to the volume and intensity of physicians' services under part B and submit to Congress an interim report on such study not later than May 1, 1988, and a final report on such study not later than May 1, 1989, and (3) conduct a survey to determine distribution of (A) the liabilities and expenditures for health care services of individuals entitled to benefits under this subchapter, including liabilities for charges (not paid on an assignment-related basis) in excess of the reasonable charge recognized, and (B) the collection rates among different classes of physicians for such liabilities, including collection rates for required coinsurance and for charges (not paid on an assignment-related basis) in excess of the reasonable charge recognized, report to Congress on such study by not later than July 1, 1990.

STUDY OF PAYMENT FOR CHEMOTHERAPY IN PHYSICIANS' OFFICES

Section 4056(d), formerly §4055(d), of Pub. L. 100–203, as renumbered by Pub. L. 100–360, title IV, §4111(f)(14), July 1, 1988, 102 Stat. 781, directed Secretary to study ways of modifying part B to permit adequate payment under such part for costs associated with providing chemotherapy to cancer patients in physicians' offices, with the Secretary to report to Congress on results of study by not later than Apr. 1, 1989, prior to repeal by Pub. L. 105–362, title VI, §601(b)(7), Nov. 10, 1998, 112 Stat. 3298.

CLINICAL DIAGNOSTIC LABORATORY TESTS; LIMITATION ON CHANGES IN FEE SCHEDULES

Section 4064(a) of Pub. L. 100–203 which provided 3-month freeze in fee schedules for clinical laboratory diagnostic laboratory tests under part B of title XVIII of the Social Security Act (this part) and directed the Secretary of Health and Human Services to not adjust the fee schedules established under subsec. (b) of this section to take into account any increase in the consumer price index, was negated in the amendment of section 4064(a) by Pub. L. 100–360, title IV, §4118(g)(3)(A), July 1, 1988, 102 Stat. 781.

GAO STUDY OF FEE SCHEDULES

Section 4064(b)(4) of Pub. L. 100–203 directed Comptroller General to conduct a study of level of fee schedules established for clinical diagnostic laboratory services under subsec. (b)(2) of this section to determine, on costs of, and revenues received for, such tests the appropriateness of such schedules, with Comptroller General to report to Congress on results of such study by not later than Jan. 1, 1990, and with provision that suppliers of such tests which fail to provide Comptroller General with reasonable access to necessary records to carry out study being subject to exclusion from the Medicare program under section 1520a–7(a) of this title.

AMOUNTS PAID FOR INDEPENDENT RURAL HEALTH CLINIC SERVICES

Section 4067(b) of Pub. L. 100–203 provided that: "The Secretary of Health and Human Services shall report to Congress, by not later than March 1, 1989, on the adequacy of the amounts paid under title XVIII of the Social Security Act [this subchapter] for rural health clinic services provided by independent rural health clinics."

REPORT ON ESTABLISHMENT OF NATIONAL FEE SCHEDULES FOR PAYMENT OF CLINICAL DIAGNOSTIC LABORATORY TESTS


STATE STANDARDS FOR DIRECTORS OF CLINICAL LABORATORIES

Section 9339(d) of Pub. L. 99–509 provided that:

"(1) IN GENERAL.—If a State (as defined for purposes of title XVIII of the Social Security Act [this subchapter]) provides for the licensing or other standards with respect to the operation of clinical laboratories (including such laboratories in hospitals) in the State under which such a laboratory may be directed by an individual with certain qualifications, nothing in such title shall be construed as authorizing the Secretary of Health and Human Services to require such a laboratory, as a condition of payment or participation under such title, to be directed by an individual with other qualifications.

"(2) EFFECTIVE DATE.—Paragraph (1) shall take effect on January 1, 1987."
TRANSLATIONAL PROVISIONS FOR PAYMENT OF FEES FOR CLINICAL DIAGNOSTIC LABORATORY TESTS

Section 9303(a)(3) of Pub. L. 99–272 provided that: "The Secretary of Health and Human Services shall provide that the annual adjustment under section 1833(h) of the Social Security Act [subsec. (h) of this section] for 1986—

"(A) shall take effect on January 1, 1987,

"(B) shall apply for the 12-month period beginning on that date, and

"(C) shall take into account the percentage increase or decrease in the Consumer Price Index for all urban consumers (United States city average) occurring over an 18-month period, rather than over a 12-month period."

EXTENSION OF MEDICARE PHYSICIAN PAYMENT PROVISIONS

Amount of payment under this part for physicians' services furnished between Oct. 1, 1985, and Mar. 14, 1986, to be determined on the same basis as the amount of such services furnished on Sept. 30, 1985, see section 5(b) of Pub. L. 99–107, as amended, set out as a note under section 1395ww of this title.

FER SCHEDULES FOR DIAGNOSTIC LABORATORY TESTS AND FEASIBILITY OF DIRECT PAYMENTS TO PHYSICIANS; REPORT TO CONGRESS

Section 2303(i) of Pub. L. 98–369 provided that:

"(1) The Comptroller General shall report to the Congress—

"(A) the appropriateness of the fee schedules under section 1833(h) of the Social Security Act [subsec. (h) of this section] and their impact on the volume and quality of clinical diagnostic laboratory tests;

"(B) the potential impact of the adoption of a national fee schedule; and

"(C) the potential impact of applying a national fee schedule to clinical diagnostic laboratory tests provided by hospitals to their outpatients.

"(2) The Secretary of Health and Human Services shall report to the Congress with respect to the feasibility and desirability of direct payment to any physician for all clinical diagnostic laboratory tests ordered by such physician.

"(3) The reports required by paragraphs (1) and (2) shall be submitted not later than January 1, 1987."

PACEKEEPER REIMBURSEMENT REVIEW AND REFORM

Section 2304(a) of Pub. L. 98–369 provided that:

"(1) The Secretary of Health and Human Services shall issue revisions to the current guidelines for the payment under part B of title XVIII of the Social Security Act [this part] for the transtelephonic monitoring of cardiac pacemakers. Such revised guidelines shall include provisions regarding the specifications for and frequency of transtelephonic monitoring procedures which will be found to be reasonable and necessary.

"(2) (A) Except as provided in subparagraph (B), if the guidelines required by paragraph (1) have not been issued and put into effect by October 1, 1984, and until such guidelines have been issued and put into effect, payment may not be made under part B of title XVIII of the Social Security Act for transtelephonic monitoring procedures, with respect to a single-chamber cardiac pacemaker powered by lithium batteries, conducted more frequently than—

"(i) weekly during the first month after implantation,

"(ii) once every two months during the period representing 50 percent of the estimated life of the implanted device, and

"(iii) monthly thereafter.

"(B) Subparagraph (A) shall not apply in cases where the Secretary determines that special medical factors (including possible evidence that the pacemaker or lead malfunction) justify more frequent transtelephonic monitoring procedures."

PAYMENT FOR PREADMISSION DIAGNOSTIC TESTING PERFORMED IN PHYSICIAN'S OFFICE

Section 2305(c) of Pub. L. 98–369 provided that: "The amendments made by this section [amending this section and enacting provisions set out above] shall not be construed as prohibiting payment, subject to the applicable copayments, under part B of title XVIII of the Social Security Act [this part] for preadmission diagnostic testing performed in a physician's office to the extent such testing is otherwise reimbursable under regulations of the Secretary."

PROVIDERS OF SERVICES TO CALCULATE AND REPORT LESSER-OF-COST-OR-CHARGES DETERMINATIONS SEPARATELY WITH RESPECT TO PAYMENTS UNDER PARTS A AND B OF THIS SUBCHAPTER; ISSUANCE OF REGULATIONS

For provision directing the Secretary to issue regulations requiring providers of services to calculate and report the lesser-of-cost-or-charges determinations separately with respect to payments for services under parts A and B of this subchapter other than diagnostic tests under subsec. (h) of this section, see section 2308(a) of Pub. L. 98–369, set out as a note under section 1395f of this title.

DETERMINATION OF NOMINAL CHARGES FOR APPLYING NOMINALITY TEST

For provision directing the Secretary to provide, in addition to other rules deemed appropriate, that charges representing 60 percent or less of costs be considered nominal for purposes of applying the nominality test under subsec. (a)(2)(B)(i) of this section, see section 2308(b)(1) of Pub. L. 98–369, set out as a note under section 1395f of this title.

STUDY OF MEDICARE PART B PAYMENTS; COMPILATION OF CENTRALIZED CHARGE DATA BASE; REPORT TO CONGRESS

Section 2309 of Pub. L. 98–369 directed Director of Office of Technology Assessment to conduct a study of physician reimbursement under the Medicare program and make a report not later than Dec. 31, 1985, covering findings and recommendations on methods by which payment amounts and other program policies under the program might be modified, and directed that Secretary of Health and Human Services compile a centralized Medicare part B charge data base to aid in the study.

MONITORING PROVISION OF HEPATITIS B VACCINE; REVIEW OF CHANGES IN MEDICAL TECHNOLOGY

Section 2323(e) of Pub. L. 98–369 provided that: "The Secretary shall monitor the provision of hepatitis B vaccine under part B of title XVIII of the Social Security Act [this part], and shall review any changes in medical technology which may have an effect on the amounts which should be paid for such service."

REPORT ON PREADMISSION DIAGNOSTIC TESTING EXPENSES

Section 932(b) of Pub. L. 96–499 required a report to Congress, no later than one year after Dec. 5, 1980, on the policy respecting expenses incurred for preadmission diagnostic testing furnished to an individual at a hospital within seven days of an individual's admission to another hospital.

STUDY OF FEASIBILITY AND DESIRABILITY OF IMPOSING COPAYMENT REQUIREMENT ON RURAL HEALTH CLINIC VISITS; REPORT NOT LATER THAN DECEMBER 13, 1978

Section 1(c) of Pub. L. 95–210 directed Secretary of Health, Education, and Welfare to conduct a study of the feasibility and desirability of imposing a copayment for each visit to a rural health clinic services under this part and that Secretary report to appropriate committee of Congress,
not later than one year after Dec. 13, 1977, on such study.

Prohibition Against Payments in Cases of Nonsensitive to Monthly Benefits Under Subchapter II or Suspension of Benefits of Aliens Outside the United States

Section 104(b)(1) of Pub. L. 89–97 provided that: “No payments shall be made under part B of title XVII of the Social Security Act [this part] with respect to expenses incurred by an individual during any month for which such individual may not be paid monthly benefits under title II of such Act (subchapter II of this chapter) or for which such monthly benefits would be suspended if he were otherwise entitled thereto by reason of section 402(t) of this title (relating to suspension of benefits of aliens who are outside the United States).”

§ 1395m. Special payment rules for particular items and services

(a) Payment for durable medical equipment

(1) General rule for payment

(A) In general

With respect to a covered item (as defined in paragraph (13)) for which payment is determined under this subsection, payment shall be made in the frequency specified in paragraphs (2) through (7) and in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) Payment basis

Subject to subparagraph (F)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item, or

(ii) the payment amount recognized under paragraphs (2) through (7) of this subsection for the item;

except that clause (i) shall not apply if the covered item is furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.

(C) Exclusive payment rule

Subject to subparagraph (F)(ii), this subsection shall constitute the exclusive provision of this subchapter for payment for covered items under this part or under part A of this subchapter to a home health agency.

(D) Reduction in fee schedules for certain items

With respect to a seat-lift chair or transportable electrical nerve stimulator furnished on or after January 1, 1990, the Secretary shall reduce the payment amount applied under subparagraph (B)(ii) for such an item by 15 percent, and, in the case of a transcutaneous electrical nerve stimulator furnished on or after January 1, 1991, the Secretary shall further reduce such payment amount (as previously reduced) by 45 percent.

(E) Clinical conditions for coverage

(i) In general

The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

(ii) Requirements

The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1395x(r) of this title), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) and a prescription for the item.

(iii) Priority of establishment of standards

In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.

(iv) Standards for power wheelchairs

Effective on December 8, 2003, in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1395x(r)(1) of this title), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) has conducted a face-to-face examination of the individual and written a prescription for the item.

(v) Limitation on payment for covered items

Payment may not be made for a covered item under this subsection unless the item meets any standards established under this subparagraph for clinical condition of coverage.

(F) Application of competitive acquisition; limitation of inherent reasonableness authority

In the case of covered items furnished on or after January 1, 2011, subject to subparagraph (G), that are included in a competitive acquisition program in a competitive acquisition area under section 1395w–3(a) of this title—

(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined under such competitive acquisition program;

(ii) the Secretary may (and, in the case of covered items furnished on or after January 1, 2016, subject to clause (iii), shall) use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1395w–3 of this title and in the case of such adjustment, paragraph (10)(B) shall not be applied; and
(iii) in the case of covered items furnished on or after January 1, 2016, the Secretary shall continue to make such adjustments described in clause (ii) as, under such competitive acquisition programs, additional covered items are phased in or information is updated as contracts under section 1395w-3 of this title are recompeted in accordance with section 1395w-3(b)(3)(B) of this title.

(G) Use of information on competitive bid rates

The Secretary shall specify by regulation the methodology to be used in applying the provisions of subparagraph (F)(ii) and subsection (h)(1)(H)(ii). In promulgating such regulation, the Secretary shall consider the costs of items and services in areas in which such provisions would be applied compared to the payment rates for such items and services in competitive acquisition areas.

(2) Payment for inexpensive and other routinely purchased durable medical equipment

(A) In general

Payment for an item of durable medical equipment (as defined in paragraph (13))—

(i) the purchase price of which does not exceed $150.

(ii) which the Secretary determines is acquired at least 75 percent of the time by purchase, or

(iii) which is an accessory used in conjunction with a nebulizer, aspirator, or a ventilator excluded under paragraph (3)(A),

shall be made on a rental basis or in a lump-sum amount for the purchase of the item. The payment amount recognized for purchase or rental of such equipment is the amount specified in subparagraph (B) for purchase or rental, except that the total amount of payments with respect to an item may not exceed the payment amount specified in subparagraph (B) with respect to the purchase of the item.

(B) Payment amount

For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to the purchase or rental of an item furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the purchase or rental, respectively, of the item for the 12-month period ending on June 30, 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 33 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iii) in 1992 is the sum of (I) 76 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year (reduced by 10 percent, in the case of a blood glucose testing strip furnished after 1997 for an individual with diabetes).

(C) Computation of local payment amount and national limited payment amount

For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994, the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the weighted average of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the weighted average of all local payment amounts determined under such clause for such item,

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year,

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item or device for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(3) Payment for items requiring frequent and substantial servicing

(A) In general

Payment for a covered item (such as IPPB machines and ventilators, excluding ventilators that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices) for which there must be frequent and substantial servicing in order to avoid risk to the


patient’s health shall be made on a monthly basis for the rental of the item and the amount recognized is the amount specified in subparagraph (B).

(B) Payment amount

For purposes of subparagraph (A), the amount specified in this subparagraph, with respect to an item or device furnished in a carrier service area—

(i) in 1989 and in 1990 is the average reasonable charge in the area for the rental of the item or device for the 12-month period ending with June 1987, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987;

(ii) in 1991 is the sum of (I) 67 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(I) for 1991, and (II) 30 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1991;

(iii) in 1992 is the sum of (I) 33 percent of the local payment amount for the item or device computed under subparagraph (C)(i)(II) for 1992, and (II) 67 percent of the national limited payment amount for the item or device computed under subparagraph (C)(ii) for 1992; and

(iv) in 1993 and each subsequent year is the national limited payment amount for the item or device computed under subparagraph (C)(ii) for that year.

(C) Computation of local payment amount and national limited payment amount

For purposes of subparagraph (B)—

(i) the local payment amount for an item or device for a year is equal to—

(I) for 1991, the amount specified in subparagraph (B)(i) for 1990 increased by the covered item update for 1991, and

(II) for 1992, 1993, and 1994, the amount determined under this clause for the preceding year increased by the covered item update for the year; and

(ii) the national limited payment amount for an item or device for a year is equal to—

(I) for 1991, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item for that year, and

(II) for 1992 and 1993, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(III) for 1994, the local payment amount determined under clause (i) for such item or device for that year, except that the national limited payment amount may not exceed 100 percent of the median of all local payment amounts determined under such clause for such item for that year and may not be less than 85 percent of the median of all local payment amounts determined under such clause for such item for that year, and

(IV) for each subsequent year, the amount determined under this clause for the preceding year increased by the covered item update for such subsequent year.

(4) Payment for certain customized items

Payment with respect to a covered item that is uniquely constructed or substantially modified to meet the specific needs of an individual patient, and for that reason cannot be grouped with similar items for purposes of payment under this subchapter, shall be made in a lump-sum amount (A) for the purchase of the item in a payment amount based upon the carrier’s individual consideration for that item, and (B) for the reasonable and necessary maintenance and servicing for parts and labor not covered by the supplier’s or manufacturer’s warranty, when necessary during the period of medical need, and the amount recognized for such maintenance and servicing shall be paid on a lump-sum, as needed basis based upon the carrier’s individual consideration for that item.

(5) Payment for oxygen and oxygen equipment

(A) In general

Payment for oxygen and oxygen equipment shall be made on a monthly basis in the monthly payment amount recognized under paragraph (9) for oxygen and oxygen equipment (other than portable oxygen equipment), subject to subparagraphs (B), (C), (E), and (F).

(B) Add-on for portable oxygen equipment

When portable oxygen equipment is used, but subject to subparagraph (D), the payment amount recognized under subparagraph (A) shall be increased by the monthly payment amount recognized under paragraph (9) for portable oxygen equipment.

(C) Volume adjustment

When the attending physician prescribes an oxygen flow rate—

(i) exceeding 4 liters per minute, the payment amount recognized under subparagraph (A), subject to subparagraph (D), shall be increased by 50 percent, or

(ii) of less than 1 liter per minute, the payment amount recognized under subparagraph (A) shall be decreased by 50 percent.

(D) Limit on adjustment

When portable oxygen equipment is used and the attending physician prescribes an oxygen flow rate exceeding 4 liters per minute, there shall only be an increase under either subparagraph (B) or (C), whichever increase is larger, and not under both such subparagraphs.
(E) Recertification for patients receiving home oxygen therapy

In the case of a patient receiving home oxygen therapy services who, at the time such services are initiated, has an initial arterial blood gas value at or above a partial pressure of 56 or an arterial oxygen saturation at or above 89 percent (or such other values, pressures, or criteria as the Secretary may specify) no payment may be made under this part for such services after the expiration of the 90-day period that begins on the date the patient first receives such services unless the patient’s attending physician certifies that, on the basis of a follow-up test of the patient’s arterial blood gas value or arterial oxygen saturation conducted during the final 30 days of such 90-day period, there is a medical need for the patient to continue to receive such services.

(F) Rental cap

(i) In general

Payment for oxygen equipment (including portable oxygen equipment) under this paragraph may not extend over a period of continuous use (as determined by the Secretary) of longer than 36 months.

(ii) Payments and rules after rental cap

After the 36th continuous month during which payment is made for the equipment under this paragraph—

(I) the supplier furnishing such equipment under this subsection shall continue to furnish the equipment during any period of medical need for the remainder of the reasonable useful lifetime of the equipment, as determined by the Secretary;

(II) payments for oxygen shall continue to be made in the amount recognized for oxygen under paragraph (9) for the period of medical need; and

(III) maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier’s or manufacturer’s warranty, as determined by the Secretary to be appropriate for the equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(6) Payment for other covered items (other than durable medical equipment)

Payment for other covered items (other than durable medical equipment and other covered items described in paragraph (3), (4), or (5)) shall be made in a lump-sum amount for the purchase of the item in the amount of the purchase price recognized under paragraph (8).

(7) Payment for other items of durable medical equipment

(A) Payment

In the case of an item of durable medical equipment not described in paragraphs (2) through (6), the following rules shall apply:

(i) Rental

(I) In general

Except as provided in clause (iii), payment for the item shall be made on a monthly basis for the rental of the item during the period of medical need (but payments under this clause may not extend over a period of continuous use (as determined by the Secretary) of longer than 13 months).

(II) Payment amount

Subject to subclause (III) and subparagraph (B), the amount recognized for the item, for each of the first 3 months of such period, is 10 percent of the purchase price recognized under paragraph (8) with respect to the item, and, for each of the remaining months of such period, is 7.5 percent of such purchase price.

(III) Special rule for power-driven wheelchairs

For purposes of payment for power-driven wheelchairs, subclause (II) shall be applied by substituting “15 percent” and “6 percent” for “10 percent” and “7.5 percent”, respectively.

(ii) Ownership after rental

On the first day that begins after the 13th continuous month during which payment is made for the rental of an item under clause (i), the supplier of the item shall transfer title to the item to the individual.

(iii) Purchase agreement option for complex, rehabilitative power-driven wheelchairs

In the case of a complex, rehabilitative power-driven wheelchair, the time the supplier furnishes the item, the supplier shall offer the individual the option to purchase the item, and payment for such item shall be made on a lump-sum basis if the individual exercises such option.

(iv) Maintenance and servicing

After the supplier transfers title to the item under clause (ii) or in the case of a power-driven wheelchair for which a purchase agreement has been entered into under clause (iii), maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier’s or manufacturer’s warranty, as determined by the Secretary to be appropriate for the particular type of durable medical equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(B) Range for rental amounts

(i) For 1989

For items furnished during 1989, the payment amount recognized under subparagraph (A)(i) shall not be more than 115 percent, and shall not be less than 85 percent, of the prevailing charge established for
(8) Purchase price recognized for miscellaneous devices and items

For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for a covered item is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) Computation of local purchase price

Each carrier under section 1395m of this title shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price, for each item described—

(I) in paragraph (6) equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987, or

(ii) in paragraph (7) equal to the average of the purchase prices on the claims submitted on an assignment-related basis for the unused item supplied during the 6-month period ending with December 1986.

(ii) For 1990

For items furnished during 1990, clause (i) shall apply in the same manner as it applies to items furnished during 1989.

(C) Replacement of items

(i) Establishment of reasonable useful lifetime

In accordance with clause (iii), the Secretary shall determine and establish a reasonable useful lifetime for items of durable medical equipment for which payment may be made under this paragraph.

(ii) Payment for replacement items

If the reasonable lifetime of such an item, as so established, has been reached during a continuous period of medical need, or the carrier determines that the item is lost or irreparably damaged, the patient may elect to have payment for an item serving as a replacement for such item made—

(I) on a monthly basis for the rental of the replacement item in accordance with subparagraph (A); or

(ii) in the case of an item for which a purchase agreement has been entered into under subparagraph (A)(iii), in a lump-sum amount for the purchase of the item.

(iii) Length of reasonable useful lifetime

The reasonable useful lifetime of an item of durable medical equipment under this subchapter, a reasonable useful lifetime of 5 years is not appropriate with respect to a particular item, the Secretary shall establish an alternative reasonable lifetime for such item.

(B) Computation of national limited purchase price

With respect to the furnishing of a particular item in a year, the Secretary shall compute a national limited purchase price—

(i) for 1991, equal to the local purchase price computed under subparagraph (A)(ii) for the item for the year, except that such national limited purchase price may not exceed 100 percent of the weighted average of all local purchase prices for the item computed under such subparagraph for the year, and may not be less than 85 percent of the average of the purchase prices for the item computed under such subparagraph for the year.

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for 1991, and decreased by the percentage by which the average of the reasonable charges for claims paid for all items described in paragraph (7) is lower than the average of the purchase prices submitted for such items during the final 9 months of 1988; or

(iii) in 1994, 1995, and 1996, the amount determined under this subparagraph for the previous year increased by the covered item update for such subsequent year.

(iv) for each subsequent year, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year.

(C) Purchase price recognized

For purposes of paragraphs (6) and (7), the amount that is recognized under this paragraph as the purchase price for each item furnished—

1 So in original. The semicolon probably should be a comma.
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For purposes of paragraph (5), the amount that is recognized under this paragraph for payment for oxygen and oxygen equipment is the monthly payment amount described in subparagraph (C) of this paragraph.

The monthly payment amount described in subparagraph (C) of this paragraph for all items of oxygen and oxygen equipment amount shall be computed separately (i) for the covered item increase for the year.

(ii) for portable oxygen equipment (each such item furnished—

(A) Computation of local monthly payment rate

Each carrier under this section shall compute a base local payment rate for each item as follows:

(i) The carrier shall compute a base local average monthly payment rate per beneficiary as an amount equal to (I) the total reasonable charges for the item during the 12-month period ending with December 1986, divided by (II) the total number of months for all beneficiaries receiving the item in the area during the 12-month period for which the carrier made payment for the 6-month period ending with December 1987, or

(ii) The carrier shall compute a local average monthly payment rate for the item applicable—

(I) to 1989 and 1990, equal to 95 percent of the base local average monthly payment rate computed for the item increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987, or

(ii) to 1991, 1992, 1993, and 1994, equal to the local average monthly payment rate computed under this clause for the item for the previous year increased by the covered item increase for the year.

(B) Computation of national limited monthly payment rate

With respect to the furnishing of an item in a year, the Secretary shall compute a national limited monthly payment rate equal to—

(i) for 1991, the local monthly payment rate computed under subparagraph (A)(ii)(I);

(ii) in 1991, is the sum of (I) 67 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1991, and (II) 33 percent of the national limited purchase price computed under subparagraph (B) for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local purchase price computed under subparagraph (A)(ii)(II) for 1992, and (II) 67 percent of the national limited purchase price computed under subparagraph (B) for 1992; and

(iv) in 1993 or a subsequent year, is the national limited purchase price computed under subparagraph (B) for that year.

(9) Monthly payment amount recognized with respect to oxygen and oxygen equipment

For purposes of paragraph (5), the amount that is recognized under this paragraph for payment for oxygen and oxygen equipment is the monthly payment amount described in subparagraph (C) of this paragraph. Such amounts shall be computed separately (i) for all items of oxygen and oxygen equipment (other than portable oxygen equipment) and (ii) for portable oxygen equipment (each such group referred to in this paragraph as an “item”).

(A) Computation of local monthly payment rate

Each carrier under this section shall compute a base local payment rate for each item as follows:

(i) The carrier shall compute a base local average monthly payment rate per beneficiary as an amount equal to (I) the total reasonable charges for the item during the 12-month period ending with December 1986, divided by (II) the total number of months for all beneficiaries receiving the item in the area during the 12-month period for which the carrier made payment for the 6-month period ending with December 1987, or

(ii) The carrier shall compute a local average monthly payment rate for the item applicable—

(I) to 1989 and 1990, equal to 95 percent of the base local average monthly payment rate computed for the item increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 6-month period ending with December 1987, or

(ii) to 1991, 1992, 1993, and 1994, equal to the local average monthly payment rate computed under this clause for the item for the previous year increased by the covered item increase for the year.

(B) Computation of national limited monthly payment rate

With respect to the furnishing of an item in a year, the Secretary shall compute a national limited monthly payment rate equal to—

(i) for 1991, the local monthly payment rate computed under subparagraph (A)(ii)(I) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year, and may not be less than 85 percent of the weighted average of all local monthly payment rates computed for the item under such subparagraph for the year;

(ii) for 1992 and 1993, the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(iii) for 1994, the local monthly payment rate computed under subparagraph (A)(ii) for the item for the year, except that such national limited monthly payment rate may not exceed 100 percent of the median of all local monthly payment rates computed for the item under such subparagraph for the year;

(iv) for 1995, 1996, and 1997, equal to the amount determined under this subparagraph for the preceding year increased by the covered item update for such subsequent year;

(v) for 1998, 75 percent of the amount determined under this subparagraph for 1997; and

(vi) for 1999 and each subsequent year, 70 percent of the amount determined under this subparagraph for 1997.

(C) Monthly payment amount recognized

For purposes of paragraph (5), the amount that is recognized under this paragraph as the base monthly payment amount for each item furnished—

(i) in 1989 and in 1990, is 100 percent of the local average monthly payment rate computed under subparagraph (A)(ii) for the item;

(ii) in 1991, is the sum of (I) 67 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1991, and (II) 33 percent of the national limited monthly payment rate computed under subparagraph (B)(i) for the item for 1991;

(iii) in 1992, is the sum of (I) 33 percent of the local average monthly payment rate computed under subparagraph (A)(ii)(II) for the item for 1992, and (II) 67 percent of the national limited monthly payment rate computed under subparagraph (B)(ii) for the item for 1992; and

(iv) in a subsequent year, is the national limited monthly payment rate computed under subparagraph (B) for the item for that year.

(D) Authority to create classes

(i) In general

Subject to clause (ii), the Secretary may establish separate classes for any item of oxygen and oxygen equipment and sepa-
rate national limited monthly payment rates for each of such classes.

(ii) Budget neutrality
The Secretary may take actions under clause (i) only to the extent such actions do not result in expenditures for any year to be more or less than the expenditures which would have been made if such actions had not been taken.

(10) Exceptions and adjustments

(A) Areas outside continental United States
Exceptions to the amounts recognized under the previous provisions of this subsection shall be made to take into account the unique circumstances of covered items furnished in Alaska, Hawaii, or Puerto Rico.

(B) Requirement of physician order

If a supplier knowingly and willfully violates the previous sentence, the Secretary may apply sanctions against the supplier for such items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(F).

(C) Transcutaneous electrical nerve stimulator (TENS)
In order to permit an attending physician time to determine whether the purchase of a transcutaneous electrical nerve stimulator is medically appropriate for a particular patient, the Secretary may determine an appropriate payment amount for the initial rental of such item for a period of not more than 2 months. If such item is subsequently purchased, the payment amount with respect to such purchase is the payment amount determined under paragraph (2).

(11) Improper billing and requirement of physician order

(A) Improper billing for certain rental items
Notwithstanding any other provision of this subsection, a supplier of a covered item for which payment is made under this subsection and which is furnished on a rental basis shall continue to supply the item without charge (other than a charge provided under this subsection for the maintenance and servicing of the item) after rental payments may no longer be made under this subsection. If a supplier knowingly and willfully violates the previous sentence, the Secretary may apply sanctions against the supplier under section 1395u(j)(2) of this title in the same manner such sanctions may apply with respect to a physician.

(B) Requirement of physician order

(i) In general
The Secretary is authorized to require, for specified covered items, that payment may be made under this subsection with respect to the item only if a physician enrolled under section 1395cc(c)(1) of this title has communicated to the supplier, before delivery of the item, a written order for the item.

(ii) Requirement for face to face encounter
The Secretary shall require that such an order be written pursuant to the physician documenting that a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) has had a face-to-face encounter (including through use of telehealth under subsection (m) and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary.

(12) Regional carriers
The Secretary may designate, by regulation under section 1395u of this title, one carrier for one or more entire regions to process all claims within the region for covered items under this section.

(13) “Covered item” defined
In this subsection, the term “covered item” means durable medical equipment (as defined in section 1395x(n) of this title), including such equipment described in section 1395x(m)(5) of this title, but not including implantable items for which payment may be made under section 1395l(t) of this title.

(14) Covered item update
In this subsection, the term “covered item update” means, with respect to a year—

(A) for 1991 and 1992, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced by 1 percentage point;

(B) for 1993, 1994, 1995, 1996, and 1997, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year;

(C) for each of the years 1998 through 2000, 0 percentage points;

(D) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(E) for 2002, 0 percentage points;

(F) for 2003, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of 2002;

(G) for 2004 through 2006—

(i) subject to clause (ii), in the case of class III medical devices described in section 360c(a)(1)(C) of title 21, the percentage increase described in subparagraph (B) for the year involved; and

(ii) in the case of covered items not described in clause (i), 0 percentage points;

(H) for 2007—

(i) subject to clause (ii), in the case of class III medical devices described in sec-
tion 360c(a)(1)(C) of title 21, the percentage change determined by the Secretary to be appropriate taking into account recommendations contained in the report of the Comptroller General of the United States under section 302(c)(1)(B) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003; and
(ii) in the case of covered items not described in clause (i), 0 percentage points;
(I) for 2008—
(i) subject to clause (ii), in the case of class III medical devices described in section 360c(a)(1)(C) of title 21, the percentage increase described in subparagraph (B) (as applied to the payment amount for 2007 determined after the application of the percentage change under subparagraph (H)(i)); and
(ii) in the case of covered items not described in clause (i), 0 percentage points;
(J) for 2009—
(i) in the case of items and services furnished in any geographic area, if such items or services were selected for competitive acquisition in any area under the competitive acquisition program under section 1395w–3(a)(1)(B)(i)(I) of this title before July 1, 2008, including related accessories but only if furnished with such items and services selected for such competition and diabetic supplies but only if furnished through mail order, -9.5 percent; or
(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2008;
(K) for 2010, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year; and
(L) for 2011 and each subsequent year—
(i) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—
(ii) the productivity adjustment described in section 1395ww(b)(3)(B)(xi)(II) of this title.

The application of subparagraph (L)(ii) may result in the covered item update under this paragraph being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.

(15) Advance determinations of coverage for certain items

(A) Development of lists of items by Secretary

The Secretary may develop and periodically update a list of items for which payment may be made under this subsection that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization throughout a carrier’s entire service area or a portion of such area.

(B) Development of lists of suppliers by Secretary

The Secretary may develop and periodically update a list of suppliers of items for which payment may be made under this subsection with respect to whom—

(i) the Secretary has found that a substantial number of claims for payment under this part for items furnished by the supplier have been denied on the basis of the application of section 1395y(a)(1) of this title;
or
(ii) the Secretary has identified a pattern of overutilization resulting from the business practice of the supplier.

(C) Determinations of coverage in advance

A carrier shall determine in advance of delivery of an item whether payment for the item may not be made because the item is not covered or because of the application of section 1395y(a)(1) of this title if—

(i) the item is included on the list developed by the Secretary under subparagraph (A);
(ii) the item is furnished by a supplier included on the list developed by the Secretary under subparagraph (B); or
(iii) the item is a customized item (other than inexpensive items specified by the Secretary) and the patient to whom the item is to be furnished or the supplier requests that such advance determination be made.

(16) Disclosure of information and surety bond

The Secretary shall not provide for the issuance (or renewal) of a provider number for a supplier of durable medical equipment, for purposes of payment under this part for durable medical equipment furnished by the supplier, unless the supplier provides the Secretary on a continuing basis—

(A) with—

(i) full and complete information as to the identity of each person with an ownership or control interest (as defined in section 1320a–3(a)(2) of this title) in which the supplier or in any subcontractor (as defined by the Secretary in regulations) in which the supplier directly or indirectly has a 5 percent or more ownership interest; and
(ii) to the extent determined to be feasible under regulations of the Secretary, the name of any disclosing entity (as defined in section 1320a–3(a)(3) of this title) in which the supplier or in any subcontractor (as defined by the Secretary in regulations) in which the supplier directly or indirectly has a 5 percent or more ownership interest; and

(B) a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000 that the Secretary determines is commensurate with the volume of the billing of the supplier.

The Secretary may waive the requirement of a bond under subparagraph (B) in the case of a
supplier that provides a comparable surety bond under State law. The Secretary, at the Secretary’s discretion, may impose the requirements of the first sentence with respect to some or all providers of items or services under part A of this subchapter or some or all suppliers or other persons (other than physicians or other practitioners, as defined in section 1395a(b)(18)(C) of this title) who furnish items or services under this part.

(17) Prohibition against unsolicited telephone contacts by suppliers

(A) In general

A supplier of a covered item under this subsection may not contact an individual enrolled under this part by telephone regarding the furnishing of a covered item to the individual unless 1 of the following applies:

(i) The individual has given written permission to the supplier to make contact by telephone regarding the furnishing of a covered item.

(ii) The supplier has furnished a covered item to the individual and the supplier is contacting the individual only regarding the furnishing of such covered item.

(iii) If the contact is regarding the furnishing of a covered item other than a covered item already furnished to the individual, the supplier has furnished at least 1 covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

(B) Prohibiting payment for items furnished subsequent to unsolicited contacts

If a supplier knowingly contacts an individual in violation of subparagraph (A), no payment may be made under this part for any item subsequently furnished to the individual by the supplier.

(C) Exclusion from program for suppliers engaging in pattern of unsolicited contacts

If a supplier knowingly contacts individuals in violation of subparagraph (A) to such an extent that the supplier’s conduct establishes a pattern of contacts in violation of such subparagraph, the Secretary shall exclude the supplier from participation in the programs under this chapter, in accordance with the procedures set forth in subsections (c), (f), and (g) of section 1320a–7 of this title.

(18) Refund of amounts collected for certain disallowed items

(A) In general

If a nonparticipating supplier furnishes to an individual enrolled under this part a covered item for which no payment may be made under this part by reason of paragraph (17)(B), the supplier shall refund on a timely basis to the patient (and shall be liable to the patient for) any amounts collected from the patient for the item, unless—

(i) the supplier establishes that the supplier did not know and could not reasonably have been expected to know that payment may not be made for the item by reason of paragraph (17)(B), or

(ii) before the item was furnished, the patient was informed that payment under this part may not be made for that item and the patient has agreed to pay for that item.

(B) Sanctions

If a supplier knowingly and willfully fails to make refunds in violation of subparagraph (A), the Secretary may apply sanctions against the supplier in accordance with section 1395a(j)(2) of this title.

(C) Notice

Each carrier with a contract in effect under this part with respect to suppliers of covered items shall send any notice of denial of payment for covered items by reason of paragraph (17)(B) and for which payment is not requested on an assignment-related basis to the supplier and the patient involved.

(D) Timely basis defined

A refund under subparagraph (A) is considered to be on a timely basis only if—

(i) in the case of a supplier who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the supplier receives a denial notice under subparagraph (C), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the supplier receives notice of an adverse determination on reconsideration or appeal.

(19) Certain upgraded items

(A) Individual's right to choose upgraded item

Notwithstanding any other provision of this subchapter, the Secretary may issue regulations under which an individual may purchase or rent from a supplier an item of upgraded durable medical equipment for which payment would be made under this subchapter if the item were a standard item.

(B) Payments to supplier

In the case of the purchase or rental of an upgraded item under subparagraph (A)—

(i) the supplier shall receive payment under this subsection with respect to such item as if such item were a standard item;

(ii) the individual purchasing or renting the item shall pay the supplier an amount equal to the difference between the supplier’s charge and the amount under clause (i).

In no event may the supplier’s charge for an upgraded item exceed the applicable fee schedule amount (if any) for such item.

(C) Consumer protection safeguards

Any regulations under subparagraph (A) shall provide for consumer protection standards with respect to the furnishing of upgraded equipment under subparagraph (A). Such regulations shall provide for—

(i) determination of fair market prices with respect to an upgraded item;

(ii) full disclosure of the availability and price of standard items and proof of re-
except of such disclosure information by the beneficiary before the furnishing of the upgraded item;
(iii) conditions of participation for suppliers in the billing arrangement;
(iv) sanctions of suppliers who are determined to engage in coercive or abusive practices, including exclusion; and
(v) such other safeguards as the Secretary determines are necessary.

(20) Identification of quality standards

(A) In general

Subject to subparagraph (C), the Secretary shall establish and implement quality standards for suppliers of items and services described in subparagraph (D) to be applied by recognized independent accreditation organizations (as designated under subparagraph (B)) and with which such suppliers shall be required to comply in order to—

(i) furnish any such item or service for which payment is made under this part; and
(ii) receive or retain a provider or supplier number used to submit claims for reimbursement for any such item or service for which payment may be made under this subchapter.

(B) Designation of independent accreditation organizations

Not later than the date that is 1 year after the date on which the Secretary implements the quality standards under subparagraph (A), notwithstanding section 1395bb(a) of this title, the Secretary shall designate and approve one or more independent accreditation organizations for purposes of such subparagraph.

(C) Quality standards

The quality standards described in subparagraph (A) may not be less stringent than the quality standards that would otherwise apply if this paragraph did not apply and shall include consumer services standards.

(D) Items and services described

The items and services described in this subparagraph are the following items and services, as the Secretary determines appropriate:

(i) Covered items (as defined in paragraph (13)) for which payment may otherwise be made under this subsection.
(ii) Prosthetic devices and orthotics and prosthetics described in subsection (h)(4) of this section.
(iii) Items and services described in section 1395u(s)(2) of this title.

(E) Implementation

The Secretary may establish by program instruction or otherwise the quality standards under this paragraph, including subparagraph (F), after consultation with representatives of relevant parties. Such standards shall be applied prospectively and shall be published on the Internet website of the Centers for Medicare & Medicaid Services.

(F) Application of accreditation requirement

In implementing quality standards under this paragraph—

(i) subject to clause (ii) and subparagraph (G), the Secretary shall require suppliers furnishing items and services described in subparagraph (D) on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted to the Secretary evidence of accreditation by an accreditation organization designated under subparagraph (B) as meeting applicable quality standards, except that the Secretary shall not require under this clause pharmacies to obtain such accreditation before January 1, 2010, except that the Secretary shall not require a pharmacy to have submitted to the Secretary evidence of accreditation prior to January 1, 2011; and

(ii) in applying such standards and the accreditation requirement of clause (i) with respect to eligible professionals (as defined in section 1395w–4(k)(3)(B) of this title), and including such other persons, such as orthotists and prosthetists, as specified by the Secretary, furnishing such items and services—

(I) such standards and accreditation requirement shall not apply to such professionals and persons unless the Secretary determines that the standards being applied are designed specifically to be applied to such professionals and persons; and

(II) the Secretary may exempt such professionals and persons from such standards and requirement if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons with respect to the furnishing of such items and services.

(G) Application of accreditation requirement to certain pharmacies

(i) In general

With respect to items and services furnished on or after January 1, 2011, in implementing quality standards under this paragraph—

(I) subject to subclause (II), in applying such standards and the accreditation requirement of subparagraph (F)(i) with respect to pharmacies described in clause (ii) furnishing such items and services, such standards and accreditation requirement shall not apply to such pharmacies; and

(II) the Secretary may apply to such pharmacies an alternative accreditation requirement established by the Secretary if the Secretary determines such alternative accreditation requirement is more appropriate for such pharmacies.

(ii) Pharmacies described

A pharmacy described in this clause is a pharmacy that meets each of the following criteria:

(I) The total billings by the pharmacy for such items and services under this subchapter are less than 5 percent of total pharmacy sales, as determined
based on the average total pharmacy sales for the previous 3 calendar years, 3 fiscal years, or other yearly period specified by the Secretary.

(II) The pharmacy has been enrolled under section 1395cc(c)(1) of this title as a supplier of durable medical equipment, prosthetics, orthotics, and supplies, has been issued (which may include the renewal of) a provider number for at least 5 years, and for which a final adverse action (as defined in section 424.57(a) of title 42, Code of Federal Regulations) has not been imposed in the past 5 years.

(III) The pharmacy submits to the Secretary an attestation, in a form and manner, and at a time, specified by the Secretary, that the pharmacy meets the criteria described in subclauses (I) and (II). Such attestation shall be subject to section 1001 of title 18.

(IV) The pharmacy agrees to submit materials as requested by the Secretary, or during the course of an audit conducted on a random sample of pharmacies selected annually, to verify that the pharmacy meets the criteria described in subclauses (I) and (II). Materials submitted under the preceding sentence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods, as requested by the Secretary.

(21) Special payment rule for specified items and supplies

(A) In general

Notwithstanding the preceding provisions of this subsection, for specified items and supplies (described in subparagraph (B)) furnished during 2005, the payment amount otherwise determined under this subsection for such specified items and supplies shall be reduced by the percentage difference between—

(i) the amount of payment otherwise determined for the specified item or supply under this subsection for 2002, and

(ii) the amount of payment for the specified item or supply under chapter 89 of title 5, as identified in the column entitled “Median FEHP Price” in the table entitled “SUMMARY OF MEDICARE PRICES COMPARED TO VA, MEDICAID, RETAIL, AND FEHP PRICES FOR 16 ITEMS” included in the Testimony of the Inspector General before the Senate Committee on Appropriations, June 12, 2002, or any subsequent report by the Inspector General.

(B) Specified item or supply described

For purposes of subparagraph (A), a specified item or supply means oxygen and oxygen equipment, standard wheelchairs (including standard power wheelchairs), nebulizers, diabetic supplies consisting of lancets and testing strips, hospital beds, and air mattresses, but only if the HCPCS code for the item or supply is identified in a table referred to in subparagraph (A)(ii).

(C) Application of update to special payment amount

The covered item update under paragraph (14) for specified items and supplies for 2006 and each subsequent year shall be applied to the payment amount under subparagraph (A) unless payment is made for such items and supplies under section 1395w–3 of this title.

(b) Fee schedules for radiologist services

(1) Development

The Secretary shall develop—

(A) a relative value scale to serve as the basis for the payment for radiologist services under this part, and

(B) using such scale and appropriate conversion factors and subject to subsection (c)(1)(A) of this section, fee schedules (on a regional, statewide, locality, or carrier service area basis) for payment for radiologist services under this part, to be implemented for such services furnished during 1989.

(2) Consultation

In carrying out paragraph (1), the Secretary shall regularly consult closely with the Physician Payment Review Commission, the American College of Radiology, and other organizations representing physicians or suppliers who furnish radiologist services and shall share with them the data and data analysis being used to make the determinations under paragraph (1), including data on variations in current medicare payments by geographic area, and by service and physician specialty.

(3) Considerations

In developing the relative value scale and fee schedules under paragraph (1), the Secretary—

(A) shall take into consideration variations in the cost of furnishing such services among geographic areas and among different sites where services are furnished, and

(B) may also take into consideration such other factors respecting the manner in which physicians in different specialties furnish such services as may be appropriate to assure that payment amounts are equitable and designed to promote effective and efficient provision of radiologist services by physicians in the different specialties.

(4) Savings

(A) Budget neutral fee schedules

The Secretary shall develop preliminary fee schedules for 1988, which are designed to result in the same amount of aggregate payments (net of any coinsurance and deductibles under sections 1395(a)(1)(J) and 1395(b) of this title) for radiologist services furnished in 1989 as would have been made if this subsection had not been enacted.

(B) Initial savings

The fee schedules established for payment purposes under this subsection for services furnished in 1989 shall be 97 percent of the amounts permitted under the preliminary fee schedules developed under subparagraph (A).

(C) 1990 fee schedules

For radiologist services (other than portable x-ray services) furnished under this
part during 1990, after March 31 of such year, the conversion factors used under this subsection shall be 96 percent of the conversion factors that applied under this subsection as of December 31, 1989.

(D) 1991 fee schedules

For radiologist services (other than portable X-ray services) furnished under this part during 1991, the conversion factors used in a locality under this subsection shall, subject to clause (vii), be reduced to the adjusted conversion factor for the locality determined as follows:

(i) National weighted average conversion factor
The Secretary shall estimate the national weighted average of the conversion factors used under this subsection for services furnished during 1990 beginning on April 1, using the best available data.

(ii) Reduced national weighted average
The national weighted average estimated under clause (i) shall be reduced by 13 percent.

(iii) Computation of 1990 locality index relative to national average
The Secretary shall establish an index which reflects, for each locality, the ratio of the conversion factor used in the locality under this subsection to the national weighted average estimated under clause (i).

(iv) Adjusted conversion factor
The adjusted conversion factor for the professional or technical component of a service in a locality is the sum of (I) the national weighted average conversion factor computed under clause (ii), and (II) the index value established under clause (iii) for the locality.

(v) Locally-adjusted amount
For purposes of clause (iv), the locally adjusted amount determined under this clause is the product of (I) the national weighted average conversion factor computed under clause (ii), and (II) the index value established under clause (iii) for the locality.

(vi) GPCI-adjusted amount
For purposes of clause (iv), the GPCI-adjusted amount determined under this clause is the sum of—

(I) the product of (a) the portion of the reduced national weighted average conversion factor computed under clause (ii) which is attributable to physician work and (b) the geographic work index value for the locality (specified in Addendum C to the Model Fee Schedule for Physician Services (published on September 4, 1990, 55 Federal Register pp. 36238-36243)); and

(II) the product of (a) the remaining portion of the reduced national weighted average conversion factor computed under clause (ii), and (b) the geographic practice cost index value specified in section 1395u(b)(14)(C)(iv) of this title for the locality.

In applying this clause with respect to the professional component of a service, 80 percent of the conversion factor shall be considered to be attributable to physician work and with respect to the technical component of the service, 0 percent shall be considered to be attributable to physician work.

(vii) Limits on conversion factor
The conversion factor to be applied to a locality to the professional or technical component of a service shall not be reduced under this subparagraph by more than 9.5 percent below the conversion factor applied in the locality under subparagraph (C) to such component, but in no case shall the conversion factor be less than 60 percent of the national weighted average of the conversion factors (computed under clause (i)).

(E) Rule for certain scanning services
In the case of the technical components of magnetic resonance imaging (MRI) services and computer assisted tomography (CAT) services furnished after December 31, 1990, the amount otherwise payable shall be reduced by 10 percent.

(F) Subsequent updating
For radiologist services furnished in subsequent years, the fee schedules shall be the schedules for the previous year updated by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year.

(G) Nonparticipating physicians and suppliers
Each fee schedule so established shall provide that the payment rate recognized for nonparticipating physicians and suppliers is equal to the appropriate percent (as defined in section 1395u(b)(4)(A)(iv) of this title) of the payment rate recognized for participating physicians and suppliers.

(5) Limiting charges of nonparticipating physicians and suppliers

(A) In general
In the case of radiologist services furnished after January 1, 1989, for which payment is made under a fee schedule under this subsection, if a nonparticipating physician or supplier furnishes the service to an individual entitled to benefits under this part, the physician or supplier may not charge the individual more than the limiting charge (as defined in subparagraph (B)).

(B) “Limiting charge” defined
In subparagraph (A), the term “limiting charge” means, with respect to a service furnished—

(i) in 1989, 125 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1),

(ii) in 1990, 120 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1), and
(iii) after 1990, 115 percent of the amount specified for the service in the appropriate fee schedule established under paragraph (1).

(C) Enforcement

If a physician or supplier knowingly and willfully bills in violation of subparagraph (A), the Secretary may apply sanctions against such physician or supplier in accordance with section 1395u(j)(2) of this title in the same manner as such sanctions may apply to a physician.

(6) “Radiologist services” defined

For the purposes of this subsection and section 1395(l)(a)(1)(J) of this title, the term “radiologist services” only includes radiology services performed by, or under the direction or supervision of, a physician—

(A) who is certified, or eligible to be certified, by the American Board of Radiology, or

(B) for whom radiology services account for at least 50 percent of the total amount of charges made under this part.

(c) Payment and standards for screening mammography

(1) In general

With respect to expenses incurred for screening mammography (as defined in section 1395x(jj) of this title), payment may be made only—

(A) for screening mammography conducted consistent with the frequency permitted under paragraph (2); and

(B) if the screening mammography is conducted by a facility that has a certificate (or provisional certificate) issued under section 263b of this title.

(2) Frequency covered

(A) In general

Subject to revision by the Secretary under subparagraph (B)—

(i) no payment may be made under this part for screening mammography performed on a woman under 35 years of age; and

(ii) payment may be made under this part for only one screening mammography performed on a woman over 34 years of age, but under 40 years of age; and

(iii) in the case of a woman over 39 years of age, payment may not be made under this part for screening mammography performed within 11 months following the month in which a previous screening mammography was performed.

(B) Revision of frequency

(i) Review

The Secretary, in consultation with the Director of the National Cancer Institute, shall review periodically the appropriate frequency for performing screening mammography, based on age and such other factors as the Secretary believes to be pertinent.

(ii) Revision of frequency

The Secretary, taking into consideration the review made under clause (i), may revise from time to time the frequency with which screening mammography may be paid for under this subsection.

(d) Frequency limits and payment for colorectal cancer screening tests

(1) Screening fecal-occult blood tests

(A) Payment amount

The payment amount for colorectal cancer screening tests consisting of screening fecal-occult blood tests is equal to the payment amount established for diagnostic fecal-occult blood tests under section 1395i(h) of this title.

(B) Frequency limit

No payment may be made under this part for a colorectal cancer screening test consisting of a screening fecal-occult blood test—

(i) if the individual is under 50 years of age; or

(ii) if the test is performed within the 11 months after a previous screening fecal-occult blood test.

(2) Screening flexible sigmoidoscopies

(A) Fee schedule

With respect to colorectal cancer screening tests consisting of screening flexible sigmoidoscopies, payment under section 1395w–4 of this title shall be consistent with payment under such section for similar or related services.

(B) Payment limit

In the case of screening flexible sigmoidoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic flexible sigmoidoscopy services.

(C) Facility payment limit

(i) In general

Notwithstanding subsections (i)(2)(A) and (t) of section 1395l of this title, in the case of screening flexible sigmoidoscopy services furnished on or after January 1, 1999, that—

(I) in accordance with regulations, may be performed in an ambulatory surgical center and for which the Secretary permits ambulatory surgical center payments under this part, and

(II) are performed in an ambulatory surgical center or hospital outpatient department,

payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) Limitation on coinsurance

Notwithstanding any other provision of this subchapter, in the case of a bene-
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ficiary who receives the services described in clause (i)—

(1) in computing the amount of any applicable copayment, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).

(D) Special rule for detected lesions

If during the course of such screening flexible sigmoidoscopy, a lesion or growth is detected which results in a biopsy or removal of the lesion or growth, payment under this part shall not be made for the screening flexible sigmoidoscopy but shall be made for the procedure classified as a flexible sigmoidoscopy with such biopsy or removal.

(E) Frequency limit

No payment may be made under this part for a colorectal cancer screening test consisting of a screening flexible sigmoidoscopy—

(i) if the individual is under 50 years of age; or

(ii) if the procedure is performed within the 47 months after a previous screening flexible sigmoidoscopy or, in the case of an individual who is not at high risk for colorectal cancer, if the procedure is performed within the 119 months after a previous screening colonoscopy.

(3) Screening colonoscopy

(A) Fee schedule

With respect to colorectal cancer screening test consisting of a screening colonoscopy, payment under section 1395w–4 of this title shall be consistent with payment amounts under such section for similar or related services.

(B) Payment limit

In the case of screening colonoscopy services, payment under this part shall not exceed such amount as the Secretary specifies, based upon the rates recognized for diagnostic colonoscopy services.

(C) Facility payment limit

(i) In general

Notwithstanding subsections (i)(2)(A) and (t) of section 1395f of this title, in the case of screening colonoscopy services furnished on or after January 1, 1999, that are performed in an ambulatory surgical center or a hospital outpatient department, payment under this part shall be based on the lesser of the amount under the fee schedule that would apply to such services if they were performed in a hospital outpatient department in an area or the amount under the fee schedule that would apply to such services if they were performed in an ambulatory surgical center in the same area.

(ii) Limitation on coinsurance

Notwithstanding any other provision of this subchapter, in the case of a beneficiar
(2) Accreditation organizations

(A) Factors for designation of accreditation organizations

The Secretary shall consider the following factors in designating accreditation organizations under subparagraph (B)(i) and in reviewing and modifying the list of accreditation organizations designated pursuant to subparagraph (C):

(i) The ability of the organization to conduct timely reviews of accreditation applications.

(ii) Whether the organization has established a process for the timely integration of new advanced diagnostic imaging services into the organization's accreditation program.

(iii) Whether the organization uses random site visits, site audits, or other strategies for ensuring accredited suppliers maintain adherence to the criteria described in paragraph (3).

(iv) The ability of the organization to take into account the capacities of suppliers located in a rural area (as defined in section 1395ww(d)(2)(D) of this title).

(v) Whether the organization has established reasonable fees to be charged to suppliers applying for accreditation.

(vi) Such other factors as the Secretary determines appropriate.

(B) Designation

Not later than January 1, 2010, the Secretary shall designate organizations to accredit suppliers furnishing the technical component of advanced diagnostic imaging services. The list of accreditation organizations so designated may be modified pursuant to subparagraph (C).

(C) Review and modification of list of accreditation organizations

(i) In general

The Secretary shall review the list of accreditation organizations designated under subparagraph (B) taking into account the factors under subparagraph (A), Taking into account the results of such review, the Secretary may, by regulation, modify the list of accreditation organizations designated under subparagraph (B).

(ii) Special rule for accreditations done prior to removal from list of designated accreditation organizations

In the case where the Secretary removes an organization from the list of accreditation organizations designated under subparagraph (B), any supplier that is accredited by the organization during the period beginning on the date on which the organization is designated as an accreditation organization under subparagraph (B) and ending on the date on which the organization is removed from such list shall be considered to have been accredited by an organization designated by the Secretary under subparagraph (B) for the remaining period such accreditation is in effect.

(3) Criteria for accreditation

The Secretary shall establish procedures to ensure that the criteria used by an accreditation organization designated under paragraph (2)(B) to evaluate a supplier that furnishes the technical component of advanced diagnostic imaging services for the purpose of accreditation of such supplier is specific to each imaging modality. Such criteria shall include—

(A) standards for qualifications of medical personnel who are not physicians and who furnish the technical component of advanced diagnostic imaging services;

(B) standards for qualifications and responsibilities of medical directors and supervising physicians, including standards that recognize the considerations described in paragraph (4);

(C) procedures to ensure that equipment used in furnishing the technical component of advanced diagnostic imaging services meets performance specifications;

(D) standards that require the supplier have procedures in place to ensure the safety of persons who furnish the technical component of advanced diagnostic imaging services and individuals to whom such services are furnished;

(E) standards that require the establishment and maintenance of a quality assurance and quality control program by the supplier that is adequate and appropriate to ensure the reliability, clarity, and accuracy of the technical quality of diagnostic images produced by such supplier; and

(F) any other standards or procedures the Secretary determines appropriate.

(4) Recognition in standards for the evaluation of medical directors and supervising physicians

The standards described in paragraph (3)(B) shall recognize whether a medical director or supervising physician—

(A) in a particular specialty receives training in advanced diagnostic imaging services in a residency program;

(B) has attained, through experience, the necessary expertise to be a medical director or a supervising physician;

(C) has completed any continuing medical education courses relating to such services; or

(D) has met such other standards as the Secretary determines appropriate.

(5) Rule for accreditations made prior to designation

In the case of a supplier that is accredited before January 1, 2010, by an accreditation organization designated by the Secretary under paragraph (2)(B), any supplier shall be considered to have been accredited by an organization designated by the Secretary under such paragraph as of January 1, 2010, for the remaining period such accreditation is in effect.

(6) Reduction in payments for physician pathology services during 1991

(1) In general

For physician pathology services furnished under this part during 1991, the prevailing charges used in a locality under this part shall be 7 percent below the prevailing charges used.
in the locality under this part in 1990 after March 31.

(2) Limitation

The prevailing charge for the technical and professional components of an \(^3\) physician pathology service furnished by a physician through an independent laboratory shall not be reduced pursuant to paragraph (1) to the extent that such reduction would reduce such prevailing charge below 115 percent of the prevailing charge for the professional component of such service when furnished by a hospital-based physician in the same locality. For purposes of the preceding sentence, an independent laboratory is a laboratory that is independent of a hospital and separate from the attending or consulting physicians’ office.

(g) Payment for outpatient critical access hospital services

(1) In general

The amount of payment for outpatient critical access hospital services of a critical access hospital is equal to 101 percent of the reasonable costs of the hospital in providing such services, unless the hospital makes the election under paragraph (2).

(2) Election of cost-based hospital outpatient service payment plus fee schedule for professional services

A critical access hospital may elect to be paid for outpatient critical access hospital services amounts equal to the sum of the following, less the amount that such hospital may charge as described in section 1395cc(a)(2)(A) of this title:

(A) Facility fee

With respect to facility services, not including any services for which payment may be made under subparagraph (B), 101 percent of the reasonable costs of the critical access hospital in providing such services.

(B) Fee schedule for professional services

With respect to professional services otherwise included within outpatient critical access hospital services, 101 percent of such amounts as would otherwise be paid under this part if such services were not included in outpatient critical access hospital services. Subsections (x) and (y) of section 1395l of this title shall not be taken into account in determining the amounts that would otherwise be paid pursuant to the preceding sentence.

The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician or other practitioner providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to those physicians and practitioners who have not assigned such billing rights.

(3) Disregarding charges

The payment amounts under this subsection shall be determined without regard to the amount of the customary or other charge.

\(^3\)So in original. Probably should be “a”.

(4) Treatment of clinical diagnostic laboratory services

No coinsurance, deductible, copayment, or other cost-sharing otherwise applicable under this part shall apply with respect to clinical diagnostic laboratory services furnished as an outpatient critical access hospital service. Nothing in this subchapter shall be construed as providing for payment for clinical diagnostic laboratory services furnished as part of outpatient critical access hospital services, other than on the basis described in this subsection. For purposes of the preceding sentence and section 1395x(m)(3) of this title, clinical diagnostic laboratory services furnished by a critical access hospital shall be treated as being furnished as part of outpatient critical access services without regard to whether the individual with respect to whom such services are furnished is physically present in the critical access hospital, or in a skilled nursing facility or a clinic (including a rural health clinic) that is operated by a critical access hospital, at the time the specimen is collected.

(5) Coverage of costs for certain emergency room on-call providers

In determining the reasonable costs of outpatient critical access hospital services under paragraphs (1) and (2)(A), the Secretary shall recognize as allowable costs, amounts (as defined by the Secretary) for reasonable compensation and related costs for physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services but who are not present on the premises of the critical access hospital involved, and are not otherwise furnishing services covered under this subchapter and are not on-call at any other provider or facility.

(h) Payment for prosthetic devices and orthotics and prosthetics

(1) General rule for payment

(A) In general

Payment under this subsection for prosthetic devices and orthotics and prosthetics shall be made in a lump-sum amount for the purchase of the item in an amount equal to 80 percent of the payment basis described in subparagraph (B).

(B) Payment basis

Except as provided in subparagraphs (C), (E), and (H)(i), the payment basis described in this subparagraph is the lesser of—

(i) the actual charge for the item; or

(ii) the amount recognized under paragraph (2) as the purchase price for the item.

(C) Exception for certain public home health agencies

Subparagraph (B)(i) shall not apply to an item furnished by a public home health agency (or by another home health agency which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low income) free of charge or at nominal charges to the public.
(D) Exclusive payment rule

Subject to subparagraph (H)(ii), this subsection shall constitute the exclusive provision of this subchapter for payment for prosthetic devices, orthotics, and prosthetics under this part or under part A of this subchapter to a home health agency.

(E) Exception for certain items

Payment for ostomy supplies, tracheostomy supplies, and urologicals shall be made in accordance with subparagraphs (B) and (C) of subsection (a)(2) of this section.

(F) Special payment rules for certain prosthetics and custom-fabricated orthotics

(i) In general

No payment shall be made under this subsection for an item of custom-fabricated orthotics described in clause (ii) or for an item of prosthetics unless such item is—

(I) furnished by a qualified practitioner; and

(II) fabricated by a qualified practitioner or a qualified supplier at a facility that meets such criteria as the Secretary determines appropriate.

(ii) Description of custom-fabricated item

(I) In general

An item described in this clause is an item of custom-fabricated orthotics that requires education, training, and experience to custom-fabricate and that is included in a list established by the Secretary in subclause (II). Such an item does not include shoes and shoe inserts.

(II) List of items

The Secretary, in consultation with appropriate experts in orthotics (including national organizations representing manufacturers of orthotics), shall establish and update as appropriate a list of items to which this subparagraph applies. No item may be included in such list unless the item is individually fabricated for the patient over a positive model of the patient.

(iii) Qualified practitioner defined

In this subparagraph, the term “qualified practitioner” means a physician or other individual who—

(I) is a qualified physical therapist or a qualified occupational therapist;

(II) in the case of a State that provides for the licensing of orthotics and prosthetics, is licensed in orthotics or prosthetics by the State in which the item is supplied; or

(III) in the case of a State that does not provide for the licensing of orthotics and prosthetics, is specifically trained and educated to provide or manage the provision of prosthetics and custom-designed or custom-fabricated orthotics, and is certified by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or is credentialed and approved by a program that is qualified and accredited by the Secretary of Health and Human Services.

(iv) Qualified supplier defined

In this subparagraph, the term “qualified supplier” means any entity that is qualified and accredited by the American Board for Certification in Orthotics and Prosthetics, Inc. or by the Board for Orthotist/Prosthetist Certification, or accredited and approved by a program that the Secretary determines has accreditation and approval standards that are essentially equivalent to those of such Board.

(G) Replacement of prosthetic devices and parts

(i) In general

Payment shall be made for the replacement of prosthetic devices which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if an ordering physician determines that the provision of a replacement device, or a replacement part of such a device, is necessary because of any of the following:

(I) A change in the patient’s condition.

(II) An irreparable change in the condition of the device, or in a part of the device.

(III) The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

(ii) Confirmation may be required if device or part being replaced is less than 3 years old

If a physician determines that a replacement device, or a replacement part, is necessary pursuant to clause (i)—

(I) such determination shall be controlling; and

(II) such replacement device or part shall be deemed to be reasonable and necessary for purposes of section 1395y(a)(1)(A) of this title; except that if the device, or part, being replaced is less than 3 years old (calculated from the date on which the beneficiary began to use the device or part), the Secretary may also require confirmation of necessity of the replacement device or replacement part, as the case may be.

(H) Application of competitive acquisition to orthotics; limitation of inherent reasonableness authority

In the case of orthotics described in paragraph (2)(C) of section 1395w–3(a) of this title furnished on or after January 1, 2011, subject to subsection (a)(1)(G), that are included in a competitive acquisition program in a competitive acquisition area under such section—
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(2) Purchase price recognized

For purposes of paragraph (1), the amount that is recognized under this paragraph as the purchase price for prosthetic devices, orthotics, and prosthetics is the amount described in subparagraph (C) of this paragraph, determined as follows:

(A) Computation of local purchase price

Each carrier under section 1395u of this title shall compute a base local purchase price for the item as follows:

(i) The carrier shall compute a base local purchase price for each item equal to the average reasonable charge in the locality for the purchase of the item for the 12-month period ending with June 1987.

(ii) The carrier shall compute a local purchase price, with respect to the furnishing of each particular item—

(I) in 1989 and 1990, equal to the base local purchase price computed under clause (i) increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 6-month period ending with December 1987, or

(II) in 1991, 1992 or 1993, equal to the local purchase price computed under this clause for the previous year increased by the applicable percentage increase for the year.

(B) Computation of regional purchase price

With respect to the furnishing of a particular item in each region (as defined by the Secretary), the Secretary shall compute a regional purchase price:

(i) for 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local purchase prices for the carriers in the region computed under subparagraph (A)(i)(II) for the year, and

(ii) for each subsequent year, equal to the regional purchase price computed under this subparagraph for the previous year increased by the applicable percentage increase for the year.

(C) Purchase price recognized

For purposes of paragraph (1) and subject to subparagraph (D), the amount that is recognized under this paragraph as the purchase price for each item furnished—

(i) in 1989, 1990, or 1991, is 100 percent of the local purchase price computed under subparagraph (A)(i); and

(ii) in 1992, is the sum of (I) 75 percent of the local purchase price computed under subparagraph (A)(i)(II) for 1992, and (II) 25 percent of the regional purchase price computed under subparagraph (B) for 1992; or

(iii) in 1993, is the sum of (I) 50 percent of the local purchase price computed under subparagraph (A)(i)(II) for 1993, and (II) 50 percent of the regional purchase price computed under subparagraph (B) for 1993; and

(iv) in 1994 or a subsequent year, is the regional purchase price computed under subparagraph (B) for that year.

(D) Range on amount recognized

The amount that is recognized under subparagraph (C) as the purchase price for an item furnished—

(i) in 1992, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year; and

(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year.

(3) Applicability of certain provisions relating to durable medical equipment

Paragraphs (12), (15), and (17) and subparagraphs (A) and (B) of paragraph (10) and paragraph (11) of subsection (a) of this section shall apply to prosthetic devices, orthotics, and prosthetics in the same manner as such provisions apply to covered items under such subsection.

(4) Definitions

In this subsection—

(A) the term “applicable percentage increase” means—

(i) for 1991, 0 percent;

(ii) for 1992 and 1993, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(iii) for 1994 and 1995, 0 percent;

(iv) for 1996 and 1997, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(v) for each of the years 1998 through 2000, 1 percent;

(vi) for 2001, the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 2000;

(vii) for 2002, 1 percent;

(viii) for 2003, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year;

(ix) for 2004, 2005, and 2006, 0 percent;
(x) for each of 2007 through 2010, the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year; and

(xi) for 2011 and each subsequent year—
(I) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—

(II) the productivity adjustment described in section 1395ww(b)(3)(B)(x)(II) of this title.

The application of subparagraph (A)(x)(II) may result in the applicable percentage increase under subparagraph (A) being less than 0.0 for a year, and may result in payment rates under this subsection for a year being less than such payment rates for the preceding year.

(B) the term “prosthetic devices” has the meaning given such term in section 1395x(s)(8) of this title, except that such term does not include parenteral and enteral nutrition nutrients, supplies, and equipment and does not include an implantable item for which payment may be made under section 1395(t) of this title;

(C) the term “orthotics and prosthetics” has the meaning given such term in section 1395x(s)(9) of this title (and includes shoes prescribed in section 1395x(s)(12) of this title), but does not include intraocular lenses or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1395x(m)(5) of this title.

(i) Payment for surgical dressings

(1) In general

Payment under this subsection for surgical dressings (described in section 1395x(s)(5) of this title) shall be made in a lump sum amount for the purchase of the item in an amount equal to 80 percent of the lesser of—

(A) the actual charge for the item; or

(B) a payment amount determined in accordance with the methodology described in subparagraphs (B) and (C) of subsection (a)(2) of this section (except that in applying such methodology, the national limited payment amount referred to in such subparagraphs shall be initially computed based on local payment amounts using average reasonable charges for the 12-month period ending December 31, 1992, increased by the covered item updates described in such subsection for 1993 and 1994).

(2) Exceptions

Paragraph (1) shall not apply to surgical dressings that are—

(A) furnished as an incident to a physician’s professional service; or

(B) furnished by a home health agency.

(j) Requirements for suppliers of medical equipment and supplies

(1) Issuance and renewal of supplier number

(A) Payment

Except as provided in subparagraph (C), no payment may be made under this part after October 31, 1994, for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number.

(B) Standards for possessing a supplier number

A supplier may not obtain a supplier number unless—

(i) for medical equipment and supplies furnished on or after October 31, 1994, and before January 1, 1996, the supplier meets standards prescribed by the Secretary in regulations issued on June 18, 1992; and

(ii) for medical equipment and supplies furnished on or after January 1, 1996, the supplier meets revised standards prescribed by the Secretary (in consultation with representatives of suppliers of medical equipment and supplies, carriers, and consumers) that shall include requirements that the supplier—

(I) comply with all applicable State and Federal licensure and regulatory requirements;

(II) maintain a physical facility on an appropriate site;

(III) have proof of appropriate liability insurance; and

(IV) meet such other requirements as the Secretary may specify.

(C) Exception for items furnished as incident to a physician’s service

Subparagraph (A) shall not apply with respect to medical equipment and supplies furnished incident to a physician’s service.

(D) Prohibition against multiple supplier numbers

The Secretary may not issue more than one supplier number to any supplier of medical equipment and supplies unless the issuance of more than one number is appropriate to identify subsidiary or regional entities under the supplier’s ownership or control.

(E) Prohibition against delegation of supplier determinations

The Secretary may not delegate (other than by contract under section 1395u of this title) the responsibility to determine whether suppliers meet the standards necessary to obtain a supplier number.

(2) Certificates of medical necessity

(A) Limitation on information provided by suppliers on certificates of medical necessity

(i) In general

Effective 60 days after October 31, 1994, a supplier of medical equipment and supplies may distribute to physicians, or to individuals entitled to benefits under this
part, a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier:

(I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.

(II) A description of such medical equipment and supplies.

(III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative information (other than information relating to the beneficiary’s medical condition) identified by the Secretary.

(ii) Information on payment amount and charges

If a supplier distributes a certificate of medical necessity containing any of the information permitted to be supplied under clause (i), the supplier shall also list on the certificate of medical necessity the fee schedule amount and the supplier’s charge for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician.

(iii) Penalty

Any supplier of medical equipment and supplies who knowingly and willfully distributes a certificate of medical necessity in violation of clause (i) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an amount not to exceed $1,000 for each such certificate of medical necessity so distributed. The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to civil money penalties under this paragraph as they apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(B) “Certificate of medical necessity” defined

For purposes of this paragraph, the term “certificate of medical necessity” means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(3) Coverage and review criteria

The Secretary shall annually review the coverage and utilization of items of medical equipment and supplies to determine whether such items should be made subject to coverage and utilization review criteria, and if appropriate, shall develop and apply such criteria to such items.

(4) Limitation on patient liability

If a supplier of medical equipment and supplies (as defined in paragraph (5))—

(A) furnishes an item or service to a beneficiary for which no payment may be made by reason of paragraph (1);

(B) furnishes an item or service to a beneficiary for which payment is denied in advance under subsection (a)(15) of this section; or

(C) furnishes an item or service to a beneficiary for which payment is denied under section 1395y(a)(1) of this title;

any expenses incurred for items and services furnished to an individual by such a supplier not on an assigned 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 subsection (a)(18) of this section shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such subsection.

(5) “Medical equipment and supplies” defined

The term “medical equipment and supplies” means—

(A) durable medical equipment (as defined in section 1395x(n) of this title);

(B) prosthetic devices (as described in section 1395x(s)(8) of this title);

(C) orthotics and prosthetics (as described in section 1395x(s)(9) of this title);

(D) surgical dressings (as described in section 1395x(s)(5) of this title);

(E) such other items as the Secretary may determine; and

(F) for purposes of paragraphs (1) and (3)—

(i) home dialysis supplies and equipment (as described in section 1395x(s)(2)(F) of this title),

(ii) immunosuppressive drugs (as described in section 1395x(s)(2)(J) of this title),

(iii) therapeutic shoes for diabetics (as described in section 1395x(s)(12) of this title),

(iv) oral drugs prescribed for use as an anticancer therapeutic agent (as described in section 1395x(s)(2)(Q) of this title), and

(v) self-administered erythropoetin (as described in section 1395x(s)(2)(P) of this title).

(k) Payment for outpatient therapy services and comprehensive outpatient rehabilitation services

(1) In general

With respect to services described in section 1395(a)(8) or 1395l(a)(9) of this title for which payment is determined under this subsection, the payment basis shall be—

(A) for services furnished during 1998, the amount determined under paragraph (2); or

(B) for services furnished during a subsequent year, 80 percent of the lesser of—

(i) the actual charge for the services, or

(ii) the applicable fee schedule amount (as defined in paragraph (3)) for the services.

(2) Payment in 1998 based upon adjusted reasonable costs

The amount under this paragraph for services is the lesser of—

(A) the charges imposed for the services, or
(B) the adjusted reasonable costs (as defined in paragraph (4)) for the services, less 20 percent of the amount of the charges imposed for such services.

(3) **Applicable fee schedule amount**

In this subsection, the term “applicable fee schedule amount” means, with respect to services furnished in a year, the amount determined under the fee schedule established under section 1395w–4 of this title for such services furnished during the year or, if there is no such fee schedule established for such services, the amount determined under the fee schedule established for such comparable services as the Secretary specifies.

(4) **Adjusted reasonable costs**

In paragraph (2), the term “adjusted reasonable costs” means, with respect to any services, reasonable costs determined for such services, reduced by 16 percent. The 16-percent reduction shall not apply to services described in section 1395w(a)(8)(B) of this title (relating to services provided by hospitals).

(5) **Uniform coding**

For claims for services submitted on or after April 1, 1998, for which the amount of payment is determined under this subsection, the claim shall include a code (or codes) under a uniform coding system specified by the Secretary that identifies the services furnished.

(6) **Restraint on billing**

The provisions of subparagraphs (A) and (B) of section 1395u(b)(18) of this title shall apply to therapy services for which payment is made under this subsection in the same manner as they apply to services provided by a practitioner described in section 1395u(b)(18)(C) of this title.

(1) **Establishment of fee schedule for ambulance services**

(1) **In general**

The Secretary shall establish a fee schedule for payment for ambulance services whether provided directly by a supplier or provider or under arrangement with a provider under this part through a negotiated rulemaking process described in title 5 and in accordance with the requirements of this subsection.

(2) **Considerations**

In establishing such fee schedule, the Secretary shall—

(A) establish mechanisms to control increases in expenditures for ambulance services under this part;

(B) establish definitions for ambulance services which link payments to the type of services provided;

(C) consider appropriate regional and operational differences;

(D) consider adjustments to payment rates to account for inflation and other relevant factors; and

(E) phase in the application of the payment rates under the fee schedule in an efficient and fair manner consistent with paragraph (11), except that such phase-in shall provide for full payment of any national mileage rate for ambulance services provided by suppliers that are paid by carriers in any of the 50 States where payment by a carrier for such services for all such suppliers in such State did not, prior to the implementation of the fee schedule, include a separate amount for all mileage within the county from which the beneficiary is transported.

(3) **Savings**

In establishing such fee schedule, the Secretary shall—

(A) ensure that the aggregate amount of payments made for ambulance services under this part during 2000 does not exceed the aggregate amount of payments which would have been made for such services under this part during such year if the amendments made by section 4531(a) of the Balanced Budget Act of 1997 continued in effect, except that in making such determination the Secretary shall assume an update in such payments for 2002 equal to percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points;

(B) set the payment amounts provided under the fee schedule for services furnished in 2001 and each subsequent year at amounts equal to the payment amounts under the fee schedule for services furnished during the previous year, increased, subject to subparagraph (C) and the succeeding sentence of this paragraph, by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points; and

(C) for 2011 and each subsequent year, after determining the percentage increase under subparagraph (B) for the year, reduce such percentage increase by the productivity adjustment described in section 1395ww(b)(3)(B)(xl)(II) of this title.

The application of subparagraph (C) may result in the percentage increase under subparagraph (B) being less than 0.0 for a year, and may result in payment rates under the fee schedule under this subsection for a year being less than such payment rates for the preceding year.

(4) **Consultation**

In establishing the fee schedule for ambulance services under this subsection, the Secretary shall consult with various national organizations representing individuals and entities who furnish and regulate ambulance services and share with such organizations relevant data in establishing such schedule.

(5) **Limitation on review**

There shall be no administrative or judicial review under section 1395ff of this title or otherwise of the amounts established under the fee schedule for ambulance services under this subsection, including matters described in paragraph (2).
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(6) Restraint on billing

The provisions of subparagraphs (A) and (B)
of section 1395u(b)(18) of this title shall apply
to ambulance services for which payment is
made under this subsection in the same man-
ner as they apply to services provided by a practi-
citioner described in section
1395u(b)(18)(C) of this title.

(7) Coding system

The Secretary may require the claim for any
services for which the amount of payment is
determined under this subsection to include a
code (or codes) under a uniform coding system
specified by the Secretary that identifies the
services furnished.

(8) Services furnished by critical access hos-
pitals

Notwithstanding any other provision of this
subsection, the Secretary shall pay 101 percent
of the reasonable costs incurred in furnishing
ambulance services if such services are fur-
nished—

(A) by a critical access hospital (as defined
in section 1395x(mm)(1) of this title), or
(B) by an entity that is owned and oper-
ated by a critical access hospital,
but only if the critical access hospital or en-
tity is the only provider or supplier of ambu-
ランス services that is located within a 35-mile
drive of such critical access hospital.

(9) Transitional assistance for rural providers

In the case of ground ambulance services
furnished on or after January 1, 2001, and before
January 1, 2004, for which the transportation
originates in a rural area (as defined in section
1395w(d)(2)(D) of this title) or in a rural cen-
sus tract of a metropolitan statistical area
(as determined under the most recent modifica-
tion of the Goldsmith Modification, originally
published in the Federal Register on February
27, 1992 (57 Fed. Reg. 6725)), the fee schedule
established under this subsection shall provide
that, with respect to the payment rate for
mileage for a trip above 17 miles, and up to 50
miles, the rate otherwise established shall be
increased by not less than ½ of the additional
payment per mile established for the first 17
miles of such a trip originating in a rural area.

(10) Phase-in providing floor using blend of fee
schedule and regional fee schedules

In carrying out the phase-in under para-
graph (2)(E) for each level of ground service
furnished in a year, the portion of the pay-
ment amount that is based on the fee schedule
shall be the greater of the amount determined
under such fee schedule (without regard to
this paragraph) or the following blended rate
of the fee schedule under paragraph (1) and of a
regional fee schedule for the region involved:

(A) For 2004 (for services furnished on or
after July 1, 2004), the blended rate shall be
based 20 percent on the fee schedule under
paragraph (1) and 80 percent on the regional
fee schedule.

(B) For 2005, the blended rate shall be
based 40 percent on the fee schedule under
paragraph (1) and 60 percent on the regional
fee schedule.

(C) For 2006, the blended rate shall be
based 60 percent on the fee schedule under
paragraph (1) and 40 percent on the regional
fee schedule.

(D) For 2007, 2008, and 2009, the blended
rate shall be based 80 percent on the fee
schedule under paragraph (1) and 20 percent
on the regional fee schedule.

(E) For 2010 and each succeeding year, the
blended rate shall be based 100 percent on
the fee schedule under paragraph (1).

For purposes of this paragraph, the Secretary
shall establish a regional fee schedule for each
of the nine census divisions (referred to in sec-
tion 1395ww(d)(2) of this title) using the meth-
odology (used in establishing the fee schedule
under paragraph (1)) to calculate a regional
conversion factor and a regional mileage pay-
ment rate and using the same payment adjust-
ments and the same relative value units as
used in the fee schedule under such paragraph.

(11) Adjustment in payment for certain long
trips

In the case of ground ambulance services
furnished on or after July 1, 2004, and before
January 1, 2009, regardless of where the trans-
portation originates, the fee schedule estab-
lished under this subsection shall provide
that, with respect to the payment rate for
mileage for a trip above 50 miles the per mile
rate otherwise established shall be increased
by ¼ of the payment per mile otherwise appli-
cable to miles in excess of 50 miles in such
trip.

(12) Assistance for rural providers furnishing
services in low population density areas

(A) In general

In the case of ground ambulance services
furnished on or after July 1, 2004, and before
January 1, 2012, for which the transportation
originates in a rural area (identified under para-
graph (B)(ii)), the Secretary shall provide for a percent increase in
the base rate of the fee schedule for a trip
established under this subsection. In estab-
lishing such percent increase, the Secretary
shall estimate the average cost per trip for
such services (not taking into account mile-
age) in the lowest quartile as compared to
the average cost per trip for such services
(not taking into account mileage) in the highest quartile of all rural county popu-
lations.

(B) Identification of qualified rural areas

(i) Determination of population density in
area

Based upon data from the United States
decennial census for the year 2000, the Sec-
detary shall determine, for each rural area,
the population density for that area.

(ii) Ranking of areas

The Secretary shall rank each such area
based on such population density.

(iii) Identification of qualified rural areas

The Secretary shall identify those areas
(in subparagraph (A) referred to as “quali-
fied rural areas”) with the lowest popu-
Temporary increase for ground ambulance services

(A) In general
After computing the rates with respect to ground ambulance services under the other applicable provisions of this subsection, in the case of such services furnished on or after July 1, 2004, and before January 1, 2007, and for such services furnished on or after January 1, 2007, and before January 1, 2012, for which the transportation originates in—
(i) a rural area described in paragraph (9) or in a rural census tract described in such paragraph, the fee schedule established under this section shall provide that the rate for the service otherwise established, after the application of any increase under paragraphs (11) and (12), shall be increased by 2 percent (or 3 percent if such service is furnished on or after January 1, 2012); and
(ii) an area not described in clause (i), the fee schedule established under this subsection shall provide that the rate for the service otherwise established, after the application of any increase under paragraph (11), shall be increased by 1 percent (or 2 percent if such service is furnished on or after July 1, 2008, and before January 1, 2012).

(B) Application of increased payments after applicable period
The increased payments under subparagraph (A) shall not be taken into account in calculating payments for services furnished after the applicable period specified in such subparagraph.

(14) Providing appropriate coverage of rural air ambulance services

(A) In general
The regulations described in section 1395x(s)(7) of this title shall provide, to the extent that any ambulance services (whether ground or air) may be covered under such section, that a rural air ambulance service (as defined in subparagraph (C)) is reimbursed under this subsection at the air ambulance rate if the air ambulance service—
(i) is reasonable and necessary based on the health condition of the individual being transported at or immediately prior to the time of the transport; and
(ii) complies with equipment and crew requirements established by the Secretary.

(B) Satisfaction of requirement of medically necessary
The requirement of subparagraph (A)(i) is deemed to be met for a rural air ambulance service if—
(i) subject to subparagraph (A)(i), such service is requested by a physician or other qualified medical personnel (as specified by the Secretary) who certifies or reasonably determines that the individual’s condition is such that the time needed to transport the individual by land or the instability of transportation by land poses a threat to the individual’s survival or seriously endangers the individual’s health; or
(ii) such service is furnished pursuant to a protocol that is established by a State or regional emergency medical service (EMS) agency and recognized or approved by the Secretary under which the use of an air ambulance is recommended, if such agency does not have an ownership interest in the entity furnishing such service.

(C) Rural air ambulance service defined
For purposes of this paragraph, the term “rural air ambulance service” means fixed wing and rotary wing air ambulance service in which the point of pick up of the individual occurs in a rural area (as defined in section 1395ww(d)(2)(D) of this title) or 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)) as a rural area for purposes of this paragraph.

(v) Judicial review
There shall be no administrative or judicial review under section 1395ff, 1395oo of this title, or otherwise, respecting the identification of an area under this subparagraph.

(13) Temporary increase for ground ambulance services

(A) In general
After computing the rates with respect to ground ambulance services under the other applicable provisions of this subsection, in the case of such services furnished on or after July 1, 2004, and before January 1, 2007, and for such services furnished on or after July 1, 2008, and before January 1, 2012, for which the transportation originates in—
(i) a rural area described in paragraph (9) or in a rural census tract described in such paragraph, the fee schedule established under this section shall provide that the rate for the service otherwise established, after the application of any increase under paragraphs (11) and (12), shall be increased by 2 percent (or 3 percent if such service is furnished on or after January 1, 2012); and
(ii) an area not described in clause (i), the fee schedule established under this subsection shall provide that the rate for the service otherwise established, after the application of any increase under paragraph (11), shall be increased by 1 percent (or 2 percent if such service is furnished on or after July 1, 2008, and before January 1, 2012).

(B) Application of increased payments after applicable period
The increased payments under subparagraph (A) shall not be taken into account in calculating payments for services furnished after the applicable period specified in such subparagraph.

1395m
(m) Payment for telehealth services

(1) In general

The Secretary shall pay for telehealth services that are furnished via a telecommunications system by a physician (as defined in section 1395x(r) of this title) or a practitioner (described in section 1395u(b)(18)(C) of this title) to an eligible telehealth individual enrolled under this part notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary. For purposes of the preceding sentence, in the case of any Federal telemedicine demonstration program conducted in Alaska or Hawaii, the term “telecommunications system” includes store-and-forward technologies that provide for the asynchronous transmission of health care information in single or multimedia formats.

(2) Payment amount

(A) Distant site

The Secretary shall pay to a physician or practitioner located at a distant site that furnishes a telehealth service to an eligible telehealth individual an amount equal to the amount that such physician or practitioner would have been paid under this subchapter had such service been furnished without the use of a telecommunications system.

(B) Facility fee for originating site

With respect to a telehealth service, subject to section 1395i(a)(1)(U) of this title, there shall be paid to the originating site a facility fee equal to—

(i) for the period beginning on October 1, 2001, and ending on December 31, 2001, and for 2002, $20; and

(ii) for a subsequent year, the facility fee specified in clause (i) or this clause for the preceding year increased by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for such subsequent year.

(C) Telepresenter not required

Nothing in this subsection shall be construed as requiring an eligible telehealth individual to be presented by a physician or practitioner at the originating site for the furnishing of a service via a telecommunications system, unless it is medically necessary (as determined by the physician or practitioner at the distant site).

(3) Limitation on beneficiary charges

(A) Physician and practitioner

The provisions of section 1395w-4(g) of this title and subparagraphs (A) and (B) of section 1395u(b)(18) of this title shall apply to a physician or practitioner receiving payment under this subsection in the same manner as they apply to physicians or practitioners under such sections.

(B) Originating site

The provisions of section 1395u(b)(18) of this title shall apply to originating sites receiving a facility fee in the same manner as they apply to practitioners under such section.

(4) Definitions

For purposes of this subsection:

(A) Distant site

The term “distant site” means the site at which the physician or practitioner is located at the time the service is furnished via a telecommunications system.

(B) Eligible telehealth individual

The term “eligible telehealth individual” means an individual enrolled under this part who receives a telehealth service furnished at an originating site.

(C) Originating site

(i) In general

The term “originating site” means only those sites described in clause (ii) at which the eligible telehealth individual is located at the time the service is furnished via a telecommunications system and only if such site is located—

(I) in an area that is designated as a rural health professional shortage area under section 254e(a)(1)(A) of this title;

(II) in a county that is not included in a Metropolitan Statistical Area; or

(III) from an entity that participates in a Federal telemedicine demonstration project that has been approved by (or receives funding from) the Secretary of Health and Human Services as of December 31, 2000.

(ii) Sites described

The sites referred to in clause (i) are the following sites:

(I) The office of a physician or practitioner.

(II) A critical access hospital (as defined in section 1395x(mm)(1) of this title).

(III) A rural health clinic (as defined in section 1395x(aa)(2) of this title).

(IV) A Federally qualified health center (as defined in section 1395x(aa)(4) of this title).

(V) A hospital (as defined in section 1395x(e) of this title).

(VI) A hospital-based or critical access hospital-based renal dialysis center (including satellites).

(VII) A skilled nursing facility (as defined in section 1395i–3(a) of this title).

(VIII) A community mental health center (as defined in section 1395xx(b)(18)(C) of this title).

(D) Physician

The term “physician” has the meaning given that term in section 1395x(r) of this title.

(E) Practitioner

The term “practitioner” has the meaning given that term in section 1395u(b)(18)(C) of this title.
(F) Telehealth service
(i) In general
The term “telehealth service” means professional consultations, office visits, and office psychiatry services (identified as of July 1, 2000, by HCPCS codes 99241-99275, 99201-99215, 90804-90809, and 90862 (and as subsequently modified by the Secretary)), and any additional service specified by the Secretary.

(ii) Yearly update
The Secretary shall establish a process that provides, on an annual basis, for the addition or deletion of services (and HCPCS codes), as appropriate, to those specified in clause (i) for authorized payments under paragraph (1).

(n) Authority to modify or eliminate coverage of certain preventive services
Notwithstanding any other provision of this subchapter, effective beginning on January 1, 2010, if the Secretary determines appropriate, the Secretary may—

(1) modify—
(A) the coverage of any preventive service described in subparagraph (A) of section 1395x(ddd)(3) of this title to the extent that such modification is consistent with the recommendations of the United States Preventive Services Task Force; and
(B) the services included in the initial preventive physical examination described in subparagraph (B) of such section; and

(2) provide that no payment shall be made under this subchapter for a preventive service described in subparagraph (A) of such section that has not received a grade of A, B, C, or I by such Task Force.

(o) Development and implementation of prospective payment system

(1) Development
(A) In general
The Secretary shall develop a prospective payment system for payment for Federally qualified health center services furnished by Federally qualified health centers under this subchapter. Such system shall include a process for appropriately describing the services furnished by Federally qualified health centers and shall establish payment rates for specific payment codes based on such appropriate descriptions of services. Such system shall be established to take into account the type, intensity, and duration of services furnished by Federally qualified health centers. Such system may include adjustments, including geographic adjustments, determined appropriate by the Secretary.

(B) Collection of data and evaluation
By not later than January 1, 2011, the Secretary shall require Federally qualified health centers to submit to the Secretary such information as the Secretary may require in order to develop and implement the prospective payment system under this subsection, including the reporting of services using HCPCS codes.

(2) Implementation
(A) In general
Notwithstanding section 1395f(a)(3)(A) of this title, the Secretary shall provide, for cost reporting periods beginning on or after October 1, 2014, for payments of prospective payment rates for Federally qualified health center services furnished by Federally qualified health centers under this subchapter in accordance with the prospective payment system developed by the Secretary under paragraph (1).

(B) Payments
(i) Initial payments
The Secretary shall implement such prospective payment system so that the estimated aggregate amount of prospective payment rates (determined prior to the application of section 1395f(a)(1)(Z) of this title) under this subchapter for Federally qualified health center services in the first year that such system is implemented is equal to 100 percent of the estimated amount of reasonable costs (determined without the application of a per visit payment limit or productivity screen and prior to the application of section 1395cc(a)(2)(A)(ii) of this title) that would have occurred for such services under this subchapter in such year if the system had not been implemented.

(ii) Payments in subsequent years
Payment rates in years after the year of implementation of such system shall be the payment rates in the previous year increased—

(I) in the first year after implementation of such system, by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year involved; and

(II) in subsequent years, by the percentage increase in a market basket of Federally qualified health center goods and services as promulgated through regulations, or if such an index is not available, by the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year involved.

(C) Preparation for PPS implementation
Notwithstanding any other provision of law, the Secretary may establish and implement by program instruction or otherwise the payment codes to be used under the prospective payment system under this section.
105–33, which amended sections 1395u and 1395x of this title. (a)(14)(C)(i), (16), (h)(1)(D), and (i)(14)(D)(ii), inserted “and” in the case of covered items furnished on or after January 1, 2016, subject to clause (iii), shall” after “may”.


Subsection (a)(14)(F)(ii). Pub. L. 111–148, § 3109(a)(1)(A), added subpars. (L) and struck out former subpars. (L) and (M) which read as follows: “(L) for 2014; “(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.”


Subsection (a)(14)(M). Pub. L. 111–148, § 3109(m)(2), added subpar. (L) and struck out former subpars. (L) and (M) which read as follows: “(L) for 2014; “(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year.”

Subsection (a)(16)(B). Pub. L. 111–148, § 6402(g)(1), inserted “that the Secretary determines is commensurate with the volume of the billing of the supplier” after “$50,000”.

Subsection (a)(20)(F)(i). Pub. L. 111–148, § 3109(a)(1)(B), which directed amendment by inserting “, except that the Secretary shall not require a pharmacy to have submitted to the Secretary such evidence of accreditation prior to January 1, 2011” before semicolon “at the end,” was executed by making the insertion before “and” to reflect the probable intent of Congress.


Subsec. (l)(5)(B). Pub. L. 111–148, § 3401(j)(2)(A), inserted “subject to subparagraph (C) and the succeeding sentence of this paragraph,” after “increased”.


Pub. L. 111–148, § 10311(c), substituted “2011” for “2010”, and on or after April 1, 2010, and before January 1, 2011.”

Pub. L. 111–148, § 3109(c), substituted “2010” and on or after April 1, 2010, and before January 1, 2011” for “2010”.


Subsec. (n). Pub. L. 111–148, § 5502(b), which directed the addition of subsec. (n) relating to development and implementation of prospective payment system, was repealed by Pub. L. 111–148, § 10501(i)(1).

Pub. L. 111–148, § 1040(a)(5), substituted “applicable period” for “2006” in heading and text of subpar. (G), and struck out “deductible or” before “coinsurance” in heading and text of subpar. (F).


Subsec. (n)(13)(B). Pub. L. 111–309, § 106(a)(2), substituted “applicable period” for “2006” in heading and text of subpar. (G), and struck out “deductible or” before “coinsurance” in heading and text of subpar. (F).

Subsec. (n)(13)(C). Pub. L. 111–309, § 106(c), inserted “certifies or reasonably determines” for “reasonably determines or certifies”.


make adjustments to the payment basis for the item described in paragraph (1)(B) if the Secretary determines (in accordance with such provisions and on the basis of prices and costs applicable at the time the item is furnished) that such payment basis is not inherently reasonable” before period at end.

Subsec. (a)(14)(C), (D). Pub. L. 105–33, § 4551(a)(1)(C), (D). Pub. L. 105–33, § 4551(a)(1)(C), (D). Pub. L. 105–33, § 4551(c), inserted at end “The Secretary, at the Secretary’s discretion, may impose the requirements of the first sentence with respect to some or all suppliers of items or services under part A of this subchapter or some or all suppliers or other persons (other than physicians or other practitioners, as defined in section 1395u(b)(18)(C) of this title) who furnish items or services under this part.”

Pub. L. 105–33, § 4312(a), added par. (16).


Subsec. (c)(2)(A)(iii). Pub. L. 105–33, § 4101(c), in introductory provisions, struck out “subject to the deductible”.

Subsec. (c)(2)(A)(iv), (v). Pub. L. 105–33, § 4101(a)(2), struck out cls. (iv) and (v), which read as follows: “(iv) In the case of a woman over 49 years of age, payment may not be made under this part for a screening mammography performed within the 23 months following the month in which a previous screening mammography was performed, or

“(v) In the case of a woman over 49 years of age, under 55 years of age, and 30 months following the month in which a previous screening mammography was performed.”

Subsec. (c)(2)(A)(v). Pub. L. 105–33, § 4101(a)(2), struck out cls. (iv) and (v), which read as follows: “(iv) In the case of a woman over 49 years of age, but under 55 years of age, payment may not be made under this part for a screening mammography performed within the 23 months following the month in which a previous screening mammography was performed.”


Subsec. (g). Pub. L. 105–33, § 4201(c)(5), amended heading and text of subsec. (g) generally. Prior to amendment, text related to payment for outpatient rural primary care hospital services as described, in par. (1), by either the cost-based facility fee plus professional charges method or the all-inclusive rate method and, in par. (2), by the prospective payment system.


Subsec. (b)(4)(D). Pub. L. 105–33, § 126(b)(2)(A), in introductory provisions substituted “shall, subject to clause (vi) for ‘clause (v)’” for “Subject to clause (vi) for ‘clause (v)’”.

Subsec. (b)(6)(C)(i). Pub. L. 105–33, § 126(b)(2)(C), struck out “this paragraph or paragraph (3)”.

Subsec. (d)(10)(B). Pub. L. 103–432, § 1314(a)(1), inserted at end “In applying such provisions to payments for an item under this subsection, the Secretary shall make adjustments to the payment basis for the item described in paragraph (1)(B) if the Secretary determines (in accordance with such provisions and on the basis of prices and costs applicable at the time the item is furnished) that such payment basis is not inherently reasonable.”


Subsec. (a)(7)(A)(iii)(II). Pub. L. 103–432, § 135(e)(3), substituted “clause (vi)” for “clause (v)”. Pub. L. 103–432, § 135(e)(4), substituted “this paragraph” for “this paragraph or paragraph (3)”.

Subsec. (a)(10)(B). Pub. L. 103–432, § 1314(a)(1), inserted at end “In applying such provisions to payments for an item under this subsection, the Secretary shall make adjustments to the payment basis for the item described in paragraph (1)(B) if the Secretary determines (in accordance with such provisions and on the basis of prices and costs applicable at the time the item is furnished) that such payment basis is not inherently reasonable.”

Pub. L. 103–432, § 126(c)(10)(B), substituted “would otherwise apply to physicians’ services” for “apply to physicians’ services” and inserted period at end “but for the application of section 1395w–4(i)(3) of this title”.


Subsec. (a)(15). Pub. L. 103–432, § 1313(b)(1), amended heading and text of par. (15) generally. Prior to amendment, text read as follows: “(A) DEVELOPMENT OF LIST OF ITEMS BY SECRETARY.—The Secretary shall develop and periodically update a list of items for which payment may be made under this subsection that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization, and shall include in such list seat-lift mechanisms, transcutaneous electrical nerve stimulators, and motorized scooters.

“(B) DETERMINATIONS OF COVERAGE IN ADVANCE.—A carrier shall determine in advance whether payment for an item included on the list developed by the Secretary under subparagraph (A) may not be made because of the application of section 1395w–4(i)(3) of this title.”

Subsec. (a)(16). Pub. L. 103–432, § 1313(a)(2), struck out heading and text of par. (16). Text read as follows: “(A) IN GENERAL.—A supplier of a covered item under this subsection may not distribute to physicians or to individuals entitled to benefits under this part for commercial purposes any completed or partially completed forms or other documents required by the Secretary to be submitted to show that a covered item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

“(B) PENALTY.—Any supplier of a covered item who knowingly and willfully distributes a form or other document in violation of subparagraph (A) is subject to a civil money penalty in an amount not to exceed $1,000 for each such form or document so distributed. The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1320a–7a of this title.”


Subsec. (b)(4)(D). Pub. L. 103–432, § 126(b)(2)(A), in introductory provisions substituted “shall, subject to clause (vi) for ‘clause (v)’” for “Subject to clause (vi) for ‘clause (v)’”.

Subsec. (b)(6)(C)(ii). Pub. L. 103–432, § 126(b)(2)(C), (D), struck out “under this subparagraph” after “apor-
applied to a locality" and inserted "reduced under this subparagraph for the preceding year increased by 15 percent".


Subsec. (a)(3)(A). Pub. L. 103–66, § 13543(a), substituted ‘‘IPPB machines and ventilators, excluding ventilators that are either continuous airway pressure devices or intermittent assist devices with continuous airway pressure devices’’ for ‘‘ventilators, inspirators, IPPB machines, and nebulizers’’.

Subsec. (a)(3)(C). Pub. L. 103–66, § 13543(a), substituted for certain scanning mammography performed under this heading ‘‘for certain scanning mammography services’’.


Public Law 103–66, § 13542(a)(1), added subsec. (a)(2)(A)(iii). Pub. L. 101–620, § 13542(a)(1), in cl. (I), added cls. (ii) to (IV), and struck out former cl. (ii) which read as follows: ‘‘in a subsequent year, is the amount specified in the item under paragraph (4) pursuant to criteria specified by the Secretary’’.

Public Law 103–66, § 13542(a)(1), added subsec. (a)(2)(A)(ii). Pub. L. 101–508, § 4152(b)(1)(A), added ‘‘or’’ after ‘‘$150,’’ in cl. (i), added cls. (ii) to (IV), and added subcls. (iii) and (iv), and redesignated subcl. (II) as (IV).


Public Law 103–66, § 13542(a)(1), added subsec. (a)(2)(A)(iii). Pub. L. 101–508, § 4152(b)(1)(A), added ‘‘or’’ after ‘‘$150,’’ in cl. (i), added cls. (ii) to (IV), and struck out former cl. (ii) which read as follows: ‘‘in a subsequent year, is the amount specified in this subparagraph for the preceding year increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of that preceding year.’’

Public Law 103–66, § 13542(a)(1), added subsec. (a)(2)(B). Pub. L. 101–508, § 4152(b)(1)(A), (B), struck out ‘‘or’’ after ‘‘1987’’ in cl. (i), added clss. (ii) to (IV), and struck out former cl. (ii) which read as follows: ‘‘in a subsequent year, is the amount specified in this subparagraph for the preceding year increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of that preceding year.’’


Public Law 103–66, § 13542(a)(1), added subsec. (a)(4). Pub. L. 101–508, § 4152(c)(4)(B)(i), directed amendment of par. (4) by inserting at end ‘‘In the case of a wheelchair furnished on or after January 1, 1992, the wheelchair shall be treated as a customized item for purposes of this paragraph if the wheelchair has been measured, fitted, or adapted in consideration of the patient’s body size, disability, period of need, or intended use, and has been assembled by a supplier or ordered from a manufacturer who makes available customized features, modifications, or components for wheelchairs that are intended for an individual patient’s use in accordance with instructions from the patient’s physician.’’ The amendment did not become effective pursuant to Pub. L. 101–508, § 4152(c)(4)(B)(ii). See Effective Date of 1990 Amendment note below.

Public Law 103–66, § 13542(a)(1), added subsec. (a)(5)(A). Pub. L. 101–508, § 4152(g)(1)(A), substituted ‘‘(B), (C), and (E)’’ for ‘‘(B) and (C)’’.


Public Law 103–66, § 13542(a)(2)(A), as amended by Pub. L. 103–432, § 135(e)(2), substituted ‘‘15 percent’’ for ‘‘15 percent’’.
months, or, in the case of an item for which a purchase agreement has been entered into under clause (ii), a period of continuous use of longer than 13 months" for "15 months".

Pub. L. 101–508, §4152(c)(1), substituted "each of the first 3 months of such period" for "each such month" and ", and each of the remaining months of such period is 7.5 percent of such purchase price;" for "semicolon at end.

Subsec. (a)(7)(A)(ii). Pub. L. 101–508, §4152(c)(2)(C), as amended by Pub. L. 103–432, §135(e)(2), added subpar. (B) which read as follows: "the substituted "national limited purchase price" for "re-

amended by Pub. L. 103–432, §135(e)(2), added cl. (ii) and (iii). Former cl. (i) and (iii) redesign-

amended by Pub. L. 103–432, §135(e)(2), redesignated (iv) and (v), respectively.

Subsec. (a)(7)(A)(iv). Pub. L. 101–508, §4152(c)(2)(B), as amended by Pub. L. 103–432, §135(e)(2), added cl. (iv) as (iv), substituted "in the case of an item for which a purchase agreement has not been entered into under clause (ii) or clause (iii)," during the first 6-month period of medical need that follows the period of medical need during which payment is made under clause (i), during the succeeding 6-month period of medical need," and struck out "and" at end.

Subsec. (a)(7)(A)(v). Pub. L. 101–508, §4152(c)(2)(C), as amended by Pub. L. 103–432, §135(e)(2), redesignated cl. (iii) as (v), inserted at beginning "in the case of an item for which a purchase agreement has not been entered into under clause (ii) or clause (iii),": and substituted "and" for period at end.


Subsec. (a)(8)(A)(i). Pub. L. 101–508, §4152(b)(2)(A), added subcl. (II), redesignated former subcl. (II) as (III), struck out "1991 or before" and "regional purchase price for durable medical equipment (as defined under clause (I) of subparagraph (D))."

Subsec. (a)(8)(A)(ii). Pub. L. 101–508, §4152(b)(2)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: "With respect to the furnishing of a particular item in each region (as defined by the Secretary), the Secretary shall compute a regional monthly payment rate—

"(i) for 1991 and 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local monthly payment rates for the carriers in the region computed under subparagraph (A)(i)(II) for the year, and

"(ii) for each subsequent year, equal to the regional monthly payment rates computed under this subparagraph for the previous year increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year."

Subsec. (a)(8)(B). Pub. L. 101–508, §4152(b)(2)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: "With respect to the furnishing of a particular item in each region (as defined by the Secretary), the Secretary shall compute a regional monthly purchase price—

"(i) for 1991 and for 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local purchase prices for the carriers in the region computed under subparagraph (A)(i)(II) for the year, and

"(ii) for each subsequent year, equal to the regional purchase price computed under this subparagraph for the previous year increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year."


and in subcl. (II) substituted "33 percent" for "25 per-

cent" and "national limited purchase price for "regional purchase price"."


and "national limited purchase price for "regional purchase price"."


Subsec. (a)(8)(D). Pub. L. 101–508, §4152(b)(2)(B)(D), struck out subpar. (D) which read as follows: "The amount that is recognized under subparagraph (C) as the base monthly payment amount for an item furnished—

"(i) in 1991, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year; and

"(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the purchase prices recognized under such subparagraph for all the carrier service areas in the United States in that year."

Subsec. (a)(9)(A)(i)(II). Pub. L. 101–508, §4152(b)(3)(A)(i)(II), substituted "the covered item increase for the year" for "the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year".

Subsec. (a)(9)(B). Pub. L. 101–508, §4152(b)(3)(B), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: "With respect to the furnishing of an item in each region (as defined by the Secretary), the Secretary shall compute a regional monthly payment rate—

"(i) for 1991 and 1992, equal to the average (weighted by relative volume of all claims among carriers) of the local monthly payment rates for the carriers in the region computed under subparagraph (A)(i)(II) for the year, and

"(ii) for each subsequent year, equal to the regional monthly payment rates computed under this subparagraph for the previous year increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year."


and in subcl. (II) substituted "33 percent" for "25 per-

cent" and "national limited monthly payment rate" for "regional monthly payment rate"."


and "national limited monthly payment rate" for "regional monthly payment rate", and subparagraph (B)(i) for subparagraph (B)(ii)."


Subsec. (a)(9)(D). Pub. L. 101–508, §4152(b)(3)(D), struck out subpar. (D) which read as follows: "The amount that is recognized under subparagraph (C) as the base monthly payment amount for an item furnished—

"(i) in 1991, may not exceed 125 percent, and may not be lower than 85 percent, of the average of the base monthly payment amounts recognized under such subparagraph for all the carrier service areas in the United States in that year; and

"(ii) in a subsequent year, may not exceed 120 percent, and may not be lower than 90 percent, of the average of the base monthly payment amounts recognized under such subparagraph for all the carrier service areas in the United States in that year."

Subsec. (a)(12). Pub. L. 101–508, §4152(b)(5), struck out "defined for purposes of paragraphs (8)(B) and (9)(B)" after "one or more regions".

Subsec. (a)(13). Pub. L. 101–508, §4153(a)(2)(D)(i)(II), substituted "means durable medical equipment (as defined in section 1395x(n) of this title), including such equipment described in section 1395x(m)(5) of this title)" for "means—

"(A) durable medical equipment (as defined in section 1395x(m) of this title), including such equipment described in section 1395x(m)(5) of this title),

"(B) prosthetic devices (described in section 1395x(s)(8) of this title), but not including parenteral and enteral nutrition nutrients, supplies, and equipment; and

"(C) orthotics and prosthetics (described in section 1395x(s)(9) of this title), but does not include intraocular lenses or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by
a home health agency under section 1395xm(m)(5) of this title.


Subsec. (a)(7)(B)(ii). Pub. L. 101–239, §6112(a)(4)(C), substituted “clause (i) shall apply in the same manner as it applies to items furnished during 1989” for “the payments amount recognized under subparagraph (A)(i) shall not be more than the maximum amount established under clause (i), and shall not be less than the minimum amount established under such clause, for 1989, such amount increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June 1989”.


Subsec. (a)(8)(B)(i). Pub. L. 101–239, §6114(a), substituted “1991, may not exceed 125 percent, and may not be lower than 85 percent” for “1991, may not exceed 130 percent, and may not be lower than 85 percent”.

Subsec. (a)(9)(A)(i)(I). Pub. L. 101–239, §6112(d)(2)(C), substituted “120 percent, and may not be lower than 90 percent” for “125 percent, and may not be lower than 85 percent”.

Subsec. (a)(10)(B). Pub. L. 101–239, §6112(e)(2), inserted before period at end “or medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care) furnished by a home health agency under section 1395xm(m)(5) of this title”.

Subsec. (b)(1)(B). Pub. L. 101–239, §201(a), repealed Pub. L. 100–360, §204(b)(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 notes below.

Subsec. (b)(4)(A). Pub. L. 101–234, §301(b)(1), (c)(1), amended subpar. (A) identically, substituting “coinsurance and deductibles under sections 1395k(a)(1)(H) for “insurance and deductibles under section 1395n(a)(1)(I)”.

Subsec. (b)(4)(C) to (E). Pub. L. 101–239, §6105(a), added subpar. (C) and redesignated former subpars. (C) and (D) as (D) and (E), respectively.


Subsec. (a)(1)(C). Pub. L. 100–360, §411(g)(1)(B)(i), inserted “or under part A of this subchapter to a home health agency” before period at end.


Subsec. (a)(4). Pub. L. 100–360, §411(g)(1)(B)(vii), inserted “, and for that reason cannot be grouped with similar items for purposes of payment under this subchapter,” after “individual patient”, inserted cl. (A) and (B) designations, and in cl. (B), substituted “servicing” for “service” in two places.


Subsec. (a)(5)(A)(i)(II). Pub. L. 100–360, §411(g)(1)(B)(vii)(viii), substituted “maintenance and servicing” for “service and maintenance”, and in subcl. (I) substituted “fee or fees established by the Secretary” for “fee established by the carrier”.

Subsec. (a)(5)(A)(ii). Pub. L. 100–360, §411(a)(3)(A), (C)(ii), provided that subsec. (a)(7)(B)(i) of this section, as inserted by section 4062(b) of Pub. L. 100–203, is deemed to have a reference to “1987” immediately after “December”.


Subsec. (a)(9)(A)(ii)(II). Pub. L. 100–360, §411(g)(1)(B)(i), substituted “as defined by the Secretary” for “(as defined in section 1395ww(d)(2)(D) of this title)”, and in cl. (i) struck out the comma after “1991”.


Subsec. (a)(10)(B). Pub. L. 100–360, §411(g)(1)(B)(xiii), inserted before period at end “and payments under this
subsection as such provisions apply to physicians' services and physicians and a reasonable charge under section 1395u(b) of this title.

Subsec. (a)(11)(A). Pub. L. 100–360, § 411(g)(1)(B)(xvii), (xviii), inserted "maintenance and before" "servicing" and substituted "section 1395u(j)(2) of this title" for "subsection (j)(2) of this section."

Subsec. (a)(12). Pub. L. 100–360, § 411(g)(1)(B)(xxv), as amended by Pub. L. 100–148, § 608(d)(22)(A)(ii), substituted "one or more entire regions defined for purposes of paragraphs (8)(B) and (9)(B)" for "each region (as defined in section 1395w(d)(2)(D) of this title)."

Subsec. (a)(14). Pub. L. 100–360, § 411(g)(1)(B)(xxvii), struck out par. (14) which read as follows: "In this subsection, any reference to the term 'carrier' includes a reference, with respect to durable medical equipment furnished by a home health agency as part of home health services, to a fiscal intermediary."


Subsec. (b)(1)(B). Pub. L. 100–360, § 209(b)(1), inserted "and subject to subsection (e)(1)(A) of this section" after "conversion factors."


Subsec. (b)(4)(D), (5). Pub. L. 100–360, § 411(f)(8)(B)(i), inserted "and suppliers" after "physicians" in heading, Pub. L. 100–360, § 411(f)(8)(B)(ii), (iii), as redesignated by Pub. L. 100–148, § 608(d)(21)(C), substituted "bills" for "imposes a charge" and inserted "in the same manner as such sanctions may apply to a physician" before period at end.


Pub. L. 100–360, § 411(f)(8)(A), substituted "radiology" for ""radiologic"."

Subsec. (b)(6)(B). Pub. L. 100–360, § 411(f)(8)(D)(vi), formerly (v), as redesignated by Pub. L. 100–148, § 608(d)(21)(C), substituted "and subject to subsection (e)(1)(A) of this title" for "section 1395a(a)(1)(A) of this title, and section 1395u(b)(1)(B) of this title."

Pub. L. 100–360, § 411(f)(8)(A), substituted "radiology" for ""radiologic"."

Subsec. (c). Pub. L. 100–360, § 202(b)(4), added subsec. (c) relating to payment for covered outpatient drugs.

Subsec. (d). Pub. L. 100–360, § 293(c)(1)(F), added subsec. (d) relating to home intravenous drug therapy services.


**Effective Date of 2010 Amendment**


Pub. L. 111–148, title III, § 3136(c), Mar. 23, 2010, 124 Stat. 438, provided that:

"(1) IN GENERAL.—Subject to paragraph (2), the amendments made by subsection (a) [amending this section] shall take effect on January 1, 2011, and shall apply to power-driven wheelchairs furnished on or after such date.

"(2) APPLICATION TO COMPETITIVE BIDDING.—The amendments made by subsection (a) shall not apply to payment made for items and services furnished pursuant to contracts entered into under section 1847 of the Social Security Act (42 U.S.C. 1395w–3) prior to January 1, 2011, pursuant to the implementation of section 1847 of such section."

Amendment by section 608(d)(2) of Pub. L. 111–148 applicable to written orders and certifications made on or after July 1, 2010, see section 608(d) of Pub. L. 111–148, set out as a note under section 1395f of this title.

**Effective Date of 2008 Amendment**

Amendment by section 125(b)(5) of Pub. L. 110–275 applicable with respect to accreditations of hospitals granted on or after the date that is 24 months after July 15, 2008, with transition rule, see section 125(d) of Pub. L. 110–275, set out as an Effective Date of 2008 Amendment; Transition Rule note under section 1395ub of this title.


Pub. L. 110–275, title I, § 146(b)(2)(B), July 15, 2008, 122 Stat. 2548, provided that: "The amendment made by subparagraph (A) [amending this section] shall apply to services furnished on or after the date of the enactment of this Act [July 15, 2008]."

Pub. L. 110–275, title I, § 148(b), July 15, 2008, 122 Stat. 2549, provided that: "The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 2009."

Pub. L. 110–275, title I, § 154(c), July 15, 2008, 122 Stat. 2549, provided that: "The amendments made by this section [amending this section and section 1395w–3 of this title, and provisions set out as notes under section 1395w–3 of this title] shall take effect as of June 30, 2008."

**Effective Date of 2006 Amendment**

Pub. L. 109–171, title V, § 5101(a)(2), Feb. 8, 2006, 120 Stat. 38, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to items furnished for which the first rental month occurs on or after January 1, 2006."


"(A) IN GENERAL.—The amendments made by paragraph (1) [amending this section] shall take effect on January 1, 2006.

"(B) APPLICATION TO CERTAIN INDIVIDUALS.—In the case of an individual receiving oxygen equipment on December 31, 2005, for which payment is made under paragraph (B), the amendment made by paragraph (1) shall begin on January 1, 2006."

Amendment by section 5113(b) of Pub. L. 109–171 applicable to services furnished on or after Jan. 1, 2007, see section 5113(c) of Pub. L. 109–171, set out as a note under section 1395f of this title.

**Effective Date of 2003 Amendment**


Pub. L. 108–173, title IV, § 405(b)(2), Dec. 8, 2003, 117 Stat. 2366, provided that: "The amendments made by paragraph (1) [amending this section] shall apply with respect to costs incurred for services furnished on or after January 1, 2005."


"(A) IN GENERAL.—Except as provided in subparagraph (B), the amendments made by paragraph (1)
(amending this section) shall apply to cost reporting periods beginning on or after July 1, 2001.

"(B) RULE OF APPLICATION.—In the case of a critical access hospital that made an election under section 1834(g)(2) of the Social Security Act (42 U.S.C. 1395m(g)(2)) before November 1, 2003, the amendment made by paragraph (1) shall apply to cost reporting periods beginning on or after July 1, 2001." Pub. L. 106–173, title IV, §415(c), Dec. 8, 2000, 117 Stat. 2282, provided that: "The amendments made by this subsection [probably should be "this section"], amending this section and section 1395x of this title shall apply to services furnished on or after January 1, 2001." Amendment by section 627(b)(1) of Pub. L. 106–173 applicable to items furnished on or after Jan. 1, 2005, see section 627(c) of Pub. L. 106–173, set out as a note under section 1395f of this title.

**Effective Date of 2000 Amendment**

Pub. L. 106–554, §1(a)(6) [title I, §103(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–469, provided that: "The amendments made by this section [amending this section and section 1395x of this title] shall apply to colorectal cancer screening services provided on or after October 1, 2001." Pub. L. 106–554, §1(a)(6) [title I, §104(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–470, provided that: "The amendments made by subsections (a) and (b) [amending this section and section 1395x–4 of this title] shall apply with respect to screening mammographies furnished on or after January 1, 2002." Amendment by section 1a(a)(6) [title II, §201(a)] of Pub. L. 106–554 applicable to items and services furnished on or after Nov. 29, 1999, see section 1a(a)(6) [title II, §201(c)] of Pub. L. 106–554, set out as a note under section 1395f of this title.

Pub. L. 106–554, §1(a)(6) [title II, §202(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–481, provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to items and services furnished on or after July 1, 2001." Pub. L. 106–554, §1(a)(6) [title II, §204(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–482, provided that: "The amendment made by subsection (a) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 2001." Amendment by section 1a(a)(6) [title II, §205(a)] of Pub. L. 106–554 applicable to items and services furnished on or after Dec. 21, 2000, see section 1a(a)(6) [title II, §205(c)] of Pub. L. 106–554, set out as a note under section 1395f of this title.

Pub. L. 106–554, §1(a)(6) [title II, §221(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–487, provided that: "The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after July 1, 2001. In applying such amendment to services furnished on or after such date and before January 1, 2002, the amount of the rate increase provided under such amendment shall equal to $1.25 per mile." Amendment by section 1a(a)(6) [title II, §222(b)] of Pub. L. 106–554 effective for services furnished on or after Oct. 1, 2001, see section 1a(a)(6) [title II, §223(e)] of Pub. L. 106–554, set out as a note under section 1395f of this title.

Pub. L. 106–554, §1(a)(6) [title IV, §423(b)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–518, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to services furnished on or after July 1, 2001." Pub. L. 106–554, §1(a)(6) [title IV, §428(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–522, provided that: "The amendment made by subsection (a) [amending this section] shall apply to items replaced on or after April 1, 2001."**

**Effective Date of 1999 Amendment**

Amendment by section 1000(a)(6) [title II, §201(e)(2)] of Pub. L. 106–113 effective as if included in the enactment of the Balanced Budget Act of 1997, Pub. L. 106–33, 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 1395f of this title.


Pub. L. 106–113, div. B, §1000(a)(6) [title IV, §493(d)(2)], Nov. 29, 1999, 113 Stat. 1536, 1501A–371, as amended by Pub. L. 106–554, §1(a)(6) [title II, §201(b)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–481, provided that: "Paragraphs (1) through (3) of section 1834(g) of the Social Security Act [subtitle (g) of this section] (as amended by paragraph (1)) apply for cost reporting periods beginning on or after October 1, 2000."**

**Effective Date of 1997 Amendment**

Amendment by section 4101(a), (c) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4101(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Amendment by section 627(b)(1) of Pub. L. 105–33 effective for 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.

Section 4104(d) of Pub. L. 105–33 provided that: "(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 1395x–2 and 1395x–4 of this title] shall apply to items and services furnished on or after July 1, 1998.

(2) TESTING STRIPS.—The amendment made by subsection (b)(2) [amending this section] shall apply with respect to blood glucose testing strips furnished on or after January 1, 1998.

Amendment by section 4201(c)(6) 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 4312(f)(1) of P.L. 105–33 provided that: "The amendment made by subsection (a) [amending this section] shall apply to suppliers of durable medical equipment with respect to such equipment furnished on or after January 1, 1998." Section 4312(f)(3) of P.L. 105–33 provided that: "The amendments made by subsections (c) through (e) [amending this section and section 1395x of this title] shall take effect on the date of the enactment of this Act [Aug. 5, 1997] and may be applied with respect to items and services furnished on or after January 1, 1998." Section 4312(c) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section and section 1395x of this title] shall take effect on the date of the enactment of this Act [Aug. 5, 1997]." Amendment by section 4531(b)(2) of Pub. L. 105–33 applicable to services furnished on or after Jan. 1, 2000, see section 4531(b)(3) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Amendment by section 4541(a)(2) 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, except that subsection (c) of this section inapplicable to services described in section 1395x(a)(8)(B) of this title that are furnished during 1998, see section 4541(e) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Section 4551(c)(2) of Pub. L. 105–33 provided that: "The amendment made by paragraph (1) [amending this section] shall apply to purchases or rentals after the effective date of any regulations issued pursuant to such amendment." Section 4552(e) of Pub. L. 105–33 provided that: "(1) OXYGEN.—The amendments made by subsection (a) [amending this section] shall apply to items furnished on and after January 1, 1998.

(2) OTHER PROVISIONS.—The amendments made by this section other than subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Aug. 5, 1997]."
Effective Date of 1994 Amendment

Section 126(l) of Pub. L. 103–432 provided that: "Except as provided in subsection (h) [amending section 1396s of this title, enacting provisions set out as notes under sections 1395u and 1395w–4 of this title, and amending provisions set out as a note under section 1395w–4 of this title], the amendments made by this section and the provisions of this section [amending this section and sections 1395u, 1395w–1, and 1395w–4 of this title, enacting provisions set out as notes under sections 1395u and 1395w–4 of this title, and amending provisions set out as notes under this section and sections 1395u and 1395w–4 of this title] shall take effect as if included in the enactment of OBRA–1990 [Pub. L. 101–508]."

Section 131(a)(2) of Pub. L. 103–432 provided that the amendment made by that section is effective 60 days after Oct. 31, 1994.

Section 132(c) of Pub. L. 103–432 provided that: "The amendments made by subsections (a) and (b) [amending this section] shall apply to items furnished after the expiration of the 60-day period that begins on the date of the enactment of this Act [Oct. 31, 1994]."

Section 133(c) of Pub. L. 103–432 provided that: "The amendments made by this section [amending this section and sections 1395m and 1395pp of this title] shall apply to items or services furnished on or after Jan. 1, 1995."

Section 134(a)(2) of Pub. L. 103–432 provided that: "The amendment made by paragraph (1) [amending this section] shall take effect on the date of the enactment of this Act [Oct. 31, 1994]."

Section 135(a)(2) of Pub. L. 103–432 provided that: "The amendment made by paragraph (1) [amending this section] shall be effective on the date of the enactment of this Act [Oct. 31, 1994]."

Section 135(b)(1) of Pub. L. 103–432 provided that the amendment made by that section is effective Oct. 31, 1994.

Section 135(b)(3) of Pub. L. 103–432 provided that the amendment made by that section is effective Oct. 31, 1994.

Section 136(d)(2) of Pub. L. 103–432 provided that: "The amendment made by paragraph (1) [amending this section] shall be effective on the date of the enactment of this Act [Oct. 31, 1994]."

Section 136(e)(8) of Pub. L. 103–432 provided that: "The amendments made by this subsection [amending this section and provisions set out as notes under this section and section 1395sc of this title] shall take effect as if included in the enactment of OBRA–1990 [Pub. L. 101–508]."

Section 145(d) of Pub. L. 103–432 provided that: "The amendments made by this section [amending this section and sections 1395x to 1396bb of this title] shall apply to mammography furnished by a facility on and after the first date that the certificate requirements of section 354(b) of the Public Health Service Act [section 354(b) of this title] apply to such mammography conducted by such facility."

Amendment by section 156(a)(2)(C) of Pub. L. 103–432 applicable to services furnished on or after Oct. 31, 1994, see section 136(a)(3) of Pub. L. 103–432, set out as a note under section 1320a–7a of this title.

Effective Date of 1995 Amendment

Section 1354h(b)(3) of Pub. L. 103–66, set out as a note under section 1396f of this title.

Section 1354s(b) of Pub. L. 103–66 provided that: "The amendment made by subsection (a) [amending this section] shall apply to items furnished on or after January 1, 1994."

Effective Date of 1990 Amendment

Section 4102(f)(1) of Pub. L. 101–508 provided that: "(1) Except as otherwise provided, the amendments made by this section [amending this section, section 1395w–4 of this title, and provisions set out as a note below] shall apply to services furnished on or after Jan. 1, 1991.

(2) The amendment made by subsection (a) [amending this section] shall be effective as if included in the enactment of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 99–509]."

Amendment by section 4104(a) of Pub. L. 101–508 applicable to services furnished on or after Jan. 1, 1991, see section 4104(d) of Pub. L. 101–508, set out as a note under section 1396f of this title.


Section 4152(c)(4)(B)(ii) of Pub. L. 101–508 provided that: "The amendment made by clause (i) [amending this section] shall apply to items furnished on or after January 1, 1992, unless the Secretary develops specific criteria before that date for the treatment of wheelchairs as customized items for purposes of section 1344(a)(4) of the Social Security Act [subsec. (a)(4) of this section] (in which case the amendment made by such clause shall not become effective)." [Criteria established by Secretary Nov. 1, 1991, see 56 F.R. 65995, Dec. 20, 1991, 42 CFR § 414.224.]

Section 4152(c)(2) of Pub. L. 101–508 provided that: "The amendment made by paragraph (1) [amending this section] shall apply to forms and documents distributed on or after January 1, 1991."

Section 4152(c)(2) of Pub. L. 101–508 provided that: "The amendments made by paragraph (1) [amending this section] shall apply to patients who first receive home oxygen therapy services on or after January 1, 1991."

Section 4152(1) of Pub. L. 101–508 provided that: "Except as otherwise provided, the amendments made by this section [amending this section, section 1395x of this title, and provisions set out as a note under section 1396f of this title] shall apply to items furnished on or after January 1, 1991."


Amendment by section 4153(a)(3) of Pub. L. 101–508 applicable to screening mammography performed on or after Jan. 1, 1991, see section 4153(e) of Pub. L. 101–508, set out as a note under section 1396f of this title.

Effective Date of 1989 Amendments


Section 6112(e)(4) of Pub. L. 101–239 provided that: "The amendments made by this subsection [amending this section and sections 1395x and 1395cc of this title] shall apply with respect to items furnished on or after January 1, 1990."

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 1395a–7a of this title.

Section 203(b)(1), (c)(1) of Pub. L. 101–239 provided that the amendments made by that section are effective as if included in the enactment of the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203.
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. 100–360, set out as a note under section 704 of this title.

Amendment by section 202(b)(4) of Pub. L. 100–360 applicable to items dispensed on or after Jan. 1, 1990, see section 202(b)(1) of Pub. L. 100–360, set out as a note under section 1395u of this title.

Amendment by section 203(c)(1)(F) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100–360, set out as a note under section 1322c–3 of this title.

Section 204(e) of Pub. L. 100–360, which provided that the amendments made by section 204 of Pub. L. 100–360 [amending this section and sections 1395, 1395x to 1395z, 1395aa, 1395bb, 1396a, and 1396n of this title] applied to screening mammography performed on or after January 1, 1990, and that subsec. (e)(5) of this section only applied until such time as the Secretary of Health and Human Services implemented the physician fee schedules based on relative value scale developed under section 1395w–1(e) of this title, was repealed by Pub. L. 101–234, title II, dec. 13, 1989, 103 Stat. 1881.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411a(b)(3)(A), (B)(ii), (C)(ii), (D)(ii), (E)(ii), (F)(ii), (G)(ii), (H)(ii), and (I)(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. 100–360, see section 411a(b) of Pub. L. 100–360, set out as a note under section 1395w–3 of this title, shall be construed to affect the application of an accreditation requirement for pharmacies to qualify for bidding in a competitive acquisition area under section 1847 of the Social Security Act (42 U.S.C. 1395w–3).

Construction of 2009 Amendment

Pub. L. 111–72, §1(b), Oct. 13, 2009, 123 Stat. 2519, provided that: “Nothing in subsection (a) [amending this section] shall be construed as affecting the application of an accreditation requirement for pharmacies to qualify for bidding in a competitive acquisition area under section 1847 of the Social Security Act (42 U.S.C. 1395w–3).”

Construction of 2008 Amendment


Transfer of Functions

Physician Payment Review Commission (PPRC) was terminated and its assets and staff transferred to the Medicare Payment Advisory Commission (MedPAC) by section 602(c)(2), (3) of Pub. L. 106–554, set out as a note under section 1395aa–6 of this title. Section 602(c)(2), (3) further provided that MedPAC was to be responsible for preparation and submission of reports required by law to be submitted by PPRC, and that, for that purpose, any reference in law to PPRC was to be deemed, after the appointment of MedPAC, to refer to MedPAC.

Implementation of 2010 Amendment

Pub. L. 111–148, title III, §3109(b), Mar. 23, 2010, 124 Stat. 419, provided that: “Notwithstanding any other provision of law, the Secretary may implement the amendments made by subsection (a) [amending this section] by program instruction or otherwise.”

Demonstration Project to Assess the Appropriate Use of Imaging Services

Pub. L. 110–275, title I, §135(b), July 15, 2008, 122 Stat. 2535, provided that:

“(1) CONDUCT OF DEMONSTRATION PROJECT.—

“(A) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall conduct a demonstration project using the models described in paragraph (2)(E) to collect data regarding physician compliance with appropriateness criteria selected under paragraph (2)(D) in order to determine the appropriateness of advanced diagnostic imaging services furnished to Medicare beneficiaries.

“(B) ADVANCED DIAGNOSTIC IMAGING SERVICES.—In this subsection, the term ‘advanced diagnostic imaging services’ has the meaning given such term in section 1834(e)(1)(B) of the Social Security Act (42 U.S.C. 1395m(e)(1)(B)), as added by subsection (a).

“(C) AUTHORITY TO FOCUS DEMONSTRATION PROJECT.—The Secretary may focus the demonstration project with respect to certain advanced diagnostic imaging services, such as services that account for a large amount of expenditures under the Medicare program, services that have recently experienced a high rate of growth, or services for which appropriate appropriateness criteria exists.

“(2) IMPLEMENTATION AND DESIGN OF DEMONSTRATION PROJECT.—

“(A) IMPLEMENTATION AND DURATION.—

“(i) IMPLEMENTATION.—The Secretary shall implement the demonstration project under this subsection not later than January 1, 2010.”

Regulations

Pub. L. 106–554, §1(a)(5), (6) (title IV, §427(b)), Dec. 21, 2000, 114 Stat. 2763, 2763A–521, provided that: “Not later than 1 year after the date of the enactment of this Act (Dec. 21, 2000), the Secretary of Health and Human Services shall promulgate revised regulations to carry out the amendments made by this section (amending this section and enacting provisions set out as a note under this section) using a negotiated rulemaking process under subchapter III of chapter 5 of title 5, United States Code.”

Construction of 2010 Amendment

Pub. L. 111–148, title III, §3109(c), Mar. 23, 2010, 124 Stat. 420, provided that: “Nothing in the provisions of or amendments made by this section (amending this section and enacting provisions set out as a note under this section) shall be construed as affecting the application of an accreditation requirement for pharmacies to qualify for bidding in a competitive acquisition area under section 1847 of the Social Security Act (42 U.S.C. 1395w–3).”
“(ii) DURATION.—The Secretary shall conduct the demonstration project under this subsection for a 2-year period.

(B) APPLICATION AND SELECTION OF PARTICIPATING PHYSICIANS.—

“(i) APPLICATION.—Each physician that desires to participate in the demonstration project under this subsection shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

“(ii) SELECTION.—The Secretary shall select physicians to participate in the demonstration project under this subsection from among physicians submitting applications under clause (i). The Secretary shall ensure that the physicians selected—

“(I) represent a wide range of geographic areas, demographic characteristics (such as urban, rural, and suburban), and practice settings (such as private and academic practices); and

“(II) have the capability to submit data to the Secretary (or an entity under a subcontract with the Secretary) in an electronic format in accordance with standards established by the Secretary.

“(C) ADMINISTRATIVE COSTS AND INCENTIVES.—The Secretary shall—

“(i) reimburse physicians for reasonable administrative costs incurred in participating in the demonstration project under this subsection; and

“(ii) provide reasonable incentives to physicians to encourage participation in the demonstration project under this subsection.

“(D) USE OF APPROPRIATENESS CRITERIA.—

“(i) In general.—The Secretary, in consultation with medical specialty societies and other stakeholders, shall select criteria with respect to the clinical appropriateness of advanced diagnostic imaging services for use in the demonstration project under this subsection.

“(ii) Criteria selected.—Any criteria selected under clause (i) shall—

“(I) be developed or endorsed by a medical specialty society; and

“(II) be developed in adherence to appropriate principles developed by a consensus organization, such as the AQA alliance.

“(E) MODELS FOR COLLECTING DATA REGARDING PHYSICIAN COMPLIANCE WITH SELECTED CRITERIA.—Subject to subparagraph (H), in carrying out the demonstration project under this subsection, the Secretary shall use each of the following models for collecting data regarding physician compliance with appropriateness criteria selected under subparagraph (D):—

“(i) A model described in subparagraph (F);

“(II) A model described in subparagraph (G);

“(III) Any other model that the Secretary determines to be useful in evaluating the use of appropriateness criteria for advanced diagnostic imaging services.

“(F) POINT OF SERVICE MODEL DESCRIBED.—A model described in this subparagraph is a model that—

“(i) uses an electronic or paper intake form that—

“(I) contains a certification by the physician furnishing the imaging service that the data on the intake form was confirmed with the Medicare beneficiary before the service was furnished;

“(II) contains standardized data elements for diagnosis, service ordered, service furnished, and such other information determined by the Secretary, in consultation with medical specialty societies and other stakeholders, to be germane to evaluating the effectiveness of the use of appropriateness criteria selected under subparagraph (D); and

“(III) is accessible to physicians participating in the demonstration project under this subsection in a format that allows for the electronic submission of such form; and

“(ii) provides for feedback reports in accordance with paragraph (3)(B).

“(G) POINT OF ORDER MODEL DESCRIBED.—A model described in this subparagraph is a model that—

“(i) uses a computerized order-entry system that requires the transmission of relevant supporting information at the time of referral for advanced diagnostic imaging services and provides automated decision-support feedback to the referring physician regarding the appropriateness of furnishing such imaging services; and

“(ii) provides for feedback reports in accordance with paragraph (3)(B).

“(H) LIMITATION.—In no case may the Secretary use prior authorization—

“(i) as a model for collecting data regarding physician compliance with appropriateness criteria selected under subparagraph (D) under the demonstration project under this subsection; or

“(ii) under any model used for collecting such data under the demonstration project.

“(I) REQUIRED CONTRACTS AND PERFORMANCE STANDARDS FOR CERTAIN ENTITIES.—

“(i) In general.—The Secretary shall enter into contracts with entities to carry out the model described in subparagraph (G).

“(ii) PERFORMANCE STANDARDS.—The Secretary shall establish and enforce performance standards for such entities under the contracts entered into under clause (i), including performance standards with respect to—

“(I) the satisfaction of Medicare beneficiaries who are furnished advanced diagnostic imaging services by a physician participating in the demonstration project; and

“(II) the satisfaction of physicians participating in the demonstration project;—

“(III) if applicable, timelines for the provision of feedback reports under paragraph (3)(B); and

“(IV) any other areas determined appropriate by the Secretary.

“(J) COMPARISON OF UTILIZATION OF ADVANCED DIAGNOSTIC imag services and feedback reports.—

“(A) COMPARISON OF UTILIZATION OF ADVANCED DIAGNOSTIC IMAGING SERVICES.—The Secretary shall consult with medical specialty societies and other stakeholders to develop mechanisms to compare the utilization of advanced diagnostic imaging services by physicians participating in the demonstration project under this subsection again—

“(i) the appropriateness criteria selected under paragraph (2)(D); and

“(ii) to the extent feasible, the utilization of such services by physicians not participating in the demonstration project.

“(B) FEEDBACK REPORTS.—The Secretary shall, in consultation with medical specialty societies and other stakeholders, develop mechanisms to provide feedback reports to physicians participating in the demonstration project under this subsection. Such feedback reports shall include—

“(i) a profile of the rate of compliance by the physician with appropriateness criteria selected under paragraph (2)(D), including a comparison of—

“(I) the rate of compliance by the physician with such criteria; and

“(II) the rate of compliance by the physician’s peers (as defined by the Secretary) with such criteria; and

“(II) to the extent feasible, a comparison of—

“(I) the rate of utilization of advanced diagnostic imaging services by the physician; and

“(II) the rate of utilization of such services by the physician’s peers (as defined by the Secretary) who are not participating in the demonstration project.

“(4) CONDUCT OF DEMONSTRATION PROJECT AND WAIVER.—

“(A) CONDUCT OF DEMONSTRATION PROJECT.—Chapter 35 of title 44, United States Code, shall not apply to the conduct of the demonstration project under this subsection.
“(B) WAIVER.—The Secretary may waive such provisions 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 project under this subsection.

“(5) EVALUATION AND REPORT.—

“(A) EVALUATION.—The Secretary shall evaluate the demonstration project under this subsection to—

“(i) assess the timeliness and efficacy of the demonstration project;

“(ii) assess the performance of entities under a contract entered into under paragraph (2)(I);

“(iii) analyze data—

“(I) on the rates of appropriate, uncertain, and inappropriate advanced diagnostic imaging services furnished by physicians participating in the demonstration project;

“(II) on patterns and trends in the appropriateness and inappropriateness of such services furnished by such physicians;

“(III) on patterns and trends in national and regional variations of care with respect to the furnishing of such services; and

“(IV) on the correlation between the appropriateness of the services furnished and image results; and

“(v) address—

“(I) the thresholds used under the demonstration project to identify acceptable and outlier levels of performance with respect to the appropriateness of advanced diagnostic imaging services furnished;

“(II) whether prospective use of appropriateness criteria could have an effect on the volume of such services furnished;

“(III) whether expansion of the use of appropriateness criteria with respect to such services to a broader population of Medicare beneficiaries would be advisable;

“(IV) whether, under such an expansion, physicians who demonstrate consistent compliance with such appropriateness criteria should be exempted from certain requirements;

“(V) the use of incident-specific versus practice-specific outlier information in formulating future recommendations with respect to the use of appropriateness criteria for such services under the Medicare program; and

“(VI) the potential for using methods (including financial incentives), in addition to those used under the models under the demonstration project, to ensure compliance with such criteria.

“(B) REPORT.—Not later than 1 year after the completion of the demonstration project under this subsection, the Secretary shall submit to Congress a report containing the results of the evaluation of the demonstration project conducted under subparagraph (A), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

“(6) FUNDING.—The Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Social Security Act (42 U.S.C. 1395f) of $10,000,000, for carrying out the demonstration project under this subsection (including costs associated with administering the demonstration project, reimbursing physicians for administrative costs and providing incentives to encourage participation under paragraph (2)(C), entering into contracts under paragraph (2)(I), and evaluating the demonstration project under paragraph (5)).”

AIR AMBULANCE PAYMENT IMPROVEMENTS

Pub. L. 110–275, title I, §154(c)(3), July 15, 2008, 122 Stat. 2566, provided that: “The Secretary of Health and Human Services shall evaluate the existing Health Care Common Procedure Coding System (HCPCS) codes for negative pressure wound therapy to ensure accurate reporting and billing for items and services under such codes. In carrying out such evaluation, the Secretary shall use an existing process, administered by the Durham Medical Equipment Medicare Administrative Contractors, for the consideration of coding changes and consider all relevant studies and information furnished pursuant to such process.”

GAO REPORT ON CLASS III MEDICAL DEVICES


USE OF DATA

Pub. L. 108–173, title IV, §414(c)(2), Dec. 8, 2003, 117 Stat. 2280, provided that: “In order to promptly implement section 1834(a)(12) of the Social Security Act [subsec. (i)(12) of this section], as added by the Serve 1y, the Secretary [of Health and Human Services] may use data furnished by the Comptroller General of the United States.”

IMPLEMENTATION OF 2003 AMENDMENT

Pub. L. 108–173, title IV, §414(e), Dec. 8, 2003, 117 Stat. 2280, provided that: “The Secretary [of Health and Human Services] may implement the amendments made by this section [amending section, section 1839x of this title, and provisions set out as a note under this section], and revise the conversion factor applicable under section 1834(a) of the Social Security Act (42 U.S.C. 1395m(a)) for purposes of implementing such amendments, on an interim final basis, or by program instruction.”

GAO REPORT ON COSTS AND ACCESS

Pub. L. 108–173, title IV, §414(f), Dec. 8, 2003, 117 Stat. 2280, which required the Comptroller General of the United States to submit to Congress initial and final reports on how costs differ among the types of ambulance providers and on access, supply, and quality of ambulance services in those regions and States that have a reduction in payment under the medicare ambulance fee schedule under section 1395m(l) of this title, was repealed by Pub. L. 111–68, div. A, title I, §1501(e)(1), Oct. 1, 2009, 123 Stat. 2041.

REPORT ON DEMONSTRATION PROJECT PERMITTING SKILLED NURSING FACILITIES TO BE ORIGINATING TELEHEALTH SITES; AUTHORITY TO IMPLEMENT

Pub. L. 108–173, title IV, §418, Dec. 8, 2003, 117 Stat. 2283, provided that: “(a) EVALUATION.—The Secretary [of Health and Human Services], acting through the Administrator of the Health Resources and Services Administration in
consultation with the Administrator of the Centers for Medicare & Medicaid Services, shall evaluate demonstration projects conducted by the Secretary under which skilled nursing facilities (as defined in section 1819(a) of the Social Security Act (42 U.S.C. 1395–3(a)(1))) are treated as originating sites for telehealth services.

(b) Report.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the evaluation conducted under subsection (a). Such report shall include recommendations on mechanisms to ensure that permitting a skilled nursing facility to serve as an originating site for the use of telehealth services or any other service delivered via a telecommunications system does not serve as a substitute for in-person visits furnished by a physician, or for in-person visits furnished by a physician assistant, nurse practitioner or clinical nurse specialist, as is otherwise required by the Secretary.

(c) Authority To Expand Originating Telehealth Sites To Include Skilled Nursing Facilities.—Insofar as the Secretary concludes in the report required under subsection (b) that it is advisable to permit a skilled nursing facility to be an originating site for telehealth services under section 1834(m) of the Social Security Act (42 U.S.C. 1395w–4), and that the Secretary can establish the mechanisms to ensure that such permission does not serve as a substitute for in-person visits furnished by a physician, or for in-person visits furnished by a physician assistant, nurse practitioner or clinical nurse specialist, the Secretary may deem a skilled nursing facility to be an originating site under paragraph (4)(C)(ii) of such section beginning on January 1, 2006.

Payment for New Technologies


“(1) Tests furnished in 2001.—

(A) Screening.—For a screening mammography (as defined in section 1833(j)) of the Social Security Act (42 U.S.C. 1395x(jj))) furnished during the period beginning on April 1, 2001, and ending on December 31, 2001, that uses a new technology, payment for such screening mammography shall be made as follows:

“(i) In the case of a technology which directly takes a digital image (without involving film), in an amount equal to 150 percent of the amount of payment under subsection (b) of section 1834(m) of such Act (42 U.S.C. 1395w–4) for a bilateral diagnostic mammography (under HCPCS code ‘76091’ for such year).

(B) Bilateral diagnostic mammography.—For a bilateral diagnostic mammography furnished during the period beginning on April 1, 2001, and ending on December 31, 2001, that uses a new technology described in subparagraph (A), payment for such mammography shall be the amount of payment provided for such new technology.

(C) Allocation of amounts.—The Secretary shall provide for an appropriate allocation of the amounts under subparagraphs (A) and (B) between the professional and technical components.

(D) Implementation of provision.—The Secretary of Health and Human Services may implement the provisions of this paragraph by program memorandum or otherwise.

(2) Consideration of new HCPCS code for new technologies after 2001.—The Secretary shall determine, for such mammographies performed after 2001, whether the assignment of a new HCPCS code is appropriate for mammography that uses a new technology. If the Secretary determines that a new code is appropriate for such mammography, the Secretary shall provide for such new code for such tests furnished after 2001.

(3) New technology discussion.—For purposes of this subsection, a new technology with respect to a mammography is an advance in technology with respect to the test or equipment that results in the following:

(A) A significant increase or decrease in the resources used in the test or in the manufacture of the equipment.

(B) A significant improvement in the performance of the test or equipment.

(C) A significant advance in medical technology that is expected to significantly improve the treatment of medicare beneficiaries.

(4) HCPCS code defined.—The term ‘HCPCS code’ means a code under the Health Care Common Procedure Coding System (HCPCS).”

MedPAC Study and Report on Medicare Coverage of Cardiac and Pulmonary Rehabilitation Therapy Services

Pub. L. 106–554, § 1(a)(6) [title I, § 127], Dec. 21, 2000, 114 Stat. 2763, 2763A–479, provided that:

“(a) Study.—

(1) In general.—The Medicare Payment Advisory Commission shall conduct a study on coverage of cardiac and pulmonary rehabilitation therapy services under the medicare program under title XVIII of the Social Security Act [this subchapter].

(2) Focus.—In conducting the study under paragraph (1), the Commission shall focus on the appropriate—

(A) qualifying diagnoses required for coverage of cardiac and pulmonary rehabilitation therapy services;

(B) level of physician direct involvement and supervision in furnishing such services; and

(C) level of reimbursement for such services.

(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 such recommendations for legislation and administrative action as the Commission determines appropriate.

GAO Studies on Costs of Ambulance Services Furnished in Rural Areas

Pub. L. 106–554, § 1(a)(6) [title II, § 221(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–486, provided that:

“(1) Study.—The Comptroller General of the United States shall conduct a study on each of the matters described in paragraph (2).

(2) Matters described.—The matters referred to in paragraph (1) are the following:

(A) The cost of efficiently providing ambulance services for trips originating in rural areas, with special emphasis on collection of cost data from rural providers.

(B) The means by which rural areas with low population densities can be identified for the purpose of designating areas in which the cost of providing ambulance services would be expected to be higher than similar services provided in more heavily populated areas because of low usage. Such study shall also include an analysis of the additional costs of providing ambulance services in areas designated under the previous sentence.

(3) Report.—Not later than June 30, 2002, the Comptroller General shall submit to Congress a report on the results of the studies conducted under paragraph (1) and shall include recommendations on steps that should be taken to assure access to ambulance services in rural areas.”

Adjustment in Rural Rates

STUDY AND REPORT ON ADDITIONAL COVERAGE FOR TELHEALTH SERVICES
Pub. L. 106–554, §1(a)(6) [title II, §223(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–489, provided that:

“(1) STUDY.—The Secretary of Health and Human Services shall conduct a study to—

“(A) settings and sites for the provision of telehealth services that are in addition to those permitted under section 1834(m) of the Social Security Act [subsec. (m) of this section], as added by subsection (b);

“(B) practitioners that may be reimbursed under such section for furnishing telehealth services that are in addition to the practitioners that may be reimbursed for such services under such section; and

“(C) geographic areas in which telehealth services may be reimbursed that are in addition to the geographic areas where such services may be reimbursed under such section.

“(2) REPORT.—Not later than 2 years after the date of the enactment of this Act [Dec. 21, 2000], the Secretary shall submit to Congress a report on the study conducted under paragraph (1) together with such recommendations for legislation that the Secretary determines are appropriate.

SPECIAL RULES FOR PAYMENTS FOR 2001
Pub. L. 106–554, §1(a)(6) [title IV, §423(a)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–518, provided that: “Notwithstanding the amendment made by paragraph (1) [amending this section], for purposes of making payments for ambulance services under part B of title XVIII of the Social Security Act [this part], for services furnished during 2001, the percentage increase in the consumer price index specified in section 1834(h)(3)(B) of such Act (42 U.S.C. 1395m(h)(3)(B))—

“(A) for services furnished on or after January 1, 2001, and before January 1, 2002, shall be the payment basis for suchservices paid for on a composite rate basis); and

“(B) for services furnished on or after July 1, 2001, and before January 1, 2002, shall be equal to 4.7 percent.”

Pub. L. 106–554, §1(a)(6) [title IV, §425(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–519, provided that: “Notwithstanding the amendments made by subsection (a) [amending this section], for purposes of making payments for durable medical equipment under section 1834(a) of the Social Security Act (42 U.S.C. 1395m(a)), other than for oxygen and oxygen equipment specified in paragraph (9) of such section, the payment basis recognized for 2001 under such section—

“(1) for items furnished on or after January 1, 2001, and before July 1, 2001, shall be the payment basis for 2001 as 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 items furnished on or after January 1, 2002, shall be the payment basis that is in effect such section 1834(a) if such section 228(a)(1) did not apply and taking into account the amendment made by subsection (a), increased by a transitional percentage allowance equal to 3.28 percent (to account for the timing of implementation of the CPI update).”

Pub. L. 106–554, §1(a)(6) [title IV, §428(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–520, provided that: “Notwithstanding the amendments made by subsection (a) [amending this section], for purposes of making payments for prosthetic devices and orthotics and prosthetics (as defined in subparagraphs (B) and (C) of paragraph (4) of section 1834(h) of the Social Security Act (42 U.S.C. 1395m(h))) under such section, the payment basis recognized for 2001 under paragraph (2) of such section—

“(1) for items furnished on or after January 1, 2001, and before July 1, 2001, shall be the payment basis for 2001 as 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 items furnished on or after July 1, 2001, and before January 1, 2002, shall be the payment basis that is determined under such section taking into account the amendments made by subsection (a), increased by a transitional percentage allowance equal to 2.6 percent (to account for the timing of implementation of the CPI update).”

PREEMPTION OF RULE
Pub. L. 106–554, §1(a)(6) [title IV, §428(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–522, provided that: “The provisions of section 1834(h)(1)(G) [subsec. (h)(1)(G) of this section] as added by subsection (a) shall supersede any rule that as of the date of the enactment of this Act [Dec. 21, 2000] may have applied a 5-year replacement rule with regard to prosthetic devices.”

GAO STUDY AND REPORT ON COSTS OF EMERGENCY AND MEDICAL TRANSPORTATION SERVICES
Pub. L. 106–554, §1(a)(6) [title IV, §436], Dec. 21, 2000, 114 Stat. 2763, 2763A–527, provided that: “(a) STUDY.—The Comptroller General of the United States shall conduct a study on the costs of providing emergency and medical transportation services across the range of acuity levels of conditions for which such transportation services are provided.

“(b) 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 subsection (a), together with recommendations for any changes in methodology or payment level necessary to fairly compensate suppliers of emergency and medical transportation services and to ensure the access of beneficiaries under the medicare program under title XVIII of the Social Security Act (this subchapter).”

TREATMENT OF TEMPORARY PAYMENT INCREASES AFTER CALENDAR YEAR 2001
Pub. L. 106–554, §1(a)(6) [title V, §547(d)], Dec. 21, 2000, 114 Stat. 2763, 2763A–553, provided that: “The payment increases provided under the following sections shall not apply after calendar year 2001 and shall not be taken into account in calculating the payment amounts applicable for items and services furnished after such year:

“(1) Section 461(c)(2) [set out as a note under section 1395I of this title] (relating to covered OPD services).

“(2) Section 422(e)(2) [set out as a note under section 1395rr of this title] (relating to renal dialysis services paid for on a composite rate basis).

“(3) Section 423(a)(2)(B) [set out above] (relating to ambulance services).

“(4) Section 425(b)(2) [set out above] (relating to durable medical equipment).
“(5) Section 426(b)(2) [set out above] (relating to prosthetic devices and orthotics and prosthetics).”

STUDY OF INTRAVENOUS IMMUNE GLOBULIN (IVIG) OUTSIDE HOSPITALS AND PHYSICIANS’ OFFICES

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §225(n)], Nov. 29, 1999, 113 Stat. 1536, 1501A–341, required the Secretary of Health and Human Services to conduct a study of the extent to which intravenous immune globulin could be delivered and reimbursed under the Medicare program outside of a hospital or physician’s office and to submit a report on such study to Congress within 18 months after Nov. 29, 1999.

TEMPORARY INCREASE IN PAYMENT RATES FOR DURABLE MEDICAL EQUIPMENT AND OXYGEN


“(a) IN GENERAL.—For purposes of payments under section 1834(a) of the Social Security Act (42 U.S.C. 1395m(a)(1) for covered items (as defined in paragraph (13) of that section) furnished during 2001 and 2002, the Secretary of Health and Human Services shall increase the payment amount in effect (but for this section) for such items for—

“(1) 2001 by 0.3 percent;

“(2) 2002 by 0.5 percent.

“(b) LIMITING APPLICATION TO SPECIFIED YEARS.—The payment amount increase—

“(1) under subsection (a)(1) shall not apply after 2001 and shall not be taken into account in calculating the payment amounts applicable for covered items furnished after such year; and

“(2) under subsection (a)(2) shall not apply after 2002 and shall not be taken into account in calculating the payment amounts applicable for covered items furnished after such year.

DEMONSTRATION OF COVERAGE OF AMBULANCE SERVICES UNDER MEDICARE THROUGH CONTRACTS WITH UNITS OF LOCAL GOVERNMENT


“(a) DEMONSTRATION PROJECT CONTRACTS WITH LOCAL GOVERNMENTS.—The Secretary of Health and Human Services shall establish up to 3 demonstration projects under which, at the request of a unit of local government, the Secretary enters into a contract with the unit of local government under which—

“(1) the unit of local government furnishes (or arranges for the furnishing of) ambulance services for which payment may be made under part B of title XVIII of the Social Security Act [this part] for individuals residing in the unit of local government who are enrolled under such part, except that the unit of local government may not enter into the contract unless the contract covers at least 80 percent of the individuals residing in the unit of local government who are enrolled under such part but not in a Medicare+Choice plan;

“(2) any individual or entity furnishing ambulance services under the contract meets the requirements otherwise applicable to individuals and entities furnishing such services under such part; and

“(3) for each month during which the contract is in effect, the Secretary makes a capitated payment to the unit of local government in accordance with subsection (b).

The projects may extend over a period of not to exceed 3 years each. Not later than July 1, 2000, the Secretary shall publish a request for proposals for such projects.

“(b) AMOUNT OF PAYMENT.—

“(1) IN GENERAL.—The amount of the monthly payment made for months occurring during a calendar year to a unit of local government under a demonstration project contract under subsection (a) shall be equal to the product of—

“(A) the Secretary’s estimate of the number of individuals covered under the contract for the month; and

“(B) ¼ of the capitated payment rate for the year established under paragraph (2).

“(2) CAPITATED PAYMENT RATE DEFINED.—In this subsection, the term ‘capitated payment rate’ means, with respect to a demonstration project—

“(A) in its first year, a rate established for the project by the Secretary, using the most current available data, in a manner that ensures that aggregate payments under the project will not exceed the aggregate payment that would have been made for ambulance services under part B of title XVIII of the Social Security Act [this part] for such services covered under the contract in the local area of government’s jurisdiction; and

“(B) in a subsequent year, the capitated payment rate established for the project for the preceding year increased by an appropriate inflation adjustment factor.

“(c) OTHER TERMS OF CONTRACT.—The Secretary and the unit of local government may include in a contract under this section such other terms as the parties consider appropriate, including—

“(1) covering individuals residing in additional units of local government (under arrangements entered into between such units and the unit of local government involved);

“(2) permitting the unit of local government to transport individuals to non-hospital providers if such providers are able to furnish quality services at a lower cost than hospital providers; or

“(3) implementing such other innovations as the unit of local government may propose to improve the quality of ambulance services and control the costs of such services.

“(d) CONTRACT PAYMENTS IN LIEU OF OTHER BENEFITS.—Payments under a contract to a unit of local government under this section shall be instead of the amounts which (in the absence of the contract) would otherwise be payable under part B of title XVIII of the Social Security Act [this part] for ambulance services furnished to such providers are able to furnish quality services at a lower cost than hospital providers or

“(e) REPORT ON EFFECTS OF CLASSIFIED CONTRACTS.—

“(1) STUDY.—The Secretary shall evaluate the demonstration projects conducted under this section. Such evaluation shall include an analysis of the quality and cost-effectiveness of ambulance services furnished under the projects.

“(2) REPORT.—Not later than January 1, 2000, the Secretary shall submit a report to Congress on the study conducted under paragraph (1), and shall include in the report such recommendations as the Secretary considers appropriate, including recommendations regarding modifications to the methodology used to determine the amount of payments made under such contracts and extending or expanding such projects.

[References to Medicare+Choice deemed to refer to Medicare Advantage, see section 201(b) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.]


PAYMENT FREEZE FOR PARENTERAL AND ENTERAL NUTRIENTS, SUPPLIES, AND EQUIPMENT

Section 4551(b) of Pub. L. 105–33 provided that: “In determining the amount of payment under part B of title XVIII of the Social Security Act [this part] with respect to parenteral and enteral nutrients, supplies, and equipment during each of the years 1998 through 2002, the charges determined to be reasonable with respect to such nutrients, supplies, and equipment may not exceed the charges determined to be reasonable with respect to such nutrients, supplies, and equipment during 1995.”
SERVICE STANDARDS FOR PROVIDERS OF OXYGEN AND OXYGEN EQUIPMENT

Section 4552(c) of Pub. L. 105-33 provided that: "The Secretary shall as soon as practicable establish service standards for persons seeking payment under part B of title XVIII of the Social Security Act [this part] for the providing of oxygen and oxygen equipment to beneficiaries within their homes.''

ACCESS TO HOME OXYGEN EQUIPMENT

Section 4552(d) of Pub. L. 105-33 provided that:

(1) STUDY—The Comptroller General of the United States shall study issues relating to access to home oxygen equipment and shall, within 18 months after the date of the enactment of this Act [Aug. 5, 1997], report to the Committees on Commerce and Ways and Means of the House of Representatives and the Committee on Finance of the Senate the results of the study, including recommendations (if any) for legislation.

(2) PEER REVIEW EVALUATION—The Secretary of Health and Human Services shall arrange for peer review organizations established under section 1154 of the Social Security Act [section 1320c-3 of this title] to evaluate access to, and quality of, home oxygen equipment.''

USE OF COVERED ITEMS BY DISABLED BENEFICIARIES

Section 131(b) of Pub. L. 103-432 provided that:

(1) IN GENERAL.—The Secretary of Health and Human Services, in consultation with representatives of suppliers of durable medical equipment under part B of the Medicare program [this part] and individuals entitled to benefits under such program on the basis of disability, shall conduct a study of the effects of the methodology for determining payments for items of such equipment under such part on the ability of such individuals to obtain items of such equipment, including customized items.

(2) REPORT.—Not later than one year after the date of the enactment of this Act [Oct. 31, 1994], the Secretary shall submit a report to Congress on the study conducted under paragraph (1), and shall include in the report such recommendations as the Secretary considers appropriate to assure that disabled Medicare beneficiaries have access to items of durable medical equipment.''

CRITERIA FOR TREATMENT OF ITEMS AS PROSTHETIC DEVICES OR ORTHOTICS AND PROSTHETICS

Section 131(c) of Pub. L. 103-432 provided that not later than one year after Oct. 31, 1994, Secretary of Health and Human Services was to submit to Congress a report describing prosthetic devices, orthotics and prosthetics covered under this part that do not require individualized or custom fitting and adjustment to be used by a patient, including recommendations for appropriate methodology for determining amount of payment for such items.

ADJUSTMENT REQUIRED FOR CERTAIN ITEMS

Section 134(b) of Pub. L. 103-432 provided that:

(1) IN GENERAL.—In accordance with section 1834(a)(10)(B) of the Social Security Act [subsec. (a)(10)(B) of this section] (as amended by subsection (a)), the Secretary of Health and Human Services shall determine whether the payment amounts for the items described in paragraph (2) are not inherently reasonable, and shall adjust such amounts in accordance with such section if the amounts are not inherently reasonable.

(2) ITEMS DESCRIBED.—The items referred to in paragraph (1) are decubitus care equipment, transcutaneous electrical nerve stimulators, and any other items considered appropriate by the Secretary.''

LIMITATION ON PAYMENTS FOR PHYSICIANS' RADIOLOGY SERVICES FURNISHED DURING 1991; EXCEPTIONS

Section 4102(c) of Pub. L. 101-508, as amended by Pub. L. 103-432, title I, §1320c-3, Oct. 31, 1994, 108 Stat. 4415, provided that:

(1) IN GENERAL.—In applying part B of title XVIII of the Social Security Act [this part], the prevailing charge for physicians' services, furnished during 1991, which are radiology services may not exceed the fee schedule amount established under section 1834(b) of such Act [subsec. (b) of this section] with respect to such services.

(2) EXCEPTION.—Paragraph (1) shall not apply to nuclear medicine services.''

LIMITATION ON CARRIER ADJUSTMENTS FOR RADIOLOGIST SERVICES FURNISHED DURING 1991

Section 4102(e) of Pub. L. 101-508 provided that: "For radiologist services furnished during 1991 for which payment is made under section 1834(b) of the Social Security Act [subsec. (b) of this section]

(1) a carrier may not make any adjustment, under section 1842(b)(3)(B) of such Act [section 1395u(b)(3)(B) of this title], in the payment amount for the service under section 1834(b) on the basis that the payment amount is higher than the charge applicable, for a comparable service and under comparable circumstances, to the policyholders and subscribers of the carrier.

(2) no payment adjustment may be made under section 1842(b)(8) of such Act, and

(3) section 1842(b)(9) of such Act shall not apply.''

STUDY OF PAYMENTS FOR PROSTHETIC DEVICES, ORTHOTICS, AND PROSTHETICS

Section 4153(c) of Pub. L. 101-508, as amended by Pub. L. 103-432, title I, §134(b), Oct. 31, 1994, 108 Stat. 4424, directed Comptroller General to conduct a study of feasibility and desirability of establishing a separate fee schedule for use in determining the amount of payments for covered items under subsec. (b) of this section with respect to suppliers of prosthetic devices, orthotics, and prosthetics who provide professional services that would take into account the costs to such providers of providing such services and, not later than 1 year after Nov. 5, 1990, submit a report on the study to Committees on Energy and Commerce and Ways and Means of House of Representatives and Committee on Finance of Senate, including any recommendations regarding payments for prosthetic devices, orthotics, and prosthetics under the Medicare program.

SPECIAL RULE FOR NUCLEAR MEDICINE PHYSICIANS

Section 6105(b) of Pub. L. 101-239, as amended by Pub. L. 101-508, title IV, §4102(g)(1), Nov. 5, 1990, 104 Stat. 1388-57, provided that: "In applying section 1834(b) of the Social Security Act [subsec. (b) of this section] with respect to nuclear medicine services furnished by a physician for whom nuclear medicine services account for at least 80 percent of the total amount of charges made under part B of title XVIII of the Social Security Act [this part] beginning April 1, 1990, and ending December 31, 1991, there shall be substituted for the fee schedule otherwise applicable a fee schedule based 1 3⁄4 on the fee schedule computed under such section (without regard to this subsection) and 5% on 101 percent of the 1988 prevailing charge for such services.''

SPECIAL RULE FOR INTERVENTIONAL RADIOLOGISTS; "SPLIT BILLING"

Section 6106(c) of Pub. L. 101-239, as amended by Pub. L. 101-508, title IV, §4102(h), Nov. 5, 1990, 104 Stat. 1388-58, provided that: "In applying section 1834(b) of the Social Security Act [subsec. (b) of this section] to radiologist services furnished in 1990 or 1991, the exception for 'split billing' set forth at section 5262J of the Medicare Carriers Manual shall apply to services furnished in 1990 or 1991 in the same manner and to the same extent as the exception applied to services furnished in 1989.'

RENTAL PAYMENTS FOR ENTERAL AND PARENTERAL PUMPS

Section 6112(b) of Pub. L. 101-239 provided that:
Section 202(k) of Pub. L. 100–360 directed Secretary of Health and Human Services to conduct a study, and make a report to Congress by Jan. 1, 1990, on possibility of including drugs which have not yet been approved under section 355 or 357 of Title 21, Food and Drugs, and biological products which have not been licensed under section 262 of this title but which are commonly used in the treatment of cancer or in immunosuppressive therapy and other experimental drugs and biological products as covered outpatient drugs under medicare program, to conduct a study, and report to Congress by Jan. 1, 1990, evaluating potential to use mail service pharmacies to reduce costs to medicare program and to medicare beneficiaries, to conduct a study, and report to Congress by Jan. 1, 1990, on methods to improve utilization review of covered outpatient drugs, and to conduct a longitudinal study, and report to Congress by Jan. 1, 1990, on use of outpatient prescription drugs by medicare beneficiaries with respect to medical necessity, potential for adverse drug interactions, cost (including whether lower cost drugs could have been used), and patient stockpiling or wastage, and which further directed Comptroller General to conduct a study, and report to Congress by not later than May 1, 1991, on comparing average wholesale prices with actual pharmacy acquisition costs by type of pharmacy, on determining the overall costs of retail pharmacies, and on discounts given by pharmacies to other third-party insurers, prior to repeal by Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1981.

DEVELOPMENT OF STANDARD MEDICARE CLAIMS FORMS

Section 202(l) of Pub. L. 100–360 directed Secretary of Health and Human Services to develop, in consultation with representatives of pharmacies and other interested individuals, a standard claims form (and a standard electronic claims format) to be used in requests for payment for covered outpatient drugs under medicare program and other third-party payors, prior to repeal by Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1981.

STUDIES AND REPORTS ON SCREENING MAMMOGRAPHY


DRAFLINE FOR ESTABLISHMENT OF FEE SCHEDULES FOR RADIOLOGIST SERVICES: REPORT TO CONGRESS


STUDY AND EVALUATION

Section 4062(c) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, §411(g)(1)(C), July 1, 1988, 102 Stat. 782, provided that:

"(1) The Secretary of Health and Human Services shall monitor the impact of the amendments made by this section [enacting this section, amending sections 1385f, 1385k, 1385l, and 1386cc of this title, and repealing section 13862 of this title] on the availability of covered items and shall evaluate the appropriateness of the volume adjustment for oxygen and oxygen equip-
ment under section 1395a(5)(C) of the Social Security Act [subsec. (a)(5)(C) of this section] (as amended by subsection (b) of this section). The Secretary shall report to Congress, by not later than January 1, 1991, on such impact and on the evaluation and shall include in such report recommendations for changes in payment methodology for covered items under section 1395(a) of such Act.

“(2) Before January 1, 1991, the Secretary may not conduct any demonstration project respecting alternative methods of payment for covered items under title XVIII of the Social Security Act [this subchapter], and only if—

“(a) Conditions for payment for services described in section 1395cc(a) of this title and only if—

§ 1395n. Procedure for payment of claims of providers of services

(a) Conditions for payment for services described in section 1395k(a)(2) of this title

Except as provided in subsections (b), (c), and (e) of this section, payment for services described in section 1395k(a)(2) of this title furnished an individual may be made only to providers of services which are eligible therefor under section 1395c(a) of this title, and only if—

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period ending 1 calendar year after the date of service; and

(2) a physician, or, in the case of services described in subparagraph (A), a physician enrolled under section 1395cc(j) of this title, certifies (and recertifies, where such services are or were required) that

(A) in the case of home health services such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1396x(m)(7) of this title) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy, (ii) a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician, (iii) such services are or were furnished while the individual is or was under the care of a physician, and (iv) in the case of a certification after January 1, 2010, prior to making such certification the physician must document that the physician, or a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1395x(gg) of this title) as authorized by State law, or a physician assistant (as defined in section 1395x(aa)(5) of this title) under the supervision of the physician, has had a face-to-face encounter (including through use of telehealth and other than with respect to encounters that are incident to services involved) with the individual during the 6-month period preceding such certification, or other reasonable timeframe as determined by the Secretary;

(B) in the case of medical and other health services, except services described in subparagraphs (B), (C), and (D) of section 1395x(s)(2) of this title, such services are or were medically required;

(C) in the case of outpatient physical therapy services or outpatient occupational therapy services, respectively, (ii) a plan for furnishing such services has been established by a physician or by the qualified physical therapist or qualified occupational therapist, respectively, providing such services and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician;

(D) in the case of outpatient speech pathology services, (i) such services are or were required because the individual needed speech pathology services, (ii) a plan for furnishing such services has been established by a physician or by the speech pathologist providing such services and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician;

(E) in the case of comprehensive outpatient rehabilitation facility services, (i) such services are or were required because the individual needed skilled rehabilitation services, (ii) a plan for furnishing such services has been established and is periodically reviewed by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician; and

(F) in the case of partial hospitalization services, (i) the individual would require inpatient psychiatric care in the absence of
such services, (ii) an individualized, written plan for furnishing such services has been established by a physician and is reviewed periodically by a physician, and (iii) such services are or were furnished while the individual is or was under the care of a physician.

For purposes of this section, the term “provider of services” shall 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) of this title (or meets the requirements of such section through the operation of subsection (g) or (ll)(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 (ll)(2) of section 1395x of this title), but only with respect to the furnishing of outpatient physical therapy services (as therein defined) or (through the operation of subsection (g) or (ll)(2) of section 1395x of this title) with respect to the furnishing of outpatient occupational therapy services, or speech-language pathology services, respectively.

To the extent provided by regulations, the certification and recertification requirements of paragraph (2) shall be deemed satisfied where, at a later date, a physician makes a certification of the kind provided in subparagraph (A) or (B) of paragraph (2) (whichever would have applied), but only where such certification is accompanied by such medical and other evidence as may be required by such regulations. With respect to the physician certification required by paragraph (2) for home health services furnished to any individual by a home health agency (other than an agency which is a governmental entity) and with respect to the establishment and review of a plan for such services, the Secretary shall prescribe regulations which shall become effective no later than July 1, 1981, and which prohibit a physician who has a significant ownership interest in, or a significant financial or contractual relationship with, such home health agency from performing such certification and from establishing or reviewing such plan, except that such prohibition shall not apply with respect to a home health agency which is a sole community home health agency (as determined by the Secretary). For purposes of the preceding sentence, service by a physician as an uncompensated officer or director of a home health agency shall not constitute having a significant ownership interest in, or a significant financial or contractual relationship with, such agency. For purposes of paragraph (2)(A), an individual shall be considered to be “confined to his home” if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as a crutch, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered “confined to his home”, the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day-care services in the State shall not disqualify an individual from being considered to be “confined to his home”. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. In applying paragraph (1), the Secretary may specify exceptions to the 1 calendar year period specified in such paragraph.

(b) Conditions for payment for services described in section 1395x(s) of this title

(1) Payment may also be made to any hospital for services described in section 1395x(s) of this title furnished as an outpatient service by a hospital or by others under arrangements made by it to an individual entitled to benefits under this part even though such hospital does not have an agreement in effect under this subchapter if (A) such services were emergency services, (B) the Secretary would be required to make such payment if the hospital had such an agreement in effect and otherwise met the conditions of payment hereunder, and (C) such hospital has made an election pursuant to section 1395f(d)(1)(C) of this title with respect to the calendar year in which such emergency services are provided. Such payments shall be made only in the amounts provided under section 1395f(a)(2) of this title and then only if such hospital agrees to comply, with respect to the emergency services provided, with the provisions of section 1395cc(a) of this title.

(2) Payment may also be made on the basis of an itemized bill to an individual for services described in paragraph (1) of this subsection if (A) payment cannot be made under such paragraph (1) solely because the hospital does not elect, in accordance with section 1395f(d)(1)(C) of this title, to claim such payments and (B) such individual files application (submitted within such time and in such form and manner, and containing and supported by such information as the Secretary shall by regulations prescribe) for reimbursement. The amounts payable under this paragraph shall, subject to the provisions of section 1395f of this title, be equal to 80 percent of the hospital’s reasonable charges for such services.

(c) Collection of charges from individuals for services specified in section 1395x(s) of this title

Notwithstanding the provisions of this section and sections 1395k, 1395l, and 1395cc(a)(4)(A) of this title, a hospital or a critical access hospital may, subject to such limitations as may be prescribed by regulations, collect from an individual the customary charges for services specified
in section 1395x(s) of this title and furnished to him by such hospital as an outpatient, but only if such charges for such services do not exceed the applicable supplementary medical insurance deductible, and such customary charges shall be recognized as expenses incurred by such individual with respect to which benefits are payable in accordance with section 1395(a)(1) of this title. Payments under this subchapter to hospitals which have elected to make collections from individuals in accordance with the preceding sentence shall be adjusted periodically to place the hospital in the same position it would have had it instead been reimbursed in accordance with section 1395(a)(2) of this title (or, in the case of a critical access hospital, in accordance with section 1395(a)(6) of this title).

(d) Payment to Federal provider of services or other Federal agencies prohibited

Subject to section 1395qq of this title, no payment may be made under this part to any Federal provider of services or other Federal agency, except a provider of services which the Secretary determines is providing services to the public generally as a community institution or agency; and no such payment may be made to any item or service which such provider or person is obligated by a law of, or a contract with, the United States to render at public expense.

(e) Payment to fund designated by medical staff or faculty of medical school

For purposes of services (1) which are inpatient hospital services by reason of paragraph (7) of section 1395x(b) of this title or for which entitlement exists by reason of clause (II) of section 1395x(v)(1)(D) of this title (or would be if section 1395sw of this title did not apply), payment under this part shall be made to such fund as may be designated by the organized medical staff of the hospital in which such services were furnished or, if such services were furnished in such hospital by the faculty of a medical school, to such fund as may be designated by such faculty, but only if—

(A) such hospital has an agreement with the Secretary under section 1395cc of this title, and

(B) the Secretary has received written assurances that (i) such payment will be used by such fund solely for the improvement of care to patients in such hospital or for educational or charitable purposes and (ii) the individuals who were furnished such services or any other persons will not be charged for such services (or if charged provision will be made for return of any moneys incorrectly collected).


AMENDMENTS

2010—Subsec. (a). Pub. L. 111–148, §6407(a)(2)(B)(ii), inserted at end of concluding provisions “In applying paragraph (1), the Secretary may specify exceptions to the 1 calendar year period specified in such paragraph.”

Subsec. (a)(1). Pub. L. 111–148, §6404(a)(2)(B)(i), substituted “period ending 1 calendar year after the date of service” for “period of 3 calendar years following the year in which such services are furnished (deeming any services furnished in the last 3 calendar months of any calendar year to have been furnished in the succeeding calendar year) except that, where the Secretary deems that efficient administration so requires, such period may be reduced to not less than 1 calendar year.”


Subsec. (a)(2A)(iv). Pub. L. 111–148, §10605(b), inserted “, or a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) as authorized by State law, or a nurse midwife or certified nurse-midwife (as defined in section 1395gg of this title) as authorized by State law, or a physician assistant (as defined in section 1395aa of this title) under the supervision of the physician,” after “must document that the physician”.


2008—Subsec. (a). Pub. L. 110–275, in second sentence, substituted “subsection (g) or (ll)(2) of section 1395x of this title” for “section 1395gg of this title” wherever appearing and inserted “or outpatient speech-language pathology services, respectively” before period at end.


2002—Subsec. (a). Pub. L. 106–554, in concluding provisions, struck out “, and that absences of the individual from home attributable to the need to receive medical treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish medical care to patients in such hospital or for educational or charitable purposes and (ii) the individuals who were furnished such services or any other persons will not be charged for such services (or if charged provision will be made for return of any moneys incorrectly collected).”
adult day-care services in the State shall not disqualify an individual from being considered to be confined to his home. Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration."

1977—Subsec. (a)(2)(A). Pub. L. 95–103, § 4615(a), inserted "(other than solely venipuncture for the purpose of obtaining a blood sample)" after "skilled nursing care".

Subsec. (c). Pub. L. 105–33, § 4201(c)(1), substituted "critical access" for "rural primary care" in two places.

1990—Subsec. (c). Pub. L. 101–508 substituted "a hospital or a rural primary care hospital may" for "a hospital may in first sentence, substituted subsec. (a)(2)(A) of this title (or, in the case of a rural primary care hospital, in accordance with section 1395(a)(6) of this title)" for "section 1395(a)(2) of this title" in second sentence, and struck out at end "A rural primary care hospital shall be considered a hospital for purposes of this subsection."

1989—Subsec. (a)(2)(G), (H). Pub. L. 101–234 replaced Pub. L. 98–369, §§ 2354(b), (9), subsec. (1)(B), (D), 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.

(c). Pub. L. 101–239 inserted at end "A rural primary care hospital shall be considered a hospital for purposes of this subsection."


Subsec. (a)(2)(H). Pub. L. 100–360, § 206(d), added subpar. (H) relating to in-home care provided to chronically dependent individuals.

1987—Subsec. (a). Pub. L. 100–203, § 4024(b), inserted second sentences at end clarifying "confined to his home"


1986—Subsec. (a). 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 "or (through the operation of section 1395x(g) of this title) with respect to the furnishing of outpatient occupational therapy services".

Subsec. (a)(2)(C). Pub. L. 99–509, § 9337(c)(1), inserted "or "occupational therapist" services in introductory provisions, "or occupational therapy services, respectively," in cl. (i), and "or qualified occupational therapist, respectively," in cl. (i).

1984—Subsec. (a). Pub. L. 98–369, § 2354(b), substituted "so disqualifying the individuals who" for "(B) the individuals who" and "return of" for "for return of".

1983—Subsec. (e). Pub. L. 98–21 inserted "(or would be if section 1395ww of this title did not apply)" after "section 1395(v)(1)(D) of this title".

1981—Subsec. (a)(2)(A). Pub. L. 97–35, § 2122(a)(1), substituted "needs or needed skilled nursing care on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or reestablished (d)."


1980—Subsec. (a). Pub. L. 96–499, § 930(e), inserted sentence at end authorizing Secretary to prescribe regulations to prohibit significantly interested physicians from performing physician certification required by par. (2) for home health services.

Subsec. (a)(2)(A). Pub. L. 96–499, § 930(j), substituted "physical, occupational, or speech" for "physical or speech care hospital, in accordance with section 1395x(g) of this title."

Subsec. (a)(2)(D)(1). Pub. L. 96–499, § 944(a), inserted "by a physician or by the speech pathologist providing such services", after "has been established".


1976—Subsec. (d). Pub. L. 94–437 substituted "section 1395qq of this title, no payment" for "No payment".


Subsec. (a)(1). Pub. L. 92–603, § 231(f), placed a 3-year time limitation on time within which a written request for payment is filed, with provision for reduction of limit to 1 year.

Subsec. (a)(2)(C). Pub. L. 92–603, § 225(b)(2), substituted "because the individual needed physical therapy services" for "because the individual needed physical therapy services on an outpatient basis".


Subsec. (c). Pub. L. 92–603, § 204(b), substituted "the applicable supplementary medical insurance deductible" for "$50".


Subsec. (a)(2)(B). Pub. L. 90–248, §§ 129(b), 133(e)(4), inserted "except services described in subparagraphs (B) and (C) of section 1395x(a)(2) of this title", after "health services", and inserted reference to subpar. (d).


Subsec. (b). Pub. L. 90–248, § 129(c)(9)(B), added subsec. (b). Former subsec. (b) redesignated (c), in turn redesignated (d).

Subsec. (c). Pub. L. 90–248, § 130(c)(9)(B), added subsec. (c). Former subsec. (c), previously designated (b), redesignated (d).

Subsec. (d). Pub. L. 90–248, §§ 129(c)(9)(B), 130(b), redesignated former subsec. (b) as (c), in turn as (d), respectively.

Effective date of 2010 Amendment
and in case of services furnished before Jan. 1, 2010, a bill or request for payment under 42 U.S.C. 1395a(a) to be filed not later than Dec. 31, 2010, see section 6404(b) of Pub. L. 111–148, set out as a note under section 1395f of this title. Amendment by section 6405(b)(2) of Pub. L. 111–148 applicable to written orders and certifications made on or after July 1, 2010, see section 6406(d) of Pub. L. 111–148, set out as a note under section 1395f of this title.

**Effective Date of 2008 Amendment**
Amendment by Pub. L. 119–275 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 2000 Amendment**
Amendment by Pub. L. 106–544 applicable to home health services furnished on or after Dec. 21, 2000, see section 1(a)(6) (title V, §567(a)(2)) of Pub. L. 106–554, set out as a note under section 1395f of this title.

**Effective Date of 1997 Amendment**
Amendment by section 4201(c)(1) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 1997, see section 4201(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

**Effective Date of 1995 Amendment**
Amendment by section 4615(a) of Pub. L. 105–33 applicable to home health services furnished after 6-month period beginning after Aug. 5, 1997, see section 4615(b) of Pub. L. 105–33, set out as a note under section 1395f of this title.

**Effective Date of 1994 Amendment**
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 Amendment**
Amendment by section 203(d)(1) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100–360, set out as a note under section 1320c–3 of this title.

**Effective Date of 1987 Amendment**
Amendment by section 4024(b) of Pub. L. 100–203 applicable to items and services provided on or after Jan. 1, 1988, see section 4024(c) of Pub. L. 100–203, set out as a note under section 1395f of this title.

**Effective Date of 1986 Amendment**
Amendment by Pub. L. 99–509 applicable to expenses incurred for outpatient occupational therapy services furnished on or after July 1, 1987, see section 937(e) of Pub. L. 99–509, set out as a note under section 1395k of this title.

**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.

**Effective Date of 1983 Amendment**
Amendment by section 236(a) of Pub. L. 98–369 applicable to certifications and plans of care made or established on or after July 18, 1984, see section 236(c)(1) of Pub. L. 98–369, set out as a note under section 1395f of this title.

Section 234(c) of Pub. L. 98–369 provided that: "The amendments made by this section [amending this section and section 1395x of this title] apply to plans of care established on or after the date of the enactment of this Act [July 18, 1984]."

Amendment by section 235(h)(1), (8), (9) 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 235(h)(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 1395ww of this title.

**Effective Date of 1981 Amendment**
Amendment by section 2122(a)(1) of Pub. L. 97–33 applicable to services furnished pursuant to plans of treatment implemented after the third month beginning after Aug. 13, 1981, see section 2122(b) of Pub. L. 97–33, set out as a note under section 1395f of this title.

**Effective Date of 1980 Amendment**
Amendment by section 930(e), (j) of Pub. L. 96–499 effective with respect to services furnished on or after July 1, 1981, see section 930(e)(1) of Pub. L. 96–499, set out as a note under section 1395f of this title.

Amendment by section 933(b) 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 1395f of this title.

Section 944(b) of Pub. L. 96–499 provided that: "The amendment made by subsection (a) [amending this section] shall apply to plans for furnishing services established on or after January 1, 1981."

**Effective Date of 1977 Amendment**
Amendment by section 204(b) of Pub. L. 92–603 effective with respect to calendar years after 1972, see section 204(c) of Pub. L. 92–603, set out as a note under section 1395f of this title.

Amendment by section 222(e)(2) of Pub. L. 92–603 applicable with respect to accounting periods beginning after June 30, 1973, see section 222(g) of Pub. L. 92–603, set out as a note under section 1395f of this title.

Amendment by section 251(b)(2) of Pub. L. 92–603 applicable with respect to services furnished on or after Oct. 31, 1972, see section 251(d)(2) of Pub. L. 92–603, set out as a note under section 1395f of this title.

Amendment by section 283(c) of Pub. L. 92–603 applicable in the case of services furnished (or deemed to have been furnished) after 1970, see section 283(g) of Pub. L. 92–603, set out as a note under section 1395gg of this title.

Section 283(c) of Pub. L. 92–603 provided that: "The provisions of this section [amending this section and section 1395x of this title] shall apply with respect to services rendered after December 31, 1972."

**Effective Date of 1968 Amendment**
Amendment by section 126(b) of Pub. L. 90–248 applicable with respect to services furnished after Jan. 2, 1968, see section 126(c) of Pub. L. 90–248, set out as a note under section 1395f of this title.

Amendment by section 126(c)(9)(A), (B) of Pub. L. 90–248 applicable with respect to services furnished after March 31, 1968, see section 126(d) of Pub. L. 90–248, set out as a note under section 1395f of this title.

Section 130(c) 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."

Amendment by section 133(e) 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 1395gg of this title.
REGULATIONS

Secretary of Health and Human Services required to provide, not later than 90 days after July 18, 1984, for revision of regulations as may be required to reflect amendments to subsection (a) by section 2236(b) of Pub. L. 98–369, see section 2366(c)(2) of Pub. L. 98–369, set out as a note under section 1395f of this title.

MEDPAC STUDY ON DIRECT ACCESS TO PHYSICAL THERAPY SERVICES


“(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the ‘Commission’) shall conduct a study on the feasibility and advisability of allowing Medicare fee-for-service beneficiaries direct access to outpatient physical therapy services and physical therapy services furnished as comprehensive rehabilitation facility services.

“(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) DIRECT ACCESS DEFINED.—The term ‘direct access’ means, with respect to outpatient physical therapy services and physical therapy services furnished as comprehensive outpatient rehabilitation facility services, coverage of and payment for such services in accordance with the provisions of title XVIII of the Social Security Act (this subchapter), except that sections 1835(a)(2), 1861(p), and 1861(cc) of such Act (42 U.S.C. 1395n(a)(2), 1395x(p), and 1395xx(cc), respectively) shall be applied—

“(1) without regard to any requirement that—

“(A) an individual be under the care of (or referred by) a physician; or

“(B) services be provided under the supervision of a physician; and

“(2) by allowing a physician or a qualified physical therapist to satisfy any requirement for—

“(A) certification and recertification; and

“(B) establishment and periodic review of a plan of care.”

HOME HEALTH PROSPECTIVE PAYMENT DEMONSTRATION PROJECT

Section 4027 of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, §411(d)(6), July 1, 1988, 102 Stat. 775, directed Secretary of Health and Human Services to provide for a demonstration project to develop and test alternative methods of paying home health agencies on a prospective basis for services furnished under the Medicare and Medicaid programs, directed that the project be designed in a manner to enable the Secretary to evaluate the effects of various methods of prospective payment (including payments on a per-visit, per-case, and per-episode basis) on program expenditures, access to, and quality of, home health care, and home health agency operations, directed Secretary to assure that services are first furnished under the project not later than April 1, 1989, and, for this purpose, authorized Secretary to reinstate a previously awarded contract, or award a sole source contract, to carry out the project, provided for funding, and directed Secretary to submit to Congress, not later than one year after Dec. 22, 1987, an interim report on the demonstration project and, not later than four years after Dec. 22, 1987, a final report on results of the project.

§ 1395p. Enrollment periods

(a) Generally; regulations

An individual may enroll in the insurance program established by this part only in such manner and form as may be prescribed by regulations, and only during an enrollment period prescribed in or under this section.


(c) Initial general enrollment period; eligible individuals before March 1, 1966

In the case of individuals who first satisfy paragraph (1) or (2) of section 1395o of this title before March 1, 1966, the initial general enrollment period shall begin on the first day of the second month which begins after July 30, 1965, and shall end on May 31, 1966. For purposes of this subsection and subsection (d) of this section, an individual who has attained age 65 and who satisfies paragraph (1) of section 1395o of this title but not paragraph (2) of such section shall be treated as satisfying such paragraph (1) on the first day on which he is (or on filing application would have been) entitled to hospital insurance benefits under part A.

(d) Eligible individuals on or after March 1, 1966

In the case of an individual who first satisfies paragraph (1) or (2) of section 1395o of this title on or after March 1, 1966, his initial enrollment period shall begin on the first day of the third month before the month in which he first satisfies such paragraphs and shall end seven months later. Where the Secretary finds that an individual who has attained age 65 failed to enroll...
under this part during his initial enrollment period (based on a determination by the Secretary of the month in which such individual attained age 65), because such individual (relying on documentary evidence) was mistaken as to his correct date of birth, the Secretary shall establish for such individual an initial enrollment period based on his attaining age 65 at the time shown in such documentary evidence (with a coverage period determined under section 1395q of this title as though he had attained such age at that time).

(e) General enrollment period

There shall be a general enrollment period during the period beginning on January 1 and ending on March 31 of each year.

(f) Individuals deemed enrolled in medical insurance program

Any individual—

(1) who is eligible under section 1395o of this title to enroll in the medical insurance program by reason of entitlement to hospital insurance benefits as described in paragraph (1) of such section, and

(2) whose initial enrollment period under subsection (d) of this section begins after March 31, 1973, and

(3) who is residing in the United States, exclusive of Puerto Rico,

shall be deemed to have enrolled in the medical insurance program established by this part.

(g) Commencement of enrollment period

All of the provisions of this section shall apply to individuals satisfying subsection (f) of this section, except that—

(1) in the case of an individual who satisfies subsection (f) of this section by reason of entitlement to disability insurance benefits described in section 423(b) of this title, his initial enrollment period shall begin on the first day of the later of (A) April 1973 or (B) the third month before the 25th month of such entitlement, and shall reoccur with each continuous period of eligibility (as defined in section 1395r(d) of this title) and upon attainment of age 65;

(2)(A) in the case of an individual who is entitled to monthly benefits under section 402 or 423 of this title on the first day of his initial enrollment period or becomes entitled to monthly benefits under section 402 of this title during the first 3 months of such period, his enrollment shall be deemed to have occurred in the third month of his initial enrollment period, and

(B) in the case of an individual who is not entitled to benefits under section 402 or 423 of this title on the first day of his initial enrollment period or becomes entitled to monthly benefits under section 402 of this title during the first 3 months of such period, his enrollment shall be deemed to have occurred in the month in which he files the application establishing his entitlement to hospital insurance benefits provided such filing occurs during the last 4 months of his initial enrollment period; and

(3) in the case of an individual who would otherwise satisfy subsection (f) of this section but does not establish his entitlement to hospital insurance benefits until after the last day of his initial enrollment period (as defined in subsection (d) of this section), his enrollment shall be deemed to have occurred on the first day of the earlier of the then current or immediately succeeding general enrollment period (as defined in subsection (e) of this section).

(h) Waiver of enrollment period requirements where individual’s rights were prejudiced by administrative error or inaction

In any case where the Secretary finds that an individual’s enrollment or nonenrollment in the insurance program established by this part or part A pursuant to section 1395I-2 of this title is unintentional, inadvertent, or erroneous and is the result of the error, misrepresentation, or inaction of an officer, employee, or agent of the Federal Government, or its instrumentalities, the Secretary may take such action (including the designation for such individual of a special initial or subsequent enrollment period, a coverage period determined on the basis thereof and with appropriate adjustments of premiums) as may be necessary to correct or eliminate the effects of such error, misrepresentation, or inaction.

(i) Special enrollment periods

(1) In the case of an individual who—

(A) at the time the individual first satisfies paragraph (1) or (2) of section 1395o of this title, is enrolled in a group health plan described in section 1395y(b)(1)(A)(v) of this title by reason of the individual’s (or the individual’s spouse’s) current employment status, and

(B) has elected not to enroll (or to be deemed enrolled) under this section during the individual’s initial enrollment period,

there shall be a special enrollment period described in paragraph (3). In the case of an individual not described in the previous sentence who has not attained the age of 65, at the time the individual first satisfies paragraph (1) of section 1395o of this title, is enrolled in a large group health plan (as that term is defined in section 1395y(b)(1)(B)(ii) of this title) by reason of the individual’s current employment status (or the current employment status of a family member of the individual), and has elected not to enroll (or to be deemed enrolled) under this section during the individual’s initial enrollment period, there shall be a special enrollment period described in paragraph (3)(B).

(2) In the case of an individual who—

(A)(i) has enrolled (or has been deemed to have enrolled) in the medical insurance program established under this part during the individual’s initial enrollment period, or (ii) is an individual described in paragraph (1)(A);

(B) has enrolled in such program during any subsequent special enrollment period under this subsection during which the individual was not enrolled in a group health plan described in section 1395y(b)(1)(A)(v) of this title by reason of the individual’s (or individual’s spouse’s) current employment status; and

(C) has not terminated enrollment under this section at any time at which the individ-
ual is not enrolled in such a group health plan by reason of the individual’s (or individual’s spouse’s) current employment status, there shall be a special enrollment period described in paragraph (3). In the case of an individual not described in the previous sentence who has not attained the age of 65, has enrolled (or has been deemed to have enrolled) in the medical insurance program established under this part during the individual’s initial enrollment period, or is an individual described in the second sentence of paragraph (1), has enrolled in such program during any subsequent special enrollment period under this subsection during which the individual was not enrolled in a large group health plan (as that term is defined in section 1395y(b)(1)(B)(iii) of this title) by reason of the individual’s current employment status (or the current employment status of a family member of the individual), and has not terminated enrollment under this section at any time at which the individual is not enrolled in such a large group health plan by reason of the individual’s current employment status (or the current employment status of a family member of the individual), there shall be a special enrollment period described in paragraph (3)(B).

(3)(A) The special enrollment period referred to in the first sentences of paragraphs (1) and (2) is the period including each month during any part of which the individual is enrolled in a group health plan described in section 1395y(b)(1)(A)(v) of this title by reason of current employment status ending with the last day of the eighth consecutive month in which the individual is at no time so enrolled.

(B) The special enrollment period referred to in the second sentences of paragraphs (1) and (2) is the period including each month during any part of which the individual is enrolled in a large group health plan (as that term is defined in section 1395y(b)(1)(B)(iii) of this title) by reason of the individual’s current employment status (or the current employment status of a family member of the individual) ending with the last day of the eighth consecutive month in which the individual is at no time so enrolled.

(4)(A) In the case of an individual who is entitled to benefits under part A pursuant to section 426(b) of this title and—

(i) who at the time the individual first satisfies paragraph (1) of section 1395o of this title—

(I) is enrolled in a group health plan described in section 1395y(b)(1)(A)(v) of this title by reason of the individual’s current or former employment or by reason of the current or former employment status of a member of the individual’s family, and

(II) has elected not to enroll (or to be deemed enrolled) under this section during the individual’s initial enrollment period; and

(ii) whose continuous enrollment under such group health plan is involuntarily terminated at a time when the enrollment under the plan is not by reason of the individual’s current employment or by reason of the current employment of a member of the individual’s family,

there shall be a special enrollment period described in subparagraph (B).

(B) The special enrollment period referred to in subparagraph (A) is the 6-month period beginning on the first day of the month which includes the date of the enrollment termination described in subparagraph (A)(ii).

(j) Special rules for individuals with ALS

In applying this section in the case of an individual who is entitled to benefits under part A pursuant to the operation of section 426(h) of this title, the following special rules apply:

(1) The initial enrollment period under subsection (d) of this section shall begin on the first day of the first month in which the individual satisfies the requirement of section 1395o(1) of this title.

(2) In applying subsection (g)(1) of this section, the initial enrollment period shall begin on the first day of the first month of entitlement to disability insurance benefits referred to in such subsection.

(k) Special enrollment period for certain volunteers serving outside United States

(1) In the case of an individual who—

(A) at the time the individual first satisfies paragraph (1) or (2) of section 1395o of this title, is described in paragraph (3), and has elected not to enroll (or to be deemed enrolled) under this section during the individual’s initial enrollment period; or

(B) has terminated enrollment under this section during a month in which the individual is described in paragraph (3),

there shall be a special enrollment period described in paragraph (2).

(2) The special enrollment period described in this paragraph is the 6-month period beginning on the first day of the month which includes the date that the individual is no longer described in paragraph (3).

(3) For purposes of paragraph (1), an individual described in this paragraph is an individual who—

(i) is serving as a volunteer outside of the United States through a program—

(I) that covers at least a 12-month period; and

(ii) that is sponsored by an organization described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of such Code; and

(B) demonstrates health insurance coverage while serving in the program.

(l) Special enrollment period for disabled TRICARE beneficiaries

(1) In the case of any individual who is a covered beneficiary (as defined in section 1072(g) of title 10) at the time the individual is entitled to part A under section 426(b) of this title or section 426–1 of this title and who is eligible to enroll but who has elected not to enroll (or to be deemed enrolled) during the individual’s initial enrollment period, there shall be a special enrollment period described in paragraph (2).

(2) The special enrollment period described in this paragraph, with respect to an individual, is the 12-month period beginning on the day after
the last day of the initial enrollment period of the individual or, if later, the 12-month period beginning with the month the individual is notified of enrollment under this section.

In the case of an individual who enrolls during the special enrollment period provided under paragraph (1), the coverage period under this part shall begin on the first day of the month in which the individual enrolls, or, at the option of the individual, the first month after the end of the individual’s initial enrollment period.

(4) An individual may only enroll during the special enrollment period provided under paragraph (1) one time during the individual’s lifetime.

(5) The Secretary shall ensure that the materials relating to coverage under this part that are provided to an individual described in paragraph (1) prior to the individual’s initial enrollment period contain information concerning the impact of not enrolling under this part, including the impact on health care benefits under the TRICARE program under chapter 55 of title 10.

(6) The Secretary of Defense shall collaborate with the Secretary of Health and Human Services and the Commissioner of Social Security to provide for the accurate identification of individuals described in paragraph (1). The Secretary of Defense shall provide such individuals with notification with respect to this subsection. The Secretary of Defense shall collaborate with the Secretary of Health and Human Services and the Commissioner of Social Security to ensure appropriate follow up pursuant to any notification provided under the preceding sentence.


REFERENCES IN TEXT

Part A, referred to in subsecs. (c), (h), (i)(4)(A), (j), and (k)(1), is classified to section 1396c et seq. of this title.


AMENDMENTS


1994—Subsec. (i)(1). Pub. L. 103–432, § 151(c)(2)(A), in closing provisions substituted “(as those terms are defined in section 1395y(b)(1)(B)(iv) of this title)” for “(as an active individual)” in clause (V) of the definition of “individual”.

Subsec. (i)(2). Pub. L. 103–432, § 151(c)(2)(A), (C), in closing provisions substituted “(as those terms are defined in section 1395y(b)(1)(B)(iv) of this title)” for “(as an active individual)”.


Subsec. (i)(1). Pub. L. 103–432, § 151(d)(2)(A), (C), in closing provisions substituted “(as those terms are defined in section 1395y(b)(1)(B)(iv) of this title)” for “(as an active individual)”.

Subsec. (i)(2)(B), (C). Pub. L. 103–432, § 151(c)(2)(D), inserted “(ii)” after “current employment”.


Pub. L. 103–432, § 147(f)(1)(A), substituted “including each month during any part of which the individual is enrolled” for “beginning with the first day of the first month in which the individual is no longer enrolled” and “ending with the last day of the eighth consecutive month in which the individual is at no time so enrolled” for “and ending seven months later”.

Subsec. (i)(3)(B). Pub. L. 103–432, § 151(c)(2)(B), substituted “in a large group health plan (as that term is defined in section 1395y(b)(1)(B)(iv) of this title)” for “(as an active individual)”.

Pub. L. 103–432, § 147(f)(1)(A), substituted “including each month during any part of which the individual is enrolled” for “beginning with the first day of the first month in which the individual is no longer enrolled” and “ending with the last day of the eighth consecutive month in which the individual is at no time so enrolled” for “and ending seven months later”.

1989—Subsec. (i)(l). Pub. L. 101–239, § 6202(c)(1)(A), redesignated subpars. (B) and (C) as (A) and (B), respectively, struck out former subpart. (A) which read as follows: “has attained the age of 65,” and inserted “not described in the previous sentence” after “In the case of an individual” in second sentence.


Subsec. (i)(2). Pub. L. 101–239, § 6202(c)(1)(B), substituted “(1)(A)” for “(1)(B)” in subpart. (B)(i), redesignated subpars. (B) and (C) as (A) and (B), respectively, struck out former subpar. (A) which read as follows: “has attained the age of 65,” and inserted “not described in the previous sentence” after “In the case of an individual” in second sentence.


enrolled in a large health plan, and having elected not to enroll during initial enrollment period.


Pub. L. 99–272, § 201(c)(2)(A), amended subpar. (A) generally, substituting “has attained the age of 65” for “meets the conditions described in clauses (i) and (iii) of section 1395y(b)(3)(A) of this title”.

Subsec. (i)(2). Pub. L. 99–599, § 9319(c)(2), inserted sentence at end providing for a special enrollment period described in paragraph (3)(B) for individuals not age 65, enrolled or deemed enrolled in the medical insurance program established under this part, or is an individual described in the second sentence of paragraph (1), has enrolled in such program during a subsequent special enrollment period during which the individual was not enrolled in a large group health plan, and has not terminated enrollment.

Subsec. (i)(2)(A). Pub. L. 99–272, § 201(c)(2)(B), amended subpar. (A) generally, substituting “has attained the age of 65” for “meets the conditions described in clauses (i) and (ii) of section 1395y(b)(3)(A) of this title.”.

Subsec. (i)(2)(B). Pub. L. 99–272, § 201(c)(2)(A), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: “has enrolled (or has been deemed to have enrolled) in the medical insurance program established under this part, or is an individual described in this section (e) of this section)’’ for “the month in which the individual files an application establishing such entitlement” for “the earlier of the then current or immediately succeeding general enrollment period (as defined in subsection (e) of this section)”.

1972—Subsec. (b). Pub. L. 92–603, § 260, struck out provisions preventing enrollment under this part more than three years after first opportunity for such enrollment.

Subsec. (c). Pub. L. 92–603, § 201(c)(2)(A), (B), substituted “paragraph (1) or (2)” for “paragraphs (1) and (2)”, and substituted provisions relating to the treatment of an individual who has attained age 65 and who satisfies paragraph (1) of section 1395o of this title but not paragraph (2) of such section, for provisions relating to the treatment of an individual who satisfies paragraph (2) of section 1395o of this title solely by reason of subparagraph (B) thereof.

Subsec. (d). Pub. L. 92–603, § 201(c)(2)(C), substituted “paragraph (1) or (2)” for “paragraphs (1) and (2)”.

Subsecs. (e), (f), (g). Pub. L. 92–603, § 206(a), added subsecs. (f) and (g).


1968—Subsec. (b)(1). Pub. L. 90–248, § 145(a), permitted an individual enrolling in supplementary medical insurance program for first time to enroll at any time in a general enrollment period which begins within 3 years of close of his initial enrollment period but has not terminated enrollment.

Subsec. (d). Pub. L. 90–248, § 139(a), inserted last sentence providing that if an individual who has attained age 65 failed to enroll in program because, relying on erroneous documentary evidence, he was mistaken about his age, he may enroll using date of attainment of age 65 that he alleges under documentary evidence.

Subsec. (e). Pub. L. 90–248, § 145(b), provided for an annual general enrollment period for supplementary medical insurance program beginning January 1 and ending March 31 of each year, commencing in 1969.


Effective Date of 2010 Amendment

Effective Date of 2006 Amendment

Effective Date of 2000 Amendment

Effective Date of 2000 Amendment
Amendment by Pub. L. 106–554 applicable to benefits for months beginning July 1, 2001, see section 1(a) (6) [title I § 115(c)] of Pub. L. 106–544, set out as a note under section 428 of this title.

Effective Date of 1997 Amendment
Section 4581(c) of Pub. L. 105–33 provided that: “The amendments made by this section [amending this section and sections 1395q and 1395r of this title] shall apply to involuntarily terminations of coverage under a group health plan occurring on or after the date of the enactment of this Act [Aug. 5, 1997].”

Effective Date of 1994 Amendment
Section 147(f)(1)(C) of Pub. L. 103–432 provided that: “The amendments made by subparagraphs (A) and (B)
[amending this section and section 1395q of this title] shall take effect on the first day of the first month that begins after the expiration of the 120-day period that begins on the date of the enactment of this Act [Oct. 31, 1994]."

Section 151(c)(2) of Pub. L. 103–432 provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 103–46.

**Effective Date of 1989 Amendment**

Amendment by section 6202(b)(4)(C) of Pub. L. 101–239 applicable to items and services furnished after Dec. 19, 1989, see section 1805(e) of Pub. L. 99–514, set out as a note under section 182 of Title 26, Internal Revenue Code.


Section 9319(f)(2) of Pub. L. 99–509, set out as a note under section 1395y of this title.

**Effective Date of 1986 Amendments**


Section 9319(f)(2) of Pub. L. 99–509, set out as a note under section 1395y of this title.

**Effective Date of 1984 Amendment**

Section 2338(d)(2) of Pub. L. 98–369 provided that:

"(A) The amendments made by subsections (b) and (c) [amending this section and section 1395q of this title] shall apply to enrollments in months beginning with the first effective month (as defined in clause (ii)), except that in the case of any individual who would have a special enrollment period under section 1837(i) of the Social Security Act [subsec. (i) of this section] that would have begun after November 1984 and before the first effective month, the period shall be deemed to begin with the first day of the first effective month.

"(ii) For purposes of clause (i), the term ‘first effective month’ means the first month that begins more than 90 days after the date of the enactment of this Act [Apr. 7, 1984]."

**Effective Date of 1961 Amendment**

Section 2151(b) of Pub. L. 97–35 provided that: "The amendments made by this section [amending this section and sections 1395q and 1395r of this title] shall not apply to enrollments pursuant to written requests for enrollment filed before October 1, 1981."

**Effective Date of 1980 Amendments**

Section 945(d) of Pub. L. 96–499 provided that: "The amendments made by subsections (a), (b), and (c) [amending this section and sections 1395q and 1395r of this title] shall apply to enrollments occurring on or after April 1, 1981."

Amendment by Pub. L. 96–265 applicable with respect to hospital insurance or supplementary medical insurance benefits for services provided on or after the first day of the sixth month which begins after June 9, 1980, see section 103(c) of Pub. L. 96–265, set out as a note under section 426 of this title.

**Effective Date of 1972 Amendment**

Section 259(b) of Pub. L. 92–603 provided that: "The amendment made by subsection (a) [amending this section] shall be effective as of July 1, 1966."

**Effective Date of 1968 Amendment**

Section 136(b) of Pub. L. 90–248 provided that: "The amendment made by subsection (a) [amending this section] shall apply to individuals enrolling under part B of title XVIII [this part] in months beginning after the date of the enactment of this Act [Jan. 2, 1968]."

Section 136(b) of Pub. L. 90–248 provided that: "The amendments made by subsections (a), (b), and (c) [amending this section and section 1395q of this title] shall become effective April 1, 1968. Notwithstanding the provisions of section 2 of Public Law 90–97, the amendments made by subsection (d) [amending section 1395r of this title] shall become effective December 1, 1968."

**Medicare Part B Special Enrollment Period**


"(1) In general.—In the case of any individual who, as of the date of the enactment of this Act (Dec. 8, 2003), is eligible to enroll but is not enrolled under part B of title XVIII of the Social Security Act [this part] and is a covered beneficiary (as defined in section 1827(b) of title 18, United States Code), the Secretary of Health and Human Services shall provide for a special enrollment period during which the individual may enroll under such part. Such period shall begin as soon as possible after the date of the enactment of this Act and shall end on December 31, 2004.

"(2) Coverage period.—In the case of an individual who enrolls during the special enrollment period provided under paragraph (1), the coverage period under part B of title XVIII of the Social Security Act [this part] shall begin on the first day of the month following the month in which the individual enrolls."

**Extension Through March 31, 1968 of 1967 General Enrollment Period**

Pub. L. 90–97, §1, Sept. 30, 1967, 81 Stat. 249, extended the general enrollment period under subsec. (e) of this section, beginning Oct. 1, 1967, and ending Dec. 31, 1967, for purposes of enrolling in the insurance program established under part B of title XVIII of such Act [this part] and of terminating such enrollment as provided in section 1395q(b)(1) of this title, through Mar. 31, 1968.

**Enrollment Before Oct. 1, 1966, of Eligible Individuals Failing For Good Cause To Enroll Before June 1, 1966; Commencement of Coverage Period**

Section 102(b) of Pub. L. 89–97, as amended by section 3(c) of Pub. L. 89–384, provided that: "If—

"(1) an individual was eligible to enroll under section 1837(c) of the Social Security Act [subsec. (c) of this section] before June 1, 1966, but failed to enroll before such date, and
(2) it is shown to the satisfaction of the Secretary of Health, Education, and Welfare [now Health and Human Services] that there was good cause for such failure to enroll before June 1, 1966.

Such individual may enroll pursuant to this subsection at any time before October 1, 1966. The determination of what constitutes good cause for purposes of the preceding sentence shall be made in accordance with regulations of the Secretary. In the case of any individual who enrolls pursuant to this subsection, the coverage period (within the meaning of section 1838 of the Social Security Act (section 1395q of this title)) shall begin on the first day of the 6th month after the month in which he enrolls.

§ 1395q. Coverage period

(a) Commencement

The period during which an individual is entitled to benefits under the insurance program established by this part (hereinafter referred to as his “coverage period”) shall begin on whichever of the following is the latest:

(1) July 1, 1966, or (in the case of a disabled individual who has not attained age 65) July 1, 1973, or

(2) the first day of the 6th month after the month in which he satisfies paragraph (1) or (2) of section 1395q of this title, the first day of such month, or

(B) in the case of an individual who enrolls pursuant to such subsection (d) in the month in which he satisfies such paragraph, the first day of the month following the month in which he so enrolls, or

(C) in the case of an individual who enrolls pursuant to such subsection (d) in the month in which he satisfies such paragraph, the first day of the second month following the month in which he so enrolls, or

(D) in the case of an individual who enrolls pursuant to such subsection (d) more than one month following the month in which he satisfies such paragraph, the first day of the third month following the month in which he so enrolls, or

(E) in the case of an individual who enrolls pursuant to subsection (e) of section 1395p of this title, the July 1 following the month in which he so enrolls; or

(3)(A) in the case of an individual who is deemed to have enrolled on or before the last day of the third month of his initial enrollment period, the first day of the month in which he first meets the applicable requirements of section 1395e of this title or July 1, 1973, whichever is later, or

(B) in the case of an individual who is deemed to have enrolled on or after the first day of the fourth month of his initial enrollment period, as prescribed under subparagraphs (B), (C), (D), and (E) of paragraph (2) of this subsection.

(b) Continuation

An individual’s coverage period shall continue until his enrollment has been terminated—

(1) by the filing of notice that the individual no longer wishes to participate in the insurance program established by this part, or

(2) for nonpayment of premiums.

The termination of a coverage period under paragraph (1) shall (except as otherwise provided in section 1395v(e) of this title) take effect at the close of the month following the month in which the notice is filed. The termination of a coverage period under paragraph (2) shall take effect on a date determined under regulations, which may be determined so as to provide a grace period in which overdue premiums may be paid and coverage continued. The grace period determined under the preceding sentence shall not exceed 90 days; except that it may be extended to not exceed 180 days in any case where the Secretary determines that there was good cause for failure to pay the overdue premiums within such 90-day period.

Where an individual who is deemed to have enrolled for medical insurance pursuant to section 1395p(f) of this title files a notice before the first day of the month in which his coverage period begins advising that he does not wish to be so enrolled, the termination of the coverage period resulting from such deemed enrollment shall take effect with the first day of the month the coverage would have been effective. Where an individual who is deemed enrolled for medical insurance benefits pursuant to section 1395p(f) of this title files a notice requesting termination of his deemed coverage in or after the month in which such coverage becomes effective, the termination of such coverage shall take effect at the close of the month following the month in which the notice is filed.

(c) Termination

In the case of an individual satisfying paragraph (1) of section 1395q of this title whose entitlement to hospital insurance benefits under part A of this subchapter is based on a disability rather than on his having attained the age of 65, his coverage period (and his enrollment under this part) shall be terminated as of the close of the last month for which he is entitled to hospital insurance benefits.

(d) Payment of expenses incurred during coverage period

No payments may be made under this part with respect to the expenses of an individual unless such expenses were incurred by such individual during a period which, with respect to him, is a coverage period.

(e) Commencement of coverage for special enrollment periods

Notwithstanding subsection (a) of this section, in the case of an individual who enrolls during a special enrollment period pursuant to section 1395p(i)(3) or 1395p(i)(4)(B) of this title—

(1) in any month of the special enrollment period in which the individual is at any time enrolled in a plan (specified in subparagraph (A) or (B), as applicable, of section 1395p(i)(3) of this title or specified in section 1395p(i)(4)(A)(i) of this title) or in the first month following such a month, the coverage period shall begin on the first day of the month in which the individual so enrolls (or, at the option of the individual, on the first day of any of the following three months), or

(2) in any other month of the special enrollment period, the coverage period shall begin
on the first day of the month following the month in which the individual so enrolls.

(f) Commencement of coverage for certain volunteers serving outside United States

Notwithstanding subsection (a), in the case of an individual who enrolls during a special enrollment period pursuant to section 1385p(k) of this title, the coverage period shall begin on the first day of the month following the month in which the individual so enrolls.

Section 1395q of this title provided:


REFERENCES IN TEXT

Part A of this subchapter, referred to in subsec. (c), is classified to section 1395c et seq. of this title.

AMENDMENTS


1994—Subsec. (e). Pub. L. 103–432 amended pars. (1) and (2) generally. Prior to amendment, pars. (1) and (2) read as follows:

“(1) in the first month of the special enrollment period, the coverage period shall begin on the first day of that month, or

“(2) in a month after the first month of the special enrollment period, the coverage period shall begin on the first day of the month following the month in which the individual so enrolls.”

1986—Subsec. (b). Pub. L. 99–509 substituted “month following the month” for “calendar quarter following the calendar quarter” in second and sixth sentences.

1984—Subsec. (b). Pub. L. 99–248 added subsec. (e) generally. Prior to amendment, subsec. (e) read as follows:

“Notwithstanding subsection (a) of this section, in the case of an individual who enrolls during a special enrollment period pursuant to—

“(1) subparagraph (A) of section 1395p(1)(3) of this title—

“(a) before the month in which he attains the age of 70, the coverage period shall begin on the first day of the month in which he has attained the age of 70, or

“(B) in or after the month in which he attains the age of 70, the coverage period shall begin on the first day of the month following the month in which he so enrolls; or

“(2) subparagraph (B) of section 1395p(1)(3) of this title—

“(A) in the first month of the special enrollment period, the coverage period shall begin on the first day of such month, or

“(B) in a month after the first month of the special enrollment period, the coverage period shall begin on the first day of the month following the month in which he so enrolls.”


1980—Subsec. (a)(2)(E). Pub. L. 96–499, § 945(c)(1), substituted “the first day of the third month” for “the July 1”.

Subsec. (b). Pub. L. 96–499, § 947(b), inserted “except as otherwise provided in section 1395v(e) of this title”.


Subsec. (a)(2). Pub. L. 92–603, § 201(c)(3)(B), substituted in subpar. (A) “paragraph (1) or (2)” for “paragraphs (1) and (2)” and in subpars. (B) to (D) “paragraph” for “paragraphs”.


Subsec. (b). Pub. L. 92–603, §§ 208(c), 257(a), inserted provisions relating to an individual who is deemed to have enrolled for medical insurance pursuant to section 1395p(f) of this title and an individual who is deemed enrolled for medical insurance benefits pursuant to section 1395p(f) of this title and struck out provisions limiting the allowable grace period to 90 days and inserted provision for extension of such period of up to 180 days where failure to pay premiums is due to good cause.

Subsecs. (c), (d). Pub. L. 92–603, § 202(c)(3)(C), added subsec. (c) and redesignated former subsec. (c) as (d).

1968—Subsec. (b). Pub. L. 90–248 substituted in first sentence following par. (2) “the calendar quarter following the calendar quarter” for “December 31 of the year”.

EFFECTIVE DATE OF 2006 AMENDMENT


EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105–33 applicable to involuntary terminations of coverage under a group health plan occurring on or after Aug. 5, 1997, see section 4581(c) of Pub. L. 105–33, set out as a note under section 1395p of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by Pub. L. 103–432 effective on first day of first month beginning after expiration of the 120-day period that begins on Oct. 31, 1994, see section 147(f)(1)(C) of Pub. L. 103–432, set out as a note under section 1395p of this title.

EFFECTIVE DATE OF 1986 AMENDMENTS

Section 9344(b)(2) of Pub. L. 99–509 provided that: “The amendments made by paragraph (1) [adding this section] shall apply to notices filed on or after July 1, 1987.”


EFFECTIVE DATE OF 1984 AMENDMENT

For effective date of amendment by Pub. L. 98–369, see section 2338(d)(2) of Pub. L. 98–369, set out as a note under section 1395p of this title.

EFFECTIVE DATE OF 1981 AMENDEMENT

Amendment by section 2106(b)(2) of Pub. L. 97–35 effective Apr. 1, 1981, see section 2106(c) of Pub. L. 97–35, set out as a note under section 1395p of this title.
Amendment by section 2151(a)(3) of Pub. L. 97–35 not applicable to enrollments pursuant to written requests for enrollment filed before Oct. 1, 1981, see section 2151(b) of Pub. L. 97–35, set out as a note under section 1395p of this title.

**Effective Date of 1980 Amendment**

Amendment by section 945(c)(1) of Pub. L. 96–499 applicable to enrollments occurring on or after Apr. 1, 1981, see section 945(d) of Pub. L. 96–499, set out as a note under section 1395p of this title.

Amendment by section 947(b) of Pub. L. 96–499 applicable to notices filed after third calendar month beginning after Dec. 5, 1980, see section 947(d) of Pub. L. 96–499, set out as a note under section 1395v of this title.

**Effective Date of 1972 Amendment**

Section 257(b) of Pub. L. 92–603 provided that: “The amendments made by subsection (a) [amending this section] shall apply with respect to nonpayment of premiums which become due and payable on or after the date of the enactment of this Act [Oct. 30, 1972] or which became payable within the 90-day period immediately preceding such date; and for purposes of such amendments any premium which became due and payable within such 90-day period shall be considered a premium becoming due and payable on the date of the enactment of this Act.”

**Effective Date of 1968 Amendment**


**Coverage Period; Termination Dates**

Pub. L. 90–97, §3(a), Sept. 30, 1967, 81 Stat. 249, provided that: “In the case of any individual who, pursuant to section 1838(a)(1) of the Social Security Act [subsec. (b)(1) of this section], terminates his enrollment in the insurance program established under part B of title XVIII of such Act [this part], his coverage period (as defined in section 1838(a) of such Act) [subsec. (a) of this section]—

(1) shall terminate at the close of December 31, 1967, if he filed his notice of termination before January 1, 1968, or

(2) shall terminate at the close of March 31, 1968, if he filed his notice of termination after December 31, 1967, and before April 1, 1968.

An individual whose coverage period terminated pursuant to paragraph (1) at the close of December 31, 1967, may, notwithstanding section 1837(b)(2) of such Act [section 1395p(b)(2) of this title], enroll in such program before April 1, 1968, and for purposes of sections 1838(a)(2)(E) [subsec. (a)(2)(E) of this section] and 1837(b)(2) of such Act [section 1395p(b)(2) of this title] such enrollment shall be deemed an enrollment under section 1837(e) of such Act [section 1395p(e) of this title] and a second enrollment under such part.”

**Extension of 1967 General Enrollment Period Through March 31, 1968**

Extension of the general enrollment period under section 1395p(e) of this title through March 31, 1968, see section 1 of Pub. L. 90–97, Sept. 30, 1967, 81 Stat. 249, set out as a note under section 1395p of this title.

**Coverage Period for Individuals Becoming Eligible in March 1966 Who Enroll in May 1966**

Pub. L. 89–384, §3(d), Apr. 8, 1966, 80 Stat. 103, provided that: “In the case of an individual who first satisfies paragraphs (1) and (2) of section 1836 of the Social Security Act [section 1395p of this title] in March, 1966, and who enrolls pursuant to subsection (d) of section 1837 of such Act [section 1395p of this title] in May, 1966, his coverage period shall, notwithstanding section 1838(a)(2)(D) of such Act [subsec. (a)(2)(D) of this section], begin on July 1, 1966.”

**Commencement of Coverage Period of Certain Enrollees**

Commencement of coverage period upon enrollment before Oct. 1, 1966 of eligible individuals failing for good cause to enroll before June 1, 1966, see section 102(b) of Pub. L. 89–97, set out as a note under section 1395p of this title.

**§1395r. Amount of premiums for individuals enrolled under this part**

(a) Determination of monthly actuarial rates and premiums

(1) The Secretary shall, during September of 1983 and of each year thereafter, determine the monthly actuarial rate for enrollees age 65 and over which shall be applicable for the succeeding calendar year. Such actuarial rate shall be the amount the Secretary estimates to be necessary so that the aggregate amount for such calendar year with respect to those enrollees age 65 and older will equal one-half of the total of the benefits and administrative costs which he estimates will be payable from the Federal Supplementary Medical Insurance Trust Fund for services performed and related administrative costs incurred in such calendar year with respect to such enrollees. In calculating the monthly actuarial rate, the Secretary shall include an appropriate amount for a contingency margin. In applying this paragraph there shall not be taken into account additional payments under section 1395w–4(o) of this title and section 1395w–23(j)(3) of this title and the Government contribution under section 1395w(a)(3) of this title.

(2) The monthly premium of each individual enrolled under this part for each month after December 1983 shall be the amount determined under paragraph (3), adjusted as required in accordance with subsections (b), (c), (f), and (i) of this section, and to reflect any credit provided under section 1395w–24(b)(1)(C)(ii)(II) of this title.

(3) The Secretary, during September of each year, shall determine and promulgate a monthly premium rate for the succeeding calendar year that (except as provided in subsection (g) of this section) is equal to 50 percent of the monthly actuarial rate for enrollees age 65 and over, determined according to paragraph (1), for that succeeding calendar year. Whenever the Secretary promulgates the dollar amount which shall be applicable as the monthly premium rate for any period, he shall, at the time such promulgation is announced, issue a public statement setting forth the actuarial assumptions and bases employed by him in arriving at the amount of an adequate actuarial rate for enrollees age 65 and older as provided in paragraph (1).

(4) The Secretary shall also, during September of 1983 and of each year thereafter, determine the monthly actuarial rate for disabled enrollees under age 65 which shall be applicable for the succeeding calendar year. Such actuarial rate shall be the amount the Secretary estimates to be necessary so that the aggregate amount for such calendar year with respect to disabled enrollees under age 65 will equal one-half of the total of the benefits and administrative costs which he estimates will be payable from the Federal Supplementary Medical Insurance Trust Fund for services performed and related admin-
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(b) Increase in monthly premium

In the case of an individual whose coverage period began pursuant to an enrollment after his initial enrollment period (determined pursuant to subsection (c) or (d) of section 1395p of this title) and not pursuant to a special enrollment period under subsection (i)(4) or (l) of section 1395p of this title, the monthly premium determined under subsection (a) of this section (without regard to any adjustment under subsection (i) of this section) shall be increased by 10 percent of the monthly premium so determined for each full 12 months (in the same continuous period of eligibility) in which he could have been but was not enrolled. For purposes of the preceding sentence, there shall be taken into account (1) the months which elapsed between the close of his initial enrollment period and the close of the enrollment period in which he enrolled, plus (in the case of an individual who reenrolls) (2) the months which elapsed between the date of termination of a previous coverage period and the close of the enrollment period in which he reenrolled, but there shall not be taken into account months for which the individual can demonstrate that the individual was enrolled in a group health plan described in section 1395y(b)(1)(A)(v) of this title by reason of the individual’s or the individual’s spouse’s current employment status or months during which the individual has not attained the age of 65 and for which the individual can demonstrate that the individual was enrolled in a large group health plan (as that term is defined in section 1395y(b)(1)(B)(iii) of this title) by reason of the individual’s current employment status (or the current employment status of a family member of the individual) or months for which the individual can demonstrate that the individual was an individual described in section 1395p(k)(3) of this title. Any increase in an individual’s monthly premium under the first sentence of this subsection with respect to a particular continuous period of eligibility shall not be applicable with respect to any other continuous period of eligibility which such individual may have. No increase in the premium shall be effected for a month in the case of an individual who enrolls under this part during 2001, 2002, 2003, or 2004 and who demonstrates to the Secretary before December 31, 2004, that the individual is a covered beneficiary (as defined in section 1072(5) of title 45). The Secretary of Health and Human Services shall consult with the Secretary of Defense in identifying individuals described in the previous sentence.

c) Premiums rounded to nearest multiple of ten cents

If any monthly premium determined under the foregoing provisions of this section is not a multiple of 10 cents, such premium shall be rounded to the nearest multiple of 10 cents.

d) “Continuous period of eligibility” defined

For purposes of subsection (b) of this section (and section 1395p(g)(1) of this title), an individual’s “continuous period of eligibility” is the period beginning with the first day on which he is eligible to enroll under section 1395b of this title and ending with his death; except that any period during all of which an individual satisfied paragraph (1) of section 1395p of this title and which terminated in or before the month preceding the month in which he attained age 65 shall be a separate “continuous period of eligibility” with respect to such individual (and each such period which terminates shall be deemed not to have existed for purposes of subsequently applying this section).

e) State payment of part B late enrollment premium increases

(1) Upon the request of a State (or any appropriate State or local governmental entity specified by the Secretary), the Secretary may enter into an agreement with the State (or such entity) under which the State (or such entity) agrees to pay on a quarterly or other periodic basis to the Secretary (to be deposited in the Treasury to the credit of the Federal Supplementary Medical Insurance Trust Fund) an amount equal to the amount of the part B late enrollment premium increases with respect to the premiums for eligible individuals (as defined in paragraph (3)(A)).

(2) No part B late enrollment premium increase shall apply to an eligible individual for premiums for months for which the amount of such an increase is payable under an agreement under paragraph (1).

(3) In this subsection:

(A) The term “eligible individual” means an individual who is enrolled under this part B and who is within a class of individuals specified in the agreement under paragraph (1).

(B) The term “part B late enrollment premium increase” means any increase in a premium as a result of the application of subsection (b) of this section.

(f) Limitation on increase in monthly premium

For any calendar year after 1988, if an individual is entitled to monthly benefits under section 402 or 423 of this title or to a monthly annuity under section 3(a), 4(a), or 4(f) of the Railroad Retirement Act of 1974 [45 U.S.C. 231b(a), 231c(a), or 231c(f) for November and December of the preceding year, if the monthly premium of the individual under this section for December and for January is deducted from those benefits under section 1395s(a)(1) of this title or section 1395s(b)(1) of this title, and if the amount of the individual’s premium is not adjusted for such January under subsection (i) of this section, the monthly premium otherwise determined under this section for an individual for that year shall not be increased, pursuant to this subsection, to the extent that such increase would reduce the amount of benefits payable to that individual for that December below the amount of benefits payable to that individual for that November (after the deduction of the premium under this section). For purposes of this subsection, retroactive adjustments or payments and deductions on account of work shall not be taken into account in determining the monthly benefits to which an individual is entitled under section 402 or 423 of this title or under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.].
(g) Exclusions from estimate of benefits and administrative costs

In estimating the benefits and administrative costs which will be payable from the Federal Supplementary Medical Insurance Trust Fund for a year for purposes of determining the monthly premium rate under subsection (a)(3) of this section, the Secretary shall exclude an estimate of any benefits and administrative costs attributable to—

(1) the application of section 1395x(v)(1)(L)(viii) of this title or to the establishment under section 1395x(v)(1)(L)(i)(V) of this title of a per visit limit at 106 percent of the median (instead of 105 percent of the median), but only to the extent payment for home health services under this subchapter is not being made under section 1395ff of this title (relating to prospective payment for home health services); and

(2) the medicare prescription drug discount card and transitional assistance program under section 1395w–141 of this title.

(h) Potential application of comparative cost adjustment in CCA areas

(1) In general

Certain individuals who are residing in a CCA area under section 1395w–29 of this title who are not enrolled in an MA plan under part C of this subchapter may be subject to a premium adjustment under subsection (f) of such section for months in which the CCA program under such section is in effect in such area.

(2) No effect on late enrollment penalty or income-related adjustment in subsidies

Nothing in this subsection or section 1395w–29(f) of this title shall be construed as affecting the amount of any premium adjustment under subsection (b) or (i) of this section. Subsection (f) of this section shall be applied without regard to any premium adjustment referred to in paragraph (1).

(3) Implementation

In order to carry out a premium adjustment under this subsection and section 1395w–29(f) of this title (insofar as it is effected through the manner of collection of premiums under section 1395s(a) of this title), the Secretary shall transmit to the Commissioner of Social Security—

(A) at the beginning of each year, the name, social security account number, and the amount of the premium adjustment (if any) for each individual enrolled under this part for each month during the year; and

(B) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.

(i) Reduction in premium subsidy based on income

(1) In general

In the case of an individual whose modified adjusted gross income exceeds the threshold amount under paragraph (2), the monthly amount of the premium subsidy applicable to the premium under this section for a month after December 2006 shall be reduced (and the monthly premium shall be increased) by the monthly adjustment amount specified in paragraph (3).

(2) Threshold amount

For purposes of this subsection, subject to paragraph (6), the threshold amount is—

(A) except as provided in subparagraph (B), $80,000, and

(B) in the case of a joint return, twice the amount applicable under subparagraph (A) for the calendar year.

(3) Monthly adjustment amount

(A) In general

Subject to subparagraph (B), the monthly adjustment amount specified in this paragraph for an individual for a month in a year is equal to the product of the following:

(i) Sliding scale percentage

Subject to paragraph (6), the applicable percentage specified in the table in subparagraph (C) for the individual minus 25 percentage points.

(ii) Unsubsidized part B premium amount

200 percent of the monthly actuarial rate for enrollees age 65 and over (as determined under subsection (a)(1) of this section for the year).

(B) 3-year phase in

The monthly adjustment amount specified in this paragraph for an individual for a month in a year before 2009 is equal to the following percentage of the monthly adjustment amount specified in subparagraph (A):

(i) For 2007, 33 percent.

(ii) For 2008, 67 percent.

(C) Applicable percentage

(i) In general

If the modified adjusted gross income is: The applicable percentage is:

More than $80,000 but not more than $100,000 ....................................................... 35 percent

More than $100,000 but not more than $150,000 ....................................................... 50 percent

More than $150,000 but not more than $200,000 ....................................................... 65 percent

More than $200,000 ....................................................... 80 percent.

(ii) Joint returns

In the case of a joint return, clause (i) shall be applied by substituting dollar amounts which are twice the dollar amounts otherwise applicable under clause (i) for the calendar year.

(iii) Married individuals filing separate returns

In the case of an individual who—

(I) is married as of the close of the taxable year (within the meaning of section 7703 of the Internal Revenue Code of 1986) but does not file a joint return for such year, and

(II) does not live apart from such individual’s spouse at all times during the taxable year,

1 See References in Text note below.
clause (i) shall be applied by reducing each of the dollar amounts otherwise applicable under such clause for the calendar year by the threshold amount for such year applicable to an unmarried individual.

(4) Modified adjusted gross income

(A) In general

For purposes of this subsection, the term “modified adjusted gross income” means adjusted gross income (as defined in section 62 of the Internal Revenue Code of 1986)—

(i) determined without regard to sections 135, 911, 931, and 933 of such Code; and

(ii) increased by the amount of interest received or accrued during the taxable year which is exempt from tax under such Code.

In the case of an individual filing a joint return, any reference in this subsection to the modified adjusted gross income of such individual shall be to such return’s modified adjusted gross income.

(B) Taxable year to be used in determining modified adjusted gross income

(i) In general

In applying this subsection for an individual’s premiums in a month in a year, subject to clause (ii) and subparagraph (C), the individual’s modified adjusted gross income shall be such income determined for the individual’s last taxable year beginning in the second calendar year preceding the year involved.

(ii) Temporary use of other data

If, as of October 15 before a calendar year, the Secretary of the Treasury does not have adequate data for an individual in appropriate electronic form for the taxable year referred to in clause (i), the individual’s modified adjusted gross income shall be determined using the data in such form from the previous taxable year. Except as provided in regulations prescribed by the Commissioner of Social Security in consultation with the Secretary, the preceding sentence shall cease to apply when adequate data in appropriate electronic form are available for the individual for the taxable year referred to in clause (i), and proper adjustments shall be made to the extent that the premium adjustments determined under the preceding sentence were inconsistent with those determined using such taxable year.

(iii) Non-filers

In the case of individuals with respect to whom the Secretary of the Treasury does not have adequate data in appropriate electronic form for either taxable year referred to in clause (i) or clause (ii), the Commissioner of Social Security, in consultation with the Secretary, shall prescribe regulations which provide for the treatment of the premium adjustment with respect to such individual under this subsection, including regulations which provide for—

(I) the application of the highest applicable percentage under paragraph (3)(C) to such individual if the Commissioner has information which indicates that such individual’s modified adjusted gross income might exceed the threshold amount for the taxable year referred to in clause (i), and

(II) proper adjustments in the case of the application of an applicable percentage under subclause (I) to such individual which is inconsistent with such individual’s modified adjusted gross income for such taxable year.

(C) Use of more recent taxable year

(i) In general

The Commissioner of Social Security in consultation with the Secretary of the Treasury shall establish a procedures under which an individual’s modified adjusted gross income shall, at the request of such individual, be determined under this subsection—

(I) for a more recent taxable year than the taxable year otherwise used under subparagraph (B), or

(II) by such methodology as the Commissioner, in consultation with such Secretary, determines to be appropriate, which may include a methodology for aggregating or disaggregating information from tax returns in the case of marriage or divorce.

(ii) Standard for granting requests

A request under clause (i)(I) to use a more recent taxable year may be granted only if—

(I) the individual furnishes to such Commissioner with respect to such year such documentation, such as a copy of a filed Federal income tax return or an equivalent document, as the Commissioner specifies for purposes of determining the premium adjustment (if any) under this subsection; and

(II) the individual’s modified adjusted gross income for such year is significantly less than such income for the taxable year determined under subparagraph (B) by reason of the death of such individual’s spouse, the marriage or divorce of such individual, or other major life changing events specified in regulations prescribed by the Commissioner in consultation with the Secretary.

(5) Inflation adjustment

(A) In general

In the case of any calendar year beginning after 2007, each dollar amount in paragraph (2) or (3) shall be increased by an amount equal to—

(i) such dollar amount, multiplied by

(ii) the percentage (if any) by which the average of the Consumer Price Index for all urban consumers (United States city average) for the 12-month period ending with August of the preceding calendar year exceeds such average for the 12-month period ending with August 2006.
(B) Rounding

If any dollar amount after being increased under subparagraph (A) is not a multiple of $1,000, such dollar amount shall be rounded to the nearest multiple of $1,000.

(6) Temporary adjustment to income thresholds

Notwithstanding any other provision of this subsection, during the period beginning on January 1, 2011, and ending on December 31, 2019—

(A) the threshold amount otherwise applicable under paragraph (2) shall be equal to such amount for 2010; and

(B) the dollar amounts otherwise applicable under paragraph (3)(C)(i) shall be equal to such dollar amounts for 2010.

(7) Joint return defined

For purposes of this subsection, the term “joint return” has the meaning given to such term by section 7701(a)(38) of the Internal Revenue Code of 1986.

AMENDMENTS

2010—Subsec. (b). Pub. L. 111–148, § 3110(b), substituted “subsection (i)(4) or (l) of section 1395p” for “section 1395p(i)(4)”.


Subsec. (i)(3)(A)(i). Pub. L. 111–148, § 3402(b), substituted “subject to paragraph (6), the applicable” for “The applicable”.

Subsec. (i)(6). Pub. L. 111–148, § 3402(b), (4), added par. (6) and redesignated former par. (6) as (7).

2009—Subsec. (a)(1). Pub. L. 111–5 inserted at end “In applying this paragraph there shall not be taken into account additional payments under section 1395w–4(o) of this title and section 1395w–23(i)(3) of this title and the Government contribution under section 1395w(a)(3) of this title.”

2006—Subsec. (b), Pub. L. 109–171, § 5111(a)(1), inserted “or months for which the individual can demonstrate that the individual was an individual described in section 1395p(c)(3) of this title” before period at end of second sentence.


Subsec. (i)(3)(B)(iii). Pub. L. 109–171, § 5111(b)(5), struck out cls. (iii) and (iv), which read as follows:

“(iii) For 2009, 60 percent.

“(iv) For 2010, 80 percent.”

2003—Subsec. (a)(2). Pub. L. 108–173, § 811(b)(1)(A)(a), substituted “(f) and (i)” for “(f)”.


Subsec. (a)(4). Pub. L. 108–173, § 736(b)(7), substituted “will equal one-half of the total” for “which will equal one-half of the total”.

Subsec. (b). Pub. L. 108–173, § 811(b)(1)(B), inserted “(without regard to any adjustment under subsection (i) of this section)” after “subsection (a) of this section”.

Pub. L. 108–173, § 625(a)(a), inserted at end “No increase in the premium shall be effected for a month in the case of an individual who enrolls under this part during 2001, 2002, 2003, or 2004 and who demonstrates to the Secretary before December 31, 2004, that the individual is a covered beneficiary (as defined in section 1395s(b)(1) of this title), or months for which the individual can demonstrate that the individual was an individual described in section 1395p(c)(3) of this title” before period at end of second sentence.

REFERENCES IN TEXT

designation before “the application of”, substituted “; and” for “period at end, and added par. (2).”


2000—Subsec. (a)(2). Pub. L. 106–554 substituted “‘subsections (b), (c), and (f)’” for “‘subsections (b), (c), and (f) of this section, to and reflect 80 percent of any reduction elected under section 1395w–24(f)(1)(E) of this title.’” for “‘shall, except as provided in subsections (b), (c), and (f) of this section, be the amount determined under paragraph (3).’”

1998—Subsec. (a)(3). Pub. L. 105–277, § 5101(e)(1), inserted “(except as provided in subsection (g) of this section)” after “year that”.


1997—Subsec. (a)(2). Pub. L. 105–33, § 4571(b)(1)(A), substituted “subsections (b), (c), and (f)” for “subsections (b) and (c)”.

Subsec. (a)(3). Pub. L. 105–33, § 4571(b)(1)(A), in last sentence, inserted “rate” after “monthly premium” and struck out “and the derivation of the dollar amount specified in this paragraph” before period at end.

Pub. L. 105–33, § 4571(a), substituted “The Secretary, during September of each year, shall determine and promulgate a monthly premium rate for the succeeding calendar year that is equal to 50 percent of the monthly actuarial rate for enrollees age 65 and over, determined according to paragraph (1), for that succeeding calendar year.” for “The Secretary shall, during September of 1983 and of each year thereafter, determine and promulgate the monthly premium applicable for individuals enrolled under this part for the succeeding calendar year. The monthly premium shall (except as otherwise provided in subsection (e) of this section) be equal to the smaller of—

“(A) the monthly actuarial rate for enrollees age 65 and over, determined according to paragraph (1) of this subsection, for that calendar year, or

“(B) the monthly premium rate most recently promulgated by the Secretary under this paragraph, increased by a percentage determined as follows: The Secretary shall ascertain the primary insurance amount computed under section 415(a)(1) of this title, based upon average indexed monthly earnings of $900, that applied to individuals who became eligible for and entitled to old-age insurance benefits on November 1 of the year before the year of the promulgation. He shall increase the monthly premium rate by the same percentage by which that primary insurance amount is increased when, by reason of the law in effect at the time the promulgation is made, it is so computed to apply to those individuals for the following November 1.”


Pub. L. 105–33, § 4571(b)(1)(C), struck out “or (e)” after “determined under subsection (a)” in first sentence.

Pub. L. 105–33, § 4581(a), inserted “and not pursuant to a special enrollment period under section 1395p(i)(4) of this title” after “section 1395p of this title” in first sentence.

Subsec. (e). Pub. L. 105–33, § 4581(b)(1)(A), (B), redesignated subsec. (g) as (e) and struck out former subsec. (e) which read as follows:

“(i) Notwithstanding the provisions of subsection (a) of this section, the monthly premium for each individual enrolled under this part for each month in—

“(ii) 1991 shall be $29.90,

“(iii) 1992 shall be $31.80,

“(iv) 1993 shall be $33.00,

“(v) 1994 shall be $34.10, and

“(vi) 1995 shall be $36.10.

“(2) Any increases in premium amounts taking effect prior to January 1986 by reason of paragraph (1) shall be taken into account for purposes of determining increases thereafter under subsection (a)(3) of this section.”

Subsec. (e)(1). Pub. L. 105–33, § 4582, inserted “(or any appropriate State or local governmental entity specified by the Secretary)” after “request of a State” and inserted “(or such entity)” after “agreement with the State”.

Subsec. (g). Pub. L. 105–33, § 4571(b)(1)(E), redesignated subsec. (g) as (e).

1994—Subsec. (b). Pub. L. 103–432, § 151(c)(3), in second sentence, inserted “status” after “current employment” and substituted “(as that term is defined in section 1395y(b)(1)(B)(iv) of this title) by reason of the individual’s current employment status (or the current employment status of a family member of the individual)” for “(as an active individual (as those terms are defined in section 1395y(b)(1)(B)(iv) of this title)”.

Subsec. (g). Pub. L. 103–432, § 144, added subsec. (g).

1993—Subsec. (e)(1). Pub. L. 103–66, § 13571(1), substituted “after December 1995 and prior to January 1999 shall be an amount equal to 50 percent” for “December 1993 and prior to January 1991 shall be an amount equal to 50 percent.”


1990—Subsec. (e)(1). Pub. L. 101–508 designated existing provisions as subpart (A) and added subpart (B).

1989—Subsec. (a). Pub. L. 101–234 repealed Pub. L. 100–360, § 211(c)(1)(A)–(D), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (b). Pub. L. 101–239, § 6202(c)(2), struck out “during which the individual has attained the age of 65 and” after “into account months” in second sentence.


Pub. L. 101–234 repealed Pub. L. 100–360, § 211(c)(1)(E), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment note below.


Subsec. (e)(1). Pub. L. 101–234 repealed Pub. L. 100–360, § 211(c)(1)(F), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (g). Pub. L. 101–234 repealed Pub. L. 100–360, § 211(a), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment note below.

1988—Subsec. (a)(1). Pub. L. 100–360, § 211(c)(1)(A), (B), inserted “(other than costs relating to the amendments made by the Medicare Catastrophic Coverage Act of 1988)” before period at end of second sentence, and “, but shall not take into account any amounts in the Trust Fund that may be attributable to receipts or outlays relating to the Medicare Catastrophic Coverage Account” before period at end of last sentence.

Subsec. (a)(2). Pub. L. 100–360, § 211(c)(1)(C), substituted “(e), and (g)” for “and (e)”.

Subsec. (a)(3). Pub. L. 100–360, § 211(c)(1)(D), substituted “subsection (e) and (g)” for “subsection (e)” in introductory provisions.

Subsec. (a)(4). Pub. L. 100–360, § 211(c)(1)(A), (B), inserted “(other than costs relating to the amendments made by the Medicare Catastrophic Coverage Act of
1988)” before period at end of second sentence, and “, but shall not take into account any amounts in the Trust Fund that may be attributable to receipts or outlays relating to the Medicare Catastrophic Coverage Account” before period at end of last sentence.

Subsec. (b). Pub. L. 100–360, § 321(c)(1)(E), substituted “otherwise determined under this section (without regard to subsections (f) and (g) of this section)” for “determined under subsection (a) or (e) of this section”.

Subsec. (e)(1). Pub. L. 100–360, § 321(c)(1)(F), inserted “except as provided in subsection (g) of this section,” after “subsection (a) of this section”.

Subsec. (f). Pub. L. 100–485, § 608(d)(8)(B), substituted “for that December below the amount of benefits payable to that individual for that November” for “for that December”.

Pub. L. 100–261, amended subsec. (f) generally, substituting a single paragraph for former pars. (1) and (2).

Subsec. (g). Pub. L. 100–360, § 321(a), added subsec. (g) relating to adjustment in Medicare part B premium.


Subsec. (g)(1)(B)(ii)(I). Pub. L. 100–485, § 608(d)(9)(A)(ii), substituted “of each such year” for “of such year”.


1986—Subsec. (b). Pub. L. 99–509, § 3913(c)(4), inserted “or months during which the individual has not attained the age of 65 and for which the individual can demonstrate that the individual was enrolled in a large group health plan as an active individual (as those terms are defined in section 1395y(b)(4)(B) of this title)” at end of second sentence.

Pub. L. 99–272, § 3219(a)(1), substituted “months during which the individual has attained the age of 65 and for which the individual can demonstrate that the individual was enrolled in a large group health plan as an active individual (as those terms are defined in section 1395y(b)(4)(B) of this title)” for “months in which the individual has met the conditions specified in clauses (i) and (ii) of section 1395y(b)(3)(A) of this title” at end of second sentence.

Pub. L. 99–272, § 3219(a)(1), substituted “the month after the month in which the individual was enrolled for the second time” for “the month after the month in which he reenrolled”.

Pub. L. 100–261, amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: “‘the monthly premium amount determined under subsection (a)(2) of this section for that December reduced by the amount (if any) necessary to make the monthly benefits under section 402 or 423 of this title for that December after the deduction of the premium (disregarding subsection (b) of this section) for that December at least equal to the monthly benefits under section 402 or 423 of this title for the preceding November after the deduction of the premium (disregarding subsection (b) of this section) for that individual for that December’.”

1985—Subsec. (b). Pub. L. 99–272, § 3219(a)(1), substituted “except as otherwise provided in subsection (d) of this section” for “except as provided in subsection (d)”.


Pub. L. 97–498 inserted reference to determination of monthly premium pursuant to subsec. (g) of this section.

Subsec. (e). Pub. L. 98–21, § 606(a)(2), redesignated subsec. (e) as (d). Former subsec. (d) redesignated (c).


1982—Subsec. (c)(2). Pub. L. 97–248, § 124(a)(1), substituted “except as provided in subsections (d) and (g)” for “except as provided in subsection (d)”.

Subsec. (c)(3). Pub. L. 97–248, § 124(a)(2), inserted “except as otherwise provided in subsection (g) of this section”.

1981—Subsec. (d). Pub. L. 97–35, substituted “the close of the enrollment period in which he reenrolled” for “the month after the month in which he reenrolled” in cl. (2).

1980—Subsec. (d). Pub. L. 96–499 substituted “who reenrolls” (2) the months which elapsed between the date of termination of a previous coverage period and the month after the month in which he reenrolled” for “who enrolls for a second time” (2) the months which elapsed between the date of the termination of his first coverage period and the close of the enrollment period in which he enrolled for the second time”.

1979—Subsec. (c)(i)(B). Pub. L. 96–206 substituted “the monthly premium rate most recently promulgated by the Secretary under this paragraph, increased by a percentage determined as follows: The Secretary shall ascertain the primary insurance amount computed under section 415(a)(1) of this title, based upon average indexed monthly earnings of $900, that applied to individuals who became eligible for and entitled to old-age insurance benefits on May 1 of the year of the promulgation for the ‘‘monthly premium rate most recently promulgated’’ by the Secretary under this paragraph or,
in the case of the determination made in December 1971, such rate promulgated under subsection (b)(2) of this section multiplied by the ratio of (i) the amount in column IV of the table which, by reason of the law in effect at the time the promulgation is made, will be in effect as of May 1 next following such determination appears (or is deemed to appear) in section 415(a) of this title on the line which includes the figure '70' in column III of such table to (ii) the amount in column IV of the table which appeared (or was deemed to appear) in section 415(a) of this title on the line which included the figure '70' in column III as of May 1 of the year in which such determination is made" and inserted "He shall increase the monthly premium rate by the same percentage by which that primary insurance amount is increased when, by reason of the law in effect at the time the promulgation is made, it is so computed to apply to those individuals on the following May 1.''

1975—Subsec. (c)(3). Pub. L. 94–182 substituted "May 1" for "June 1" wherever appearing.


Subsec. (b)(2). Pub. L. 92–603, § 203(b), substituted "ending on or before December 31, 1971" for "thereafter".

Subsec. (c). Pub. L. 92–603, § 203(c), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 92–603, §§ 201(c)(4), 203(c), (d)(1), redesignated former subsec. (c) as (d), inserted reference to subsec. (c) after reference to subsec. (b), inserted "in the same continuous period of eligibility" after "for each full 12 months", and inserted provisions relating to any increase in an individual's monthly premium under the first sentence of this subsection.

former subsec. (d) redesignated (e).

Subsec. (e). Pub. L. 92–603, § 203(c), redesignated former subsec. (d) as (e). Former subsec. (e) redesignated (f).


Subsec. (f). Pub. L. 92–603, § 203(c), (d)(2), redesignated former subsec. (e) as (f) and substituted "subsection (d)(1) for "subsection (c)".

1968—Subsec. (b)(2). Pub. L. 90–248 required Secretary, during December of each year, beginning in 1968, to determine and announce amount (whether or not such amount was applicable for premiums for any prior month) of supplementary medical insurance premium for 12-month period beginning on July 1 of each following year, which premium is to be such that aggregate premiums will equal one-half estimated benefit and administrative expenses of supplementary medical insurance program for such 12-month period, and that at time of announcement of premium amount, Secretary must make public actuarial assumptions and bases used in deciding amount of premium.

Effective Date of 2003 Amendment
Amendment by section 6202(b)(2) of Pub. L. 108–173 applicable with respect to plan years beginning on or after Jan. 1, 2006, see section 222(a) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

Effective Date of 2002 Amendment
Pub. L. 106–554, § 166(a)(6) [title VI, § 606(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–558, provided that: "The amendments made by section (a) [amending this section and sections 1395a, 1395w, 1395w–21, 1395w–23, and 1395w–24 of this title] shall apply to years beginning with 2003."

Effective Date of 1997 Amendment
Amendment by section 4581(a) of Pub. L. 105–33 applicable to involuntary terminations of coverage under a group health plan occurring on or after Aug. 5, 1997, see section 4581(c) of Pub. L. 105–33, set out as a note under section 1395p of this title.

Effective Date of 1994 Amendment
Section 151(c)(3) of Pub. L. 103–422 provided that the amendment made by that section is effective as if included in the enactment of Pub. L. 103–66.

Effective Date of 1989 Amendments
Amendment by section 6202(b)(4)(C) of Pub. L. 101–239 applicable to items and services furnished after Dec. 19, 1989, see section 6202(b)(5) of Pub. L. 101–239, set out as a note under section 162 of Title 26, Internal Revenue Code.

Amendment by section 6202(c)(2) of Pub. L. 101–239 applicable to enrollments occurring after, and premiums for months after, second calendar quarter beginning after Dec. 19, 1989, see section 6202(c)(5) of Pub. L. 101–239, set out as a note under section 1395p of this title.


Effective Date of 1988 Amendments
Amendment by Pub. L. 100–465 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. 100–360, set out as a note under section 704 of this title.

Section 211(d) of Pub. L. 100–360, which provided that the amendments made by section 211 of Pub. L. 100–360 [amending this section and sections 1395w and 1395mm of this title] applied (except as otherwise specified in such amendments) to monthly premiums for months beginning with January 1986, was repealed by Pub. L. 101–234, title II, § 202(a), Dec. 13, 1989, 103 Stat. 814.

Effective Date of 1986 Amendments
Amendment by Pub. L. 99–509 applicable with respect to monthly premiums under this section for months after December 1986, see section 9001(d)(3) of Pub. L. 99–509, set out as a note under section 415 of this title.


Section 2213(a)(3)(A) of Pub. L. 99–372 provided that: "The amendment made by paragraph (1) [amending this section] shall apply to months beginning with January 1983 for premiums for months beginning with the first month that begins more than 30 days after the date of the enactment of this Act [Apr. 7, 1986]."

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 2522(c) of Pub. L. 98–369 provided that: "The amendments made by this section [amending this section] shall apply to premiums for months beginning with January 1986."

Section 2536(d)(1) of Pub. L. 98–369 provided that: "The amendment made by subsection (a) [amending this section] shall apply to months beginning with January 1983 for premiums for months beginning with the
first month which begins more than 30 days after the
date of the enactment of this Act [July 18, 1984]."

**Effective Date of 1983 Amendments: Transitional Rule**

Section 606(c) of Pub. L. 98-21 provided that: "The amendments made by this section [amending this section and sections 1395s, 1395v, 1395w, and 1395mm of this title] shall apply to premiums for months beginning with January 1984, and for months after June 1983 and before January 1984—

"(1) the monthly premiums under part A and under part B of title XVIII of the Social Security Act [parts A and B of this subchapter] for individuals enrolled under each respective part shall be the monthly premium under that part for the month of June 1983, and

"(2) the amount of the Government contributions under section 1844(a)(1) of such Act [section 1395w(a)(1) of this title] shall be computed on the basis of the actuarially adequate rate which would have been in effect under part B of title XVIII of such Act for such months without regard to the amendments made by this section, but using the amount of the premium in effect for the month of June 1983.

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. 97–286, see section 306(d)(2) of Pub. L. 97–448, set out as a note under section 426-1 of this title.

**Effective Date of 1981 Amendment**

Amendment by Pub. L. 97–35 not applicable to enrollments pursuant to written requests for enrollment filed before Oct. 1, 1981, see section 2151(b) of Pub. L. 97–35, set out as a note under section 1395p of this title.

**Effective Date of 1980 Amendment**

Amendment by Pub. L. 96–499 applicable to enrollments occurring on or after Apr. 1, 1981, see section 945(d) of Pub. L. 96–499, set out as a note under section 1395p of this title.

**Effective Date of 1977 Amendment**


**Effective Date of 1975 Amendment**

Section 104(b) of Pub. L. 94–182 provided that: "The amendments made by subsection (a) [amending this section] shall apply with respect to determinations made under section 1839(c)(3) of the Social Security Act [subsec. (c)(3) of this section] after the date of the enactment of this Act [Dec. 31, 1975]."

**Effective Date of 1968 Amendment**

Amendment by Pub. L. 90–97 effective Dec. 1, 1968, see section 145(c) of Pub. L. 90–97, set out as a note under section 1395p of this title.

**No Change in Medicare's Defined Benefit Package**

Pub. L. 108–173, title II, §241(c), Dec. 8, 2003, 117 Stat. 2221, provided that: "Nothing in this part [probably should be this section, enacting former section 1395w–29 of this title and amending this section and sections 1395w and 1395w–23 of this title] (or the amendments made by this part) shall be construed as changing the entitlement to defined benefits under parts A and B of title XVIII of the Social Security Act [parts A and B of this subchapter]."

**Determination of Premium Amounts by Secretary**

Pub. L. 90–97, §2, Sept. 30, 1967, 81 Stat. 248, provided that: "Notwithstanding the provisions of section 1396(a) and (b) of the Social Security Act [subsecs. (a) and (b) of this section]—

"(1) the dollar amount applicable for premiums under part B of title XVIII of such Act [this part] for each month before April 1968 shall be $3, and

"(2) the Secretary of Health, Education, and Welfare may determine and promulgate such dollar amount for months after March 1968 and before January 1970 at any time on or before December 31, 1967.

**Persons Enrolling Before April 1, 1968, Who Did Not Enroll During Their Initial Enrollment Period**

Pub. L. 90–97, §3(b), Sept. 30, 1967, 81 Stat. 250, provided that: "In the case of any individual who did not enroll in the insurance program established under part B of title XVIII of the Social Security Act [this part] in his initial enrollment period, but does so enroll before April 1, 1968, the enrollment period in which he so enrolls shall, for purposes of section 1839(c) of such Act [subsec. (c) of this section], be deemed to have closed on December 31, 1967."

§1395s. Payment of premiums

**(a) Deductions from section 402 or 423 monthly benefits**

(1) In the case of an individual who is entitled to monthly benefits under section 402 or 423 of this title, his monthly premiums under this part shall (except as provided in subsections (b)(1) and (c) of this section) be collected by deducting the amount thereof from the amount of such monthly benefits. Such deduction shall be made in such manner and at such times as the Commissioner of Social Security shall by regulation prescribe. Such regulations shall be prescribed after consultation with the Secretary.

(2) The Secretary of the Treasury shall, from time to time, transfer from the Federal Old-Age and Survivors Insurance Trust Fund or the Federal Disability Insurance Trust Fund to the Federal Supplementary Medical Insurance Trust Fund the aggregate amount deducted under paragraph (1) for the period to which such transfer relates from benefits under section 402 or 423 of this title which are payable from such Trust Fund. Such transfer shall be made on the basis of a certification by the Commissioner of Social Security and shall be appropriately adjusted to the extent that prior transfers were too great or too small.

**(b) Deductions from railroad retirement annuities or pensions**

(1) In the case of an individual who is entitled to receive for a month an annuity under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.] (whether or not such individual is also entitled for such month to a monthly insurance benefit under section 402 of this title), his monthly premiums under this part shall (except as provided in subsection (c) of this section) be collected by deducting the amount thereof from such annuity or pension. Such deduction shall be made in such manner and at such time and in such form as the Secretary shall by regulations prescribe. Such regulations shall be prescribed only after consultation with the Railroad Retirement Board.

The Secretary of the Treasury shall, from time to time, transfer from the Railroad Retirement Account to the Federal Supplementary Medical Insurance Trust Fund the aggregate amount deducted under paragraph (1) for the period to which such transfer relates. Such trans-
bers shall be made on the basis of a certification by the Railroad Retirement Board and shall be appropriately adjusted to the extent that prior transfers were too great or too small.

(c) Portion of monthly premium in excess of deducted amount

If an individual to whom subsection (a) or (b) of this section applies estimates that the amount which will be available for deduction under such subsection for any premium payment period will be less than the amount of the monthly premiums for such period, he may (under regulations) pay to the Secretary such portion of the monthly premiums for such period as he desires.

(d) Deductions from civil service retirement annuities

(1) In the case of an individual receiving an annuity under subchapter III of chapter 83 of title 5 or any other law administered by the Director of the Office of Personnel Management providing retirement or survivorship protection, to whom neither subsection (a) nor subsection (b) of this section applies, his monthly premiums under this part (and the monthly premiums of the spouse of such individual under this part if neither subsection (a) nor subsection (b) of this section applies to such spouse and if such individual agrees) shall, upon notice from the Secretary of Health and Human Services to the Director of the Office of Personnel Management, be collected by deducting the amount thereof from each installment of such annuity. Such deduction shall be made in such manner and at such times as the Director of the Office of Personnel Management may determine. The Director of the Office of Personnel Management shall furnish such information as the Secretary of Health and Human Services may reasonably request in order to carry out his functions under this part with respect to individuals to whom this subsection applies. A plan described in section 8993 or 8993a of title 5 may reimburse each annuitant enrolled in such plan an amount equal to the premiums paid by him under this part if such reimbursement is paid entirely from funds of such plan which are derived from sources other than the contributions described in section 8906 of such title.

(2) The Secretary of the Treasury shall, from time to time, but not less often than quarterly, transfer from the Civil Service Retirement and Disability Fund, or the account (if any) applicable in the case of such other law administered by the Director of the Office of Personnel Management, to the Federal Supplementary Medical Insurance Trust Fund the aggregate amount deducted under paragraph (1) for the period to which such transfer relates. Such transfer shall be made on the basis of a certification by the Director of the Office of Personnel Management and shall be appropriately adjusted to the extent that prior transfers were too great or too small.

(e) Manner and time of payment prescribed by Secretary

In the case of an individual who participates in the insurance program established by this part but with respect to whom none of the preceding provisions of this section applies, or with respect to whom subsection (c) of this section applies, the premiums shall be paid to the Secretary at such times, and in such manner, as the Secretary shall by regulations prescribe.

(f) Deposit of amounts in Treasury

Amounts paid to the Secretary under subsection (c) or (e) of this section shall be deposited in the Treasury to the credit of the Federal Supplementary Medical Insurance Trust Fund.

(g) Premium payability period

In the case of an individual who participates in the insurance program established by this part, premiums shall be payable for the period commencing with the first month of his coverage period and ending with the month in which he dies or, if earlier, in which his coverage under such program terminates.

(h) Exempted monthly benefits

In the case of an individual who is enrolled under the program established by this part as a member of a coverage group to which an agreement with a State entered into pursuant to section 1395v of this title is applicable, subsections (a), (b), (c), and (d) of this section shall not apply to his monthly premium for any month in his coverage period which is determined under section 1395v(d) of this title.

(i) Adjustments for individuals enrolled in Medicare+Choice plans

In the case of an individual enrolled in a Medicare+Choice plan, the Secretary shall provide for necessary adjustments of the monthly beneficiary premium to reflect 80 percent of any reduction elected under section 1395w–24(f)(1)(B) of this title and to reflect any credit provided under section 1395w–24(b)(1)(C)(i)(v) of this title. To the extent to which the Secretary determines that such an adjustment is appropriate, with the concurrence of any agency responsible for the administration of such benefits, such premium adjustment may be provided directly, as an adjustment to any social security, railroad retirement, or civil service retirement benefits, or, in the case of an individual who receives medical assistance under subchapter XIX of this chapter for medicare costs described in section 1396d(p)(3)(A)(i) of this title, as an adjustment to the amount otherwise owed by the State for such medical assistance.


*1* See References in Text note below.

REFERENCES IN TEXT


AMENDMENTS


1994—Subsec. (a)(1). Pub. L. 103–296, § 108(h)(2)(A), substituted “Commissioner of Social Security” for “Secretary” and inserted at end “Such regulations shall be prescribed after consultation with the Secretary.”


1993—Subsec. (i). Pub. L. 103–1–214 repealed Pub. L. 100–360, § 212(b), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment note below.


Pub. L. 100–360 added subsec. (i) relating to transfer to flat prescription drug premiums to Federal Catastrophic Drug Insurance Trust Fund.


1984—Subsec. (a)(2). Pub. L. 98–369, § 2664(c), substituted “subsections (b)(1) and (c)” for “subsection (d)” and inserted reference to section 423 of this title.


Subsec. (b)(1). Pub. L. 98–369, § 2663(b), inserted “whether or not such individual is also entitled for such month to a monthly insurance benefit under section 402 of this title” after “1937” and substituted “subsection (c)” for “subsection (d)”.

Subsec. (c). Pub. L. 98–369, § 2683(c), struck out subsec. (c) covering individuals entitled both to monthly benefits under section 402 of this title and to an annuity or pension under Railroad Retirement Act of 1937 and redesignated former subsec. (d) as (c).

Subsec. (d). Pub. L. 92–663, § 263(c), redesignated subsec. (e) as (d). Former subsec. (d) redesignated (c).

Subsec. (e). Pub. L. 92–663, § 263(c), (d)(1), redesignated subsec. (f) as (e) and substituted “subsection (c)” for “subsection (d)”. Former subsec. (e) redesignated (d).

Subsec. (f). Pub. L. 92–663, § 263(c), (d)(2), redesignated subsec. (g) as (f) and substituted “subsections (c) or (e)” for “subsections (d) or (f)”. Former subsec. (f) redesignated (e) and amended.

Subsec. (g). Pub. L. 92–663, § 263(c), redesignated subsec. (h) as (g). Former subsec. (g) redesignated (f) and amended.

Subsecs. (h), (i). Pub. L. 92–663, § 263(c), (d)(3), redesignated subsec. (i) as (h) and substituted “(c) and (d)” for “(c), (d), and (e)”.

1988—Subsec. (e). Pub. L. 90–248 provided for reimbursement of civil service retirement annuitants for certain premium payments under supplementary medical insurance program, and substituted “subchapter III of chapter 83 of Title 5” for “Civil Service Retirement Act”.


EFFECTIVE DATE OF 2003 AMENDMENT

EFFECTIVE DATE OF 2000 AMENDMENT
Amendment by Pub. L. 106–554 applicable to years beginning with 2003, see section 110(a) of Pub. L. 106–554, set out as a note under section 1395r of this title.

EFFECTIVE DATE OF 1994 AMENDMENT
Amendment by Pub. L. 103–296 effective Mar. 31, 1995, see section 2663(j)(2)(C)(iv) of this title, effective for years beginning on or after Mar. 31, 1995, see section 2664(b) of Pub. L. 103–296, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 1993 AMENDMENT

EFFECTIVE DATE OF 1989 AMENDMENT

EFFECTIVE DATE OF 1988 AMENDMENT
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. 100–360, set out as a note under section 704 of this title.

EFFECTIVE DATE OF 1984 AMENDMENT
Amendment by section 2354(b)(11) 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.

Amendment by section 2663(j)(2)(F)(ii) 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 2664(b) of Pub. L. 98–369, set out as a note under section 1320a–1 of this title.

EFFECTIVE DATE OF 1974 AMENDMENT
Fund shall consist of such gifts and bequests as
part or section 9008(c)
1 or appropriated to, such fund as provided in this
tion referred to as the "Trust Fund''). The Trust
Insurance Trust Fund'' (hereinafter in this sec-
known as the "Federal Supplementary Medical

(b) Board of Trustees; composition; meetings; du-
With respect to the Trust Fund, there is here-
created a body to be known as the Board of
of Trustees of the Trust Fund (hereinafter in this section referred to as the "Board of Trustees")
posed of the Commissioner of Social Secu-
ity, the Secretary of the Treasury, the Sec-
retary of Labor, and the Secretary of Health and
Human Services, all ex officio, and of two mem-
ers of the public (both of whom may not be
from the same political party), who shall be
ominated by the President for a term of four
years and subject to confirmation by the Sen-
ate. A member of the Board of Trustees serving
as a member of the public and nominated and
confirmed to fill a vacancy occurring during a
term shall be nominated and confirmed only for
the remainder of such term. An individual nomi-
nated and confirmed as a member of the public
may serve in such position after the expiration of
such member's term until the earlier of the time at which the member's successor takes of-
the Board of Trustees (hereinafter in this sec-
cted of market quotations as of the end of the cal-
stimulated and confirmed as a member of the public
shall not be
person serving on the Board of Trustees shall not be
personally liable for actions taken in such capacity
with respect to the Trust Fund.
(c) Investment of Trust Fund by Managing
Trustee
It shall be the duty of the Managing Trustee
to invest such portion of the Trust Fund as is
not, in his judgment, required to meet current
withdrawals. Such investments may be made
only in interest-bearing obligations of the
States or in obligations guaranteed as to both principal and interest by the United States. For
such purpose such obligations may be ac-
quired (1) on original issue at the issue price, or
(2) by purchase of outstanding obligations at the
market price. The purposes for which obliga-
tions of the United States may be issued under
chapter 31 of title 31 are hereby extended to au-
orate the issuance at par of public-debt obliga-
tions for purchase by the Trust Fund. Such obli-
gations issued for purchase by the Trust Fund
shall have maturities fixed with due regard for
the needs of the Trust Fund and shall bear inter-
est at a rate equal to the average market yield
(computed by the Managing Trustee on the basis
of market quotations as of the end of the cal-
endar month next preceding the date of such
issue) on all marketable interest-bearing obliga-
tions of the United States then forming a part of
the public debt which are not due or callable
until after the expiration of 4 years from the end
of such calendar month: except that where such
average market yield is not a multiple of one-
eighth of 1 per centum, the rate of interest on

1 See References in Text note below.
2 So in original. See 2003 Amendment note below.
such obligations shall be the multiple of one-eighth of 1 per centum nearest such market yield. The Managing Trustee may purchase other interest-bearing obligations of the United States or obligations guaranteed as to both principal and interest by the United States, on original issue or at the market price, only where he determines that the purchase of such other obligations is in the public interest.

(d) Authority of Managing Trustee to sell obligations

Any obligations acquired by the Trust Fund (except public-debt obligations issued exclusively to the Trust Fund) may be sold by the Managing Trustee at the market price, and such public-debt obligations may be redeemed at par plus accrued interest.

(e) Interest on or proceeds from sale or redemption of obligations

The interest on, and the proceeds from the sale or redemption of, any obligations held in the Trust Fund shall be credited to and form a part of the Trust Fund.

(f) Transfers to other Funds

There shall be transferred periodically (but not less often than once each fiscal year) to the Trust Fund from the Federal Old-Age and Survivors Insurance Trust Fund and from the Federal Disability Insurance Trust Fund amounts equivalent to the amounts not previously so transferred which the Secretary of Health and Human Services shall have certified as overpayments to the Railroad Retirement Board.

(g) Payments from Trust Fund of amounts provided for by this part or with respect to administrative expenses

The Managing Trustee shall pay from time to time from the Trust Fund such amounts as the Secretary of Health and Human Services certifies are necessary to make the payments provided for by this part, and the payments with respect to administrative expenses in accordance with section 401(g)(1) of this title. The payments provided for under part D of this subchapter, other than under section 1395w–141(k)(2) of this title, shall be made from the Medicare Prescription Drug Account in the Trust Fund. The payments provided for under section 1395w–141(k)(2) of this title shall be made from the Transitional Assistance Account in the Trust Fund.

(h) Payments from Trust Fund of costs incurred by Director of Office of Personnel Management

The Managing Trustee shall pay from time to time from the Trust Fund such amounts as the Secretary of Health and Human Services certifies are necessary to pay the costs incurred by the Director of the Office of Personnel Management in making deductions pursuant to section 1395(d) of this title or pursuant to section 1395w–113(c)(1) or 1395w–24(d)(2)(A) of this title (in which case payments shall be made in appropriate part from the Medicare Prescription Drug Account in the Trust Fund). During each fiscal year, or after the close of such fiscal year, the Director of the Office of Personnel Management shall certify to the Secretary the amount of the costs the Director incurred in making such deductions, and such certified amount shall be the basis for the amount of such costs certified by the Secretary to the Managing Trustee.

(i) Payments from Trust Fund of costs incurred by Railroad Retirement Board

The Managing Trustee shall pay from time to time from the Trust Fund such amounts as the Secretary of Health and Human Services certifies are necessary to pay the costs incurred by the Railroad Retirement Board for services performed pursuant to section 1395w–113(b) and section 1395u(g) of this title and pursuant to sections 1395w–113(c)(1) and 1395w–24(d)(2)(A) of this title (in which case payments shall be made in appropriate part from the Medicare Prescription Drug Account in the Trust Fund). During each fiscal year or after the close of such fiscal year, the Railroad Retirement Board shall certify to the Secretary the amount of the costs it incurred in performing such services and such certified amount shall be the basis for the amount of such costs certified by the Secretary to the Managing Trustee.

References in text

Section 9008(c) of the Patient Protection and Affordable Care Act of 2009, referred to in subsec. (a), probably means section 9008(c) of Pub. L. 111–148, known as the Patient Protection and Affordable Care Act, which is set out as a note preceding section 4001 of Title 26, Internal Revenue Code.

Section 801(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, referred to in subsec. (b)(2), is section 801(a) of Pub. L. 108–173, which is set out as a note under section 1395i of this title.

Part D of this subchapter, referred to in subsec. (g), is classified to section 1395w–101 et seq. of this title.
care financing administration''
for ''chief actuarial officer of the health care financing administration'' and, in concluding provisions, substituted ''chief actuary of the centers for medicare & medicaid services'' for ''civil service commission'' in two places.

Pub. L. 98–369, § 801(d)(2), inserted at end, "The payments provided for under section 1395w–141(k)(2) of this title shall be made from the Medicare Prescription Drug Account established by section 1395w–116 of this title before period at end of this subsection.


Subsec. (g). Pub. L. 108–173, § 105(d)(2), inserted at end, "The payments provided for under section 1395w–141(k)(2) of this title shall be made from the Transitional Assistance Account in the Trust Fund.''

Pub. L. 108–173, § 103(e)(3)(C), inserted, at end, "The payments provided for under part D of this subchapter, other than under section 1395w–141(k)(2) of this title, shall be made from the Medicare Prescription Drug Account in the Trust Fund.''

Subsec. (h). Pub. L. 108–173, § 101(e)(3)(C)(iii), inserted, at end, "or pursuant to section 1395s(d) of this title or 1395s(e)(2)(A) of this title (in which case payments shall be made in appropriate part from the Medicare Prescription Drug Account in the Trust Fund)" after "section 1395s(d) of this title''.

Pub. L. 108–173, § 101(e)(3)(C)(iv), inserted, at end, "and pursuant to sections 1395w–113(c)(1) and 1395w–24(d)(2)(A) of this title (in which case payments shall be made in appropriate part from the Medicare Prescription Drug Account in the Trust Fund)'' after "section 1395s(g) of this title.''


1989—Subsecs. (a), (b). Pub. L. 101–234 repealed Pub. L. 100–360, § 2354(b)(2), (c)(4), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 amendment notes below.


Subsec. (b). Pub. L. 100–360 inserted after first sentence, "A member of the Board of Trustees serving as a member of the public and nominated and confirmed to fill a vacancy occurring during a term shall be nominated and confirmed only for the remainder of such term. An individual nominated and confirmed as a member of the public may serve in such position after the expiration of such member's term until the earlier of the time at which the member's successor takes office or the time at which a report of the Board is first issued under paragraph (2) after the expiration of the member's term.''

Pub. L. 100–360, § 2354(b)(2), inserted after sixth sentence, "Such report shall also identify (and treat separately) those receipts and outlays in the Trust Fund which are also receipts and outlays in the Medicare Catastrophic Coverage Account created under section 1395w–24(h)(2) of this title.''

1986—Subsec. (b). Pub. L. 99–272 struck out provision at end of penultimate sentence that the certification shall not refer to economic assumptions underlying Trustee's report.

1984—Subsec. (c). Pub. L. 98–369, § 2354(b)(2), substituted "under chapter 31 of title 31'' for "under the Second Liberty Bond Act, as amended'',


Pub. L. 98–369, § 2354(b)(12), substituted "the Director'' for "it''.


1983—Subsec. (b). Pub. L. 98–21, § 341(c)(1), substituted "Secretary of Health and Human Services, all ex officio, and of two members of the public (both of whom may not be from the same political party), who shall be nominated by the President for a term of four years and subject to confirmation by the Senate'' for "Secretary of Health, Education, and Welfare, all ex officio'' in provisions preceding par. (1).

Pub. L. 98–21, § 341(c), inserted at end provision that the report referred to in par. (2) shall also include an actuarial opinion by the Chief Actuarial Officer of the Health Care Financing Administration certifying that the techniques and methodologies used are generally accepted within the actuarial profession and that the assumptions and cost estimates used are reasonable, and provided further that the certification shall not refer to economic assumptions underlying the Trustee's report.

Pub. L. 98–21, § 341(c)(2), inserted, at end provision that a person serving on the Board of Trustees shall not be considered to be a fiduciary and shall not be personally liable for actions taken in such capacity with respect to the Trust Fund.


1972—Subsec. (a). Pub. L. 92–603, § 132(e), inserted "such gifts and bequests as may be made as provided in section 401(i)(1) of this title, and'' after "consist of'' and before "such amounts''.

Subsec. (b). Pub. L. 92–603, § 263(d)(4), substituted "1395s(d)'' for "1395s(e)''.

Pub. L. 92–603, § 263(e), added subsec. (i).

1968—Subsec. (b)(2), Pub. L. 90–248 substituted "April'' for "March''.

 EFFECTIVE DATE OF 1994 AMENDMENT

 EFFECTIVE DATE OF 1989 AMENDMENT

 EFFECTIVE DATE OF 1988 AMENDMENT
Amendment by Pub. L. 100–647 applicable to members of Board of Trustees of Federal Supplementary Medical Insurance Trust Fund serving on such Board as members of the public on or after Nov. 10, 1988, see section 8005(b) of Pub. L. 100–647, set out as a note under section 401 of this title.

 EFFECTIVE DATE OF 1984 AMENDMENT
Amendment by section 2354(b)(2), (11), (12) 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.

Amendment by section 2663(i)(2)(F)(ii) 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 2664(b) of Pub. L. 98–369, set out as a note under section 401 of this title.

**Effective Date of 1983 Amendment**

Amendment by sections 154(c) and 341(c) of Pub. L. 98–21 effective Apr. 20, 1983, see sections 154(e) and 341(d) of Pub. L. 98–21, set out as notes under section 401 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 second month following the month of June 1978, and except that provisions for reimbursement rates for home dialysis to become effective 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 1972 Amendment**

Amendment by section 132(e) of Pub. L. 92–663 applicable with respect to gifts and bequests received after Oct. 30, 1972, see section 132(f) of Pub. L. 92–663, set out as a note under section 401 of this title.

Amendment by section 263(d)(4), (e) of Pub. L. 92–663 with respect to collection of premiums applicable to premiums becoming due and payable after the fourth month following the month of enactment of Pub. L. 92–663 which was approved on Oct. 30, 1972, see section 263(f) of Pub. L. 92–663, set out as a note under section 1395s of this title.

**Disposal of Funds in Federal Hospital Insurance Catastrophic Coverage Reserve Fund**

Section 102(c) of Pub. L. 101–234 provided that: “Any balance in the Federal Hospital Insurance Catastrophic Coverage Reserve Fund created under section 1317A(a) of the Social Security Act [former section 1395j–1(a)(a) of this title], as inserted by section 112(a) of MCCA [Pub. L. 100–360] as of January 1, 1990, shall be transferred into the Federal Supplementary Medical Insurance Trust Fund and any amounts payable due to overpayments into such Trust Fund shall be payable from the Federal Supplementary Medical Insurance Trust Fund.”

**Due Date for 1983 Report on Operation and Status of Trust Fund**

Notwithstanding subsec. (b)(2) of this section, the annual report of the Board of Trustees of the Trust Fund required for calendar year 1983 under this section may be filed at any time not later than forty-five days after Apr. 20, 1983, see section 154(d) of Pub. L. 98–21, set out as a note under section 401 of this title.


**Effective Date of Repeal**

Repeal effective Jan. 1, 1990, see section 202(b) of Pub. L. 101–234, set out as an Effective Date of 1989 Amendment note under section 401 of this title.

§ 1395u. Provisions relating to the administration of part B

(a) In general

The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1395kk–1 of this title.

(b) Determination of reasonable charges


(C) In the case of residents of nursing facilities who receive services described in clause (i) or (ii) of section 1395x(s)(2)(K) of this title performed by a member of a team, the Secretary shall instruct medicare administrative contractors to develop mechanisms which permit routine payment under this part for up to 1.5 visits per month per resident. In the previous sentence, the term “team” refers to a physician and includes a physician assistant acting under the supervision of the physician or a nurse practitioner working in collaboration with that physician, or both.

(3) The Secretary—

(A) shall take such action as may be necessary to assure that, where payment under this part for a service is on a cost basis, the cost is reasonable cost (as determined under section 1395gg(f) of this title);

(B) shall take such action as may be necessary to assure that, where payment under this part for a service is on a charge basis, such charge will be reasonable and not higher than the charge applicable, for a comparable service and under comparable circumstances, to the policyholders and subscribers of the medicare administrative contractor, and such payment will (except as otherwise provided in section 1395gg(f) of this title) be made—

(i) on the basis of an itemized bill; or

(ii) on the basis of an assignment under the terms of which (I) the reasonable charge is the full charge for the service, (II) the physician or other person furnishing such service agrees not to charge (and to refund amounts already collected) for services for which payment may not be made therefor by reason of the provisions of paragraph (1) of section 1395y(a) of this title, and (III) the individual to whom such service was furnished was without fault in incurring the expenses of such service, and if the Secretary’s deter-
ministration that payment (pursuant to such assignment) was incorrect and 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 (except in the case of physicians' services and ambulance service furnished as described in section 1395y(a)(4) of this title, other than for purposes of section 1395gg(f) of this title);

but (in the case of bills submitted, or requests for payment made, after March 1968) only if the bill is submitted, or a written request for payment is made in such other form as may be permitted under regulations, no later than the period ending 1 calendar year after the date of service;


but (in the case of bills submitted, or requests for payment made, after March 1968) only if the bill is submitted, or a written request for payment is made in such other form as may be permitted under regulations, no later than the period ending 1 calendar year after the date of service;

(F) shall take such action as may be necessary to assure that where payment under this part for a service rendered is on a charge basis, such payment shall be determined on the basis of the charge that is determined in accordance with this section on the basis of customary and prevailing charge levels in effect at the time the service was rendered or, in the case of services rendered more than 12 months before the year in which the bill is submitted or request for payment is made, on the basis of such levels in effect for the 12-month period preceding such year;

(G) shall, for a service that is furnished with respect to an individual enrolled under this part, that is not paid on an assignment-related basis, and that is subject to a limiting charge under section 1395w–4(g) of this title—

(i) determine, prior to making payment, whether the amount billed for such service exceeds the limiting charge applicable under section 1395w–4(g)(2) of this title;

(ii) notify the physician, supplier, or other person periodically (but not less often than once every 30 days) of determinations that amounts billed exceeded such applicable limiting charges; and

(iii) provide for prompt response to inquiries of physicians, suppliers, and other persons concerning the accuracy of such limiting charges for their services;

(H) shall implement—

(i) programs to recruit and retain physicians as participating physicians in the area served by the medicare administrative contractor, including educational and outreach activities and the use of professional relations personnel to handle billing and other problems relating to payment of claims of participating physicians; and

(ii) programs to familiarize beneficiaries with the participating physician program and to assist such beneficiaries in locating participating physicians;¹


(L) shall monitor and profile physicians' billing patterns within each area or locality and provide comparative data to physicians whose utilization patterns vary significantly from other physicians in the same payment area or locality.

In determining the reasonable charge for services for purposes of this paragraph, there shall be taken into consideration the customary charges for similar services generally made by the physician or other person furnishing such services, as well as the prevailing charge level in the locality for similar services. No charge may be determined to be reasonable in the case of bills submitted or requests for payment made under this part after December 31, 1970, if it exceeds the higher of (i) the prevailing charge recognized by the carrier and found acceptable by the Secretary for similar services in the same locality in administering this part on December 31, 1970, or (ii) the prevailing charge level on the basis of statistical data and methodology acceptable to the Secretary, which level shall cover 75 percent of the customary charges made for similar services in the same locality during the 12-month period ending on the June 30 last preceding the start of the calendar year in which the service is rendered. In the case of physicians' services the prevailing charge level determined for purposes of clause (ii) of the preceding sentence for any twelve-month period (beginning after June 30, 1973) specified in clause (ii) of such sentence may not exceed (in the aggregate) the level determined under such clause for the fiscal year ending June 30, 1973, or (with respect to physicians' services furnished in a year after 1987) the level determined under this sentence (or under any other provision of law affecting the prevailing charge level for the previous year except to the extent that the Secretary finds, on the basis of appropriate economic index data, that such higher level is justified by year-to-year economic changes. With respect to power-operated wheelchairs for which payment may be made in accordance with section 1395x(s)(6) of this title, charges determined to be reasonable may not exceed the lowest charge at which power-operated wheelchairs are available in the locality. In the case of medical services, supplies, and equipment (including equipment servicing) that, in the judgment of the Secretary, do not generally vary significantly in quality from one supplier to another, the charges incurred after December 31, 1972, determined to be reasonable may not exceed the lowest charge levels at which such services, supplies, and equipment are widely and consistently available in a locality except to the extent and under the circumstances specified by the Secretary. The requirement in subparagraph (B) that a bill be submitted or request for payment be made by the close of the following calendar year shall not apply if (I) failure to submit the bill or request the payment by the close of such year is due to the error or misrepresentation of an officer, employee, fiscal intermediary, carrier, medicare administrative contractor, or agent of the Department of Health and Human Services performing functions under this sub-

¹ So in original. Probably should be followed by "and".
chapter and acting within the scope of his or its authority, and (II) the bill is submitted or the payment is requested promptly after such error or misrepresentation is eliminated or corrected. Notwithstanding the provisions of the third and fourth sentences preceding this sentence, the prevailing charge level in the case of a physician service in a particular locality determined pursuant to such third and fourth sentences for any calendar year after 1974 shall, if lower than the prevailing charge level for the fiscal year ending June 30, 1975, in the case of a similar physician service in the same locality by reason of the application of economic index data, be raised to such prevailing charge level for the fiscal year ending June 30, 1975, and shall remain at such prevailing charge level until the prevailing charge for a year (as adjusted by economic index data) equals or exceeds such prevailing charge level. The amount of any charges for outpatient services which shall be considered reasonable shall be subject to the limitations established by regulations issued by the Secretary pursuant to section 1395x(v)(1)(K) of this title, and in determining the reasonable charge for such services, the Secretary may limit such reasonable charge to a percentage of the amount of the prevailing charge for similar services furnished in a physician’s office, taking into account the extent to which overhead costs associated with such outpatient services have been included in the reasonable cost or charge of the facility. In applying subparagraph (B), the Secretary may specify exceptions to the 1 calendar year period specified in such subparagraph.

(4)(A)(i) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians’ services furnished during the 15-month period beginning July 1, 1983, by a physician who is not a participating physician (as defined in subsection (h)(1) of this section) during the 8-month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1) of this section) at the time of furnishing the services, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning July 1, 1983.

(ii) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians’ services furnished during the 15-month period beginning July 1, 1984, by a physician who is not a participating physician (as defined in subsection (h)(1) of this section) at the time of furnishing the services, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning July 1, 1983.

(iii) In determining the prevailing charge levels under the fourth sentence of paragraph (3) for physicians’ services furnished during the 8-month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1) of this section) at the time of furnishing the services, the Secretary shall permit an additional one percentage point increase in the increase otherwise permitted under that sentence.

(iv) In determining the maximum allowable prevailing charges which may be recognized consistent with the index described in the fourth sentence of paragraph (3) for physicians’ services furnished on or after January 1, 1987, by participating physicians, the Secretary shall treat the maximum allowable prevailing charges recognized as of December 31, 1986, under such sentence with respect to participating physicians as having been justified by economic changes.

(iv) The reasonable charge for physicians’ services furnished on or after January 1, 1987, and before January 1, 1992, by a nonparticipating physician shall be no greater than the applicable percent of the prevailing charge levels established under the third and fourth sentences of paragraph (3) (or under any other applicable provision of law affecting the prevailing charge level). In the previous sentence, the term “applicable percent” means for services furnished (I) on or after January 1, 1987, and before April 1, 1988, 96 percent, (II) on or after April 1, 1988, and before January 1, 1989, 95.5 percent, and (III) on or after January 1, 1989, 95 percent.

(v) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians’ services furnished during the 3-month period beginning January 1, 1988, the Secretary shall not set any level higher than the same level as was set for the 12-month period beginning January 1, 1987.

(vi) Before each year (beginning with 1989), the Secretary shall establish a prevailing charge floor for primary care services (as defined in subsection (i)(4) of this section) equal to 60 percent of the estimated average prevailing charge levels based on the best available data (determined, under the third and fourth sentences of paragraph (3) and under paragraph (4), without regard to this clause and without regard to physician specialty) for such service for all localities in the United States (weighted by the relative frequency of the service in each locality) for the year.

(vii) Beginning with 1987, the percentage increase in the MEI (as defined in subsection (i)(3) of this section) for each year shall be the same for nonparticipating physicians as for participating physicians.

(B)(i) In determining the reasonable charge under paragraph (3) for physicians’ services furnished during the 15-month period beginning May 1, 1986, by a physician who is not a participating physician (as defined in subsection (h)(1) of this section) at the time of furnishing the services—

(I) if the physician was not a participating physician at any time during the 12-month period beginning on October 1, 1984, the customary charges shall be the same customary charges as were recognized under this section for the 12-month period beginning July 1, 1983, and

(ii) if the physician was a participating physician at any time during the 12-month period beginning on October 1, 1984, the physician’s customary charges shall be determined based upon the physician’s actual charges billed during the 12-month period ending on March 31, 1985.

(iii) In determining the reasonable charge under paragraph (3) for physicians’ services furnished during the 3-month period beginning January 1, 1988, the customary charges shall be the same customary charges as were recognized
under this section for the 12-month period beginning January 1, 1987.

(iv) In determining the reasonable charge under paragraph (3) for physicians' services (other than primary care services, as defined in subsection (i)(4) of this section) furnished during 1991, the customary charges shall be the same customary charges as were recognized under this section for the 9-month period beginning April 1, 1990. In a case in which subparagraph (F) applies (relating to new physicians) so as to limit the customary charges of a physician during 1990 to a percent of prevailing charges, the previous sentence shall not prevent such limit on customary charges under such subparagraph from increasing in 1991 to a higher percent of such prevailing charges.

(C) In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians' services furnished during periods beginning after September 30, 1985, the Secretary shall treat the level as set under subparagraph (A)(i) as having fully provided for the economic changes which would have been taken into account but for the limitations contained in subparagraph (A)(i).

(D)(i) In determining the customary charges for physicians' services furnished during the 8-month period beginning May 1, 1986, or the 12-month period beginning January 1, 1987, by a physician who was not a participating physician (as defined in subsection (h)(1) of this section) on September 30, 1985, the Secretary shall not recognize increases in actual charges for services furnished during the 15-month period beginning on July 1, 1984, above the level of the physician's actual charges billed in the 3-month period ending on June 30, 1984.

(ii) In determining the customary charges for physicians' services furnished during the 12-month period beginning January 1, 1987, by a physician who was not a participating physician (as defined in subsection (h)(1) of this section) on April 30, 1986, the Secretary shall not recognize increases in actual charges for services furnished during the 7-month period beginning on October 1, 1985, above the level of the physician's actual charges billed during the 3-month period ending on June 30, 1984.

(iii) In determining the customary charges for physicians' services furnished during the 12-month period beginning January 1, 1987, or January 1, 1988, by a physician who is not a participating physician (as defined in subsection (h)(1) of this section) on December 31, 1986, the Secretary shall not recognize increases in actual charges for services furnished during the 8-month period beginning on May 1, 1986, above the level of the physician's actual charges billed during the 3-month period ending on June 30, 1984.

(iv) In determining the customary charges for a physician's service furnished on or after January 1, 1988, if a physician was a nonparticipating physician in a previous year (beginning with 1987), the Secretary shall not recognize any amount of such actual charges (for that service furnished during such previous year) that exceeds the maximum allowable actual charge for such service established under subsection (j)(1)(C) of this section.

(E)(i) For purposes of this part for physicians' services furnished in 1987, the percentage increase in the MEI is 3.2 percent.

(ii) For purposes of this part for physicians' services furnished in 1988, on or after April 1, the percentage increase in the MEI is—

(I) 3.6 percent for primary care services (as defined in subsection (i)(4) of this section), and

(II) 1 percent for other physicians' services.

(iii) For purposes of this part for physicians' services furnished in 1989, the percentage increase in the MEI is—

(I) 3.0 percent for primary care services, and

(II) 1 percent for other physicians' services.

(iv) For purposes of this part for items and services furnished in 1990, after March 31, 1990, the percentage increase in the MEI is—

(I) 0 percent for radiology services, for anesthesia services, and for other services specified in the list referred to in paragraph (14)(C)(1),

(II) 2 percent for other services (other than primary care services), and

(III) such percentage increase in the MEI (as defined in subsection (i)(3) of this section) as would be otherwise determined for primary care services (as defined in subsection (i)(4) of this section).

(v) For purposes of this part for items and services furnished in 1991, the percentage increase in the MEI is—

(I) 0 percent for services (other than primary care services), and

(II) 2 percent for primary care services (as defined in subsection (i)(4) of this section).


(6) No payment under this part for a service provided to any individual shall (except as provided in section 1395ggg of this title) be made to anyone other than such individual or (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) the physician or other person who provided the service, except that (A) payment may be made to an entity (i) which provides coverage of the services under a health program, to the entity if, under the contractual arrangement, the entity submits the bill for the service and the contractual arrangement meets such program integrity and other safeguards as the Secretary may determine to be appropriate, (B) payment may be made to an entity (i) which provides coverage of the services under a health benefits plan, but only to the extent that payment is not made under this part, (ii) which has paid the person who provided the service an amount (including the amount payable under this part) which that person has accepted as payment in full for the service, and (iii) to which the individual has agreed in writing that payment may be made under this part, (C) in the case of services described in clause (i) of section 1395x(s)(2)(K) of this title, payment shall be made to either (i) the employer of the physician assistant involved, or (ii) with respect to a phy-
sician assistant who was the owner of a rural health clinic (as described in section 1395x(aa)(2) of this title) for a continuous period beginning prior to August 5, 1997, and ending on the date that the Secretary determines such rural health clinic no longer meets the requirements of section 1395x(aa)(2) of this title, payment may be made directly to the physician assistant. (D) payment may be made to a physician for physicians' services (and services furnished incident to such services) furnished by a second physician to patients of the first physician if (1) the first physician is unavailable to provide the services; (ii) the services are furnished pursuant to an arrangement between the two physicians that (I) is informal and reciprocal, or (II) involves per diem or other fee-for-time compensation for such services; (iii) the services are not provided by the second physician over a continuous period of more than 60 days or are provided over a longer continuous period during all of which the first physician has been called or ordered to active duty as a member of a reserve component of the Armed Forces; and (iv) the claim form submitted to the medicare administrative contractor for such services includes the second physician's unique identifier (provided under the system established under subsection (r) of this section) and indicates that the claim meets the requirements of this subparagraph for payment to the first physician, (E) in the case of an item or service (other than services described in section 1395yy(e)(2)(A)(ii) of this title) furnished by, or under arrangements made by, a skilled nursing facility to an individual who (at the time the item or service is furnished) is a resident of a skilled nursing facility, payment shall be made to the facility, (F) in the case of 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 (at the time the item or service is furnished) is under a plan of care of a home health agency, payment shall be made to the agency (without regard to whether or not the item or service was furnished by the agency, by others under arrangement with the agency, or when any other contracting or consulting arrangement, or otherwise), (G) in the case of services in a hospital or clinic to which section 1395yy(e) of this title applies, payment shall be made to such hospital or clinic, and (H) in the case of services described in section 1395x(aa)(3) of this title that are furnished by a health care professional under contract with a Federally qualified health center, payment shall be made to the center. No payment which under the preceding sentence may be made directly to the physician or other person providing the service involved (pursuant to an assignment described in subparagraph (B)(ii) of paragraph (3)) shall be made to anyone else under a reassignment or power of attorney (except to an employer or entity as described in subparagraph (A) of such sentence); but nothing in this subsection shall be construed (i) to prevent the making of such a payment in accordance with an assignment from the individual to whom the service was provided or a reassignment from the physician or other person providing such service if such assignment or reassignment is made to a governmental agency or entity or is established by or pursuant to the order of a court of competent jurisdiction, or (ii) to preclude an agent of the physician or other person providing the service from receiving such payment if (but only if) such agent does so pursuant to an agency agreement under which the compensation to be paid to the agent for his services or in connection with the billing or collection of payments due such physician or other person under this subchapter is unrelated (directly or indirectly) to the amount of such payments or the billings therefor, and is not dependent upon the actual collection of any such payment. For purposes of subparagraph (C) of the first sentence of this paragraph, an employment relationship may include any independent contractor arrangement, and employer status shall be determined in accordance with the law of the State in which the services described in such clause are performed.

(7)(A) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1395x(b)(6) of this title but which does not meet the conditions described in section 1395x(b)(7) of this title, the Secretary shall not provide (except on the basis described in subparagraph (C)) for payment for such services under this part—

(I) unless—

(i) the physician renders sufficient personal and identifiable physicians' services to the patient to exercise full, personal control over the management of the portion of the case for which the payment is sought,

(ii) the services are of the same character as the services the physician furnishes to patients not entitled to benefits under this subchapter, and

(iii) at least 25 percent of the hospital's patients (during a representative past period, as determined by the Secretary) who were not entitled to benefits under this subchapter and who were furnished services described in subclauses (I) and (II) paid all or a substantial part of charges (other than nominal charges) imposed for such services; and

(ii) to the extent that the payment is based upon a reasonable charge for the services in excess of the customary charge as determined in accordance with subparagraph (B).

(B) The customary charge for such services in a hospital shall be determined in accordance with regulations issued by the Secretary and taking into account the following factors:

(i) In the case of a physician who is not a teaching physician (as defined by the Secretary), the Secretary shall take into account the amounts the physician charges for similar services in the physician's practice outside the teaching setting.

(ii) In the case of a teaching physician, if the hospital, its physicians, or other appropriate billing entity has established one or more schedules of charges which are collected for medical and surgical services, the Secretary shall base payment under this subchapter on the greatest of—
(I) the charges (other than nominal charges) which are most frequently collected in full or substantial part with respect to patients who were not entitled to benefits under this subchapter and who were furnished services described in subclauses (I) and (II) of subparagraph (A)(i).

(II) the mean of the charges (other than nominal charges) which were collected in full or substantial part with respect to such patients, or

(III) 85 percent of the prevailing charges paid for similar services in the same locality.

(iii) If all the teaching physicians in a hospital agree to have payment made for all of their physicians' services under this part furnished to patients in such hospital on an assignment-related basis, the customary charge for such services shall be equal to 90 percent of the prevailing charges paid for similar services in the same locality.

(C) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1395x(b)(6) of this title but which does not meet the conditions described in section 1395x(b)(7) of this title, if the conditions described in subclauses (I) and (II) of subparagraph (A)(i) are met and if the physician elects payment to be determined under this subparagraph, the Secretary shall provide for payment for such services under this part on the basis of regulations of the Secretary governing reimbursement for the services of hospital-based physicians (and not on any other basis).

(D)(i) In the case of physicians' services furnished to a patient in a hospital with a teaching program approved as specified in section 1395x(b)(6) of this title but which does not meet the conditions described in section 1395x(b)(7) of this title, no payment shall be made under this part for services of assistants at surgery with respect to a surgical procedure if such hospital has a training program relating to the medical specialty required for such surgical procedure and a qualified individual on the staff of the hospital is available to provide such services; except that payment may be made under this part for such services, to the extent that such payment is otherwise allowed under this paragraph, if such services, as determined under regulations of the Secretary—

(I) are required due to exceptional medical circumstances,

(II) are performed by team physicians needed to perform complex medical procedures, or

(III) constitute concurrent medical care relating to a medical condition which requires the presence of, and active care by, a physician of another specialty during surgery, and under such other circumstances as the Secretary determines by regulation to be appropriate.

(ii) For purposes of this subparagraph, the term "assistant at surgery" means a physician who actively assists the physician in charge of a case in performing a surgical procedure.

(iii) The Secretary shall determine appropriate methods of reimbursement of assistants at surgery where such services are reimbursable under this part.

(B)(A)(i) The Secretary shall by regulation—

(I) describe the factors to be used in determining the cases of particular items or services in which the application of this subchapter to payment under this part (other than to physicians' services paid under section 1395w-4 of this title) results in the determination of an amount that, because of its being grossly excessive or grossly deficient, is not inherently reasonable, and

(ii) provide in those cases for the factors to be considered in determining an amount that is realistic and equitable.

(ii) Notwithstanding the determination made in clause (i), the Secretary may not apply factors that would increase or decrease the payment under this part during any year for any particular item or service by more than 15 percent from such payment during the preceding year except as provided in subparagraph (B).

(B) The Secretary may make a determination under this subparagraph that would result in an increase or decrease under subparagraph (A) of more than 15 percent of the payment amount for a year, but only if—

(i) the Secretary's determination takes into account the factors described in subparagraph (C) and any additional factors the Secretary determines appropriate,

(ii) the Secretary's determination takes into account the potential impacts described in subparagraph (D), and

(iii) the Secretary complies with the procedural requirements of paragraph (9).

(C) The factors described in this subparagraph are as follows:

(i) The programs established under this subchapter and subchapter XIX of this chapter are the sole or primary sources of payment for an item or service.

(ii) The payment amount does not reflect changing technology, increased facility with that technology, or reductions in acquisition or production costs.

(iii) The payment amount for an item or service under this part is substantially higher or lower than the payment made for the item or service by other purchasers.

(D) The potential impacts of a determination under subparagraph (B) on quality, access, and beneficiary liability, including the likely effects on assignment rates and participation rates.

(9)(A) The Secretary shall consult with representatives of suppliers or other individuals who furnish an item or service before making a determination under paragraph (8)(B) with regard to that item or service.

(B) The Secretary shall publish notice of a proposed determination under paragraph (8)(B) in the Federal Register—

(i) specifying the payment amount proposed to be established with respect to an item or service,

(ii) explaining the factors and data that the Secretary took into account in determining the payment amount so specified, and

(iii) explaining the potential impacts described in paragraph (8)(D).
(C) After publication of the notice required by subparagraph (B), the Secretary shall allow not less than 60 days for public comment on the proposed determination.

(D)(i) Taking into consideration the comments made by the public, the Secretary shall publish in the Federal Register a final determination under paragraph (B) with respect to the payment amount to be established with respect to the item or service.

(ii) A final determination published pursuant to clause (i) shall explain the factors and data that the Secretary took into consideration in making the final determination.

(10)(A)(i) In determining the reasonable charge for procedures described in subparagraph (B) and performed during the 9-month period beginning on April 1, 1988, the prevailing charge for such procedure shall be the prevailing charge otherwise recognized for such procedure for 1987—

(I) subject to clause (iii), reduced by 2.0 percent, and

(II) further reduced by the applicable percentage specified in clause (ii).

(ii) For purposes of clause (i), the applicable percentage specified in this clause is—

(I) 15 percent, in the case of a prevailing charge otherwise recognized (without regard to physician specialty) that is at least 150 percent of the weighted national average (as determined by the Secretary) of such prevailing charges for such procedure for all localities in the United States for 1987;

(II) 0 percent, in the case of a prevailing charge that does not exceed 85 percent of such weighted national average; and

(III) in the case of any other prevailing charge, a percent determined on the basis of a straight-line sliding scale, equal to 3 1/3 of a percentage point for each percent by which the prevailing charge exceeds 85 percent of such weighted national average.

(iii) In no case shall the reduction under clause (i) for a procedure result in a prevailing charge in a locality for 1988 which is less than 85 percent of the Secretary’s estimate of the weighted national average of such prevailing charges for such procedure for all localities in the United States for 1987 (based upon the best available data and determined without regard to physician specialty) after making the reduction described in clause (i)(I).

(B) The procedures described in this subparagraph are as follows: bronchoscopy, carpal tunnel repair, cataract surgery (including subsequent insertion of an intraocular lens), coronary artery bypass surgery, diagnostic and/or therapeutic dilation and curettage, knee arthroscopy, knee arthroplasty, pacemaker implantation surgery, total hip replacement, suprapubic prostatectomy, transurethral resection of the prostate, and upper gastrointestinal endoscopy.

(C) In the case of a reduction in the reasonable charge for a physician’s service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of such reduction, the physician’s actual charge is subject to a limit under subsection (j)(1)(D) of this section.

(D) There shall be no administrative or judicial review under section 1395ff of this title or otherwise of any determination under subparagraph (A) or under paragraph (11)(B)(ii).

(11)(A) In providing payment for cataract eyeglasses and cataract contact lenses, and professional services relating to them, under this part, each carrier shall—

(i) provide for separate determinations of the payment amount for the eyeglasses and lenses and of the payment amount for the professional services of a physician (as defined in section 1395x(r) of this title), and

(ii) not recognize as reasonable for such eyeglasses and lenses more than such amount as the Secretary establishes in guidelines relating to the inherent reasonableness of charges for such eyeglasses and lenses.

(B)(i) In determining the reasonable charge under paragraph (3) for a cataract surgical procedure, subject to clause (ii), the prevailing charge for such procedure otherwise recognized for participating and nonparticipating physicians shall be reduced by 10 percent with respect to procedures performed in 1987.

(ii) In no case shall the reduction under clause (i) for a surgical procedure result in a prevailing charge in a locality for a year which is less than 75 percent of the weighted national average of such prevailing charges for such procedure for all the localities in the United States for 1988.

(C)(i) The prevailing charge level determined with respect to A-mode ophthalmic ultrasound procedures may not exceed 5 percent of the prevailing charge level established with respect to extracapsular cataract removal with lens insertion.

(ii) The reasonable charge for an intraocular lens inserted during or subsequent to cataract surgery in a physician’s office may not exceed the actual acquisition cost for the lens (taking into account any discount) plus a handling fee (not to exceed 5 percent of such actual acquisition cost).

(D) In the case of a reduction in the reasonable charge for a physicians’ service or item under subparagraph (B) or (C), if a nonparticipating physician furnishes the service or item to an individual entitled to benefits under this part after the effective date of such reduction, the physician’s actual charge is subject to a limit under subsection (j)(1)(D) of this section.


(13)(A) In determining payments under section 1395u(l) of this title and section 1395w–4 of this title for anesthesia services furnished on or after January 1, 1994, the methodology for determining the base and time units used shall be the same for services furnished by physicians, for medical direction by physicians of two, three, or four certified registered nurse anesthetists, or for services furnished by a certified registered nurse anesthetist (whether or not medically directed) and shall be based on the methodology in effect, for anesthesia services furnished by physicians, as of August 10, 1993.

(B) The Secretary shall require claims for physicians’ services for medical direction of nurse anesthetists during the periods in which the provisions of subparagraph (A) apply to indicate the
number of such anesthetists being medically directed concurrently at any time during the procedure, the name of each nurse anesthetist being directed, and the type of procedure for which the services are provided.

(14)(C) In determining the reasonable charge for a physicians’ service specified in subparagraph (C)(i) and furnished during the 9-month period beginning on April 1, 1990, the prevailing charge for such service shall be the prevailing charge otherwise recognized for such service for 1989 reduced by 15 percent or, if less, \( \frac{3}{4} \) of the percent (if any) by which the prevailing charge otherwise applied in the locality in 1989 exceeds the locally-adjusted reduced prevailing amount (as determined under subparagraph (B)(i)) for the service.

(ii) In determining the reasonable charge for a physicians’ service specified in subparagraph (C)(i) and furnished during 1991, the prevailing charge for such service shall be the prevailing charge otherwise recognized for such service for the period during 1990 beginning on April 1, reduced by the same amount as the amount of the reduction effected under this paragraph (as amended by the Omnibus Budget Reconciliation Act of 1990) for such service during such period.

(B) For purposes of this paragraph:

(i) The “locally-adjusted reduced prevailing amount” for a locality for a physicians’ service is equal to the product of—

(I) the reduced national weighted average prevailing charge for the service (specified under clause (ii)), and

(II) the adjustment factor (specified under clause (iii)) for the locality.

(ii) The “reduced national weighted average prevailing charge” for a physicians’ service is equal to the national weighted average prevailing charge for the service (specified in subparagraph (C)(i)) reduced by the percentage change (specified in subparagraph (C)(iii)) for the service.

(iii) The “adjustment factor”, for a physicians’ service for a locality, is the sum of—

(I) the practice expense component (percent), divided by 100, specified in appendix A (pages 187 through 194) of the Report of the Medicare and Medicaid Health Budget Reconciliation Amendments of 1989, prepared by the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives, (Committee Print 101–M, 101st Congress, 1st Session) for the service, multiplied by the geographic practice cost index value (specified in subparagraph (C)(iv)) for the locality, and

(II) 1 minus the practice expense component (percent), divided by 100.

(C) For purposes of this paragraph:

(i) The physicians’ services specified in this clause are the procedures specified (by code and description) in the Overvalued Procedures List for Finance Committee, Revised September 20, 1989, prepared by the Physician Payment Review Commission which specification is of physicians’ services that have been identified as overvalued by at least 10 percent based on a comparison of payments for such services under a resource-based relative value scale and of the national average prevailing charges under this part.

(ii) The “national weighted average prevailing charge” specified in this clause, for a physicians’ service specified in clause (i), is the national weighted average prevailing charge for the service in 1989 as determined by the Secretary using the best data available.

(iii) The “percentage change” specified in this clause, for a physicians’ service specified in clause (i), is the percent difference (but expressed as a positive number) specified for the service in the list referred to in clause (i).

(iv) The geographic practice cost index value specified in this clause for a locality is the Geographic Overhead Costs Index specified for the locality in table 1 of the September 1989 Supplement to the Geographic Medicare Economic Index: Alternative Approaches (prepared by the Urban Institute and the Center for Health Economics Research).

(D) In the case of a reduction in the prevailing charge for a physicians’ service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of such reduction, the physician’s actual charge is subject to a limit under subsection (j)(1)(D) of this section.

(15)(A) In determining the reasonable charge for surgery, radiology, and diagnostic physicians’ services which the Secretary shall designate (based on their high volume of expenditures under this part) and for which the prevailing charge (but for this paragraph) differs by physician specialty, the prevailing charge for such a service may not exceed the prevailing charge or fee schedule amount for that specialty of physicians that furnish the service most frequently nationally.

(B) In the case of a reduction in the prevailing charge for a physician’s service under subparagraph (A), if a nonparticipating physician furnishes the service to an individual entitled to benefits under this part, after the effective date of the reduction, the physician’s actual charge is subject to a limit under subsection (j)(1)(D) of this section.

(16)(A) In determining the reasonable charge for all physicians’ services other than physicians’ services specified in subparagraph (B) furnished during 1991, the prevailing charge for a locality shall be 6.5 percent below the prevailing charges used in the locality under this part in 1990 after March 31.

(B) For purposes of subparagraph (A), the physicians’ services specified in this subparagraph are as follows:

(i) Radiology, anesthesia and physician pathology services, the technical components of diagnostic tests specified in paragraph (17) and physicians’ services specified in paragraph (14)(C)(i).

(ii) Primary care services specified in subsection (1)(c) of this section, hospital inpatient medical services, consultations, other visits, preventive medicine visits, psychiatric services, emergency care facility services, and critical care services.

(iii) Partial mastectomy; tendon sheath injections and small joint arthrocentesis; fem-
oral fracture and trochanteric fracture treatments; endotracheal intubation; thoracentesis; thoracotomy; aneurysm repair; cystourethroscopy; transurethral fulguration and resection; tympanoplasty with mastoidectomy; and ophthalmoscopy.

(17) With respect to payment under this part for the technical (as distinct from (professional) component of diagnostic tests (other than clinical diagnostic laboratory tests, tests specified in paragraph (14)(C)(1), and radiology services, including portable x-ray services) which the Secretary shall designate (based on their high volume of expenditures under this part), the reasonable charge for such technical component (including the applicable portion of a global service) may not exceed the national median of such charges for all localities, as estimated by the Secretary using the best available data.

(18)(A) Payment for any service furnished by a practitioner described in subparagraph (C) and for which payment may be made under this part on a reasonable charge or fee schedule basis may only be made under this part on an assignment-related basis.

(B) A practitioner described in subparagraph (C) or other person may not bill (or collect any amount from) the individual or another person for any service described in subparagraph (A), except for deductible and coinsurance amounts applicable under this part. No person is liable for payment of any amounts billed for such a service in violation of the previous sentence. If a practitioner or other person knowingly and willfully bills (or collects an amount) for such a service in violation of such sentence, the Secretary may apply sanctions against the practitioner or other person in the same manner as the Secretary may apply sanctions against a physician in accordance with subsection (j) of this section.

(c) Prompt payment of claims


(2)(A) Each contract under section 1395kk–1 of this title that provides for making payments under this part shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to not less than 95 percent of all claims submitted under this part—

(i) which are clean claims, and

(ii) for which payment is not made on a periodic interim payment basis, within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph:

(i) The term “clean claim” means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.

(ii) The term “applicable number of calendar days” means—

(I) with respect to claims received in the 12-month period beginning October 1, 1986, 30 calendar days.

(II) with respect to claims received in the 12-month period beginning October 1, 1987, 26 calendar days (or 19 calendar days with respect to claims submitted by participating physicians),

(III) with respect to claims received in the 12-month period beginning October 1, 1988, 25 calendar days (or 18 calendar days with respect to claims submitted by participating physicians),

(IV) with respect to claims received in the 12-month period beginning October 1, 1989, and claims received in any succeeding 12-month period ending on or before September 30, 1993, 24 calendar days (or 17 calendar days with respect to claims submitted by participating physicians), and

(V) with respect to claims received in the 12-month period beginning October 1, 1993, and claims received in any succeeding 12-month period, 30 calendar days.

(C) If payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in clause (ii) of subparagraph (B)) after a clean claim (as defined in clause (i) of such subparagraph) is received, interest shall be paid at the rate used for purposes of section 3902(a) of title 31 (relating to interest penalties for failure to make prompt payments) for the period beginning on the day after the required payment date and ending on the date on which payment is made.
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(3)(A) Each contract under this section which provides for the disbursement of funds, as described in section 1395kk–1(a)(3)(B) of this title, shall provide that no payment shall be issued, mailed, or otherwise transmitted with respect to any claim submitted under this subchapter within the applicable number of calendar days after the date on which the claim is received.

(B) In this paragraph, the term "applicable number of calendar days" means—

(i) with respect to claims submitted electronically as prescribed by the Secretary, 13 days, and

(ii) with respect to claims submitted otherwise, 28 days.

(4) Neither a medicare administrative contractor nor the Secretary may impose a fee under this subchapter—

(A) for the filing of claims related to physicians' services,

(B) for an error in filing a claim relating to physicians' services or for such a claim which is denied,

(C) for any appeal under this subchapter with respect to physicians' services,

(D) for applying for (or obtaining) a unique identifier under subsection (r) of this section, or

(E) for responding to inquiries respecting physicians' services or for providing information with respect to medical review of such services.


(g) Authority of Railroad Retirement Board to enter into contracts with medicare administrative contractors

The Railroad Retirement Board shall, in accordance with such regulations as the Secretary may prescribe, contract with a medicare administrative contractor or contractors to perform the functions set out in this section with respect to individuals entitled to benefits as qualified railroad retirement beneficiaries pursuant to section 426(a) of this title and section 231f(d) of title 45.

(h) Participating physician or supplier; agreement with Secretary; publication of directories; availability; inclusion of program in explanation of benefits; payment of claims on assignment-related basis

(1) Any physician or supplier may voluntarily enter into an agreement with the Secretary to become a participating physician or supplier. For purposes of this section, the term "participating physician or supplier" means a physician or supplier (excluding any provider of services) who, before the beginning of any year beginning with 1984, enters into an agreement with the Secretary which provides that such physician or supplier will accept payment under this part on an assignment-related basis for all items and services furnished to individuals enrolled under this part during such year. In the case of a newly licensed physician or a physician who begins a practice in a new area, or in the case of a new supplier who begins a new business, or in such similar cases as the Secretary may specify, such physician or supplier may enter into such an agreement after the beginning of a year, for items and services furnished during the remainder of the year.

(2) The Secretary shall maintain a toll-free telephone number or numbers at which individuals enrolled under this part may obtain the names, addresses, specialty, and telephone numbers of participating physicians and suppliers and may request a copy of an appropriate directory published under paragraph (4). The Secretary shall, without charge, mail a copy of such directory upon such a request.

(3)(A) In any case in which a medicare administrative contractor having a contract under section 1395kk–1 of this title that provides for making payments under this part is able to develop a system for the electronic transmission to such contractor of bills for services, such contractor shall establish direct lines for the electronic receipt of claims from participating physicians and suppliers.

(B) The Secretary shall establish a procedure whereby an individual enrolled under this part may assign, in an appropriate manner on the form claiming a benefit under this part for an item or service furnished by a participating physician or supplier, the individual's rights of payment under a medicare supplemental policy (as described in section 1395ss(g)(1) of this title) in which the individual is enrolled. In the case such an assignment is properly executed and a payment determination is made by a medicare administrative contractor with a contract under this section, the contractor shall transmit to the private entity issuing the medicare supplemental policy notice of such fact and shall include an explanation of benefits and any additional information that the Secretary may determine to be appropriate in order to enable the entity to decide whether (and the amount of) any payment is due under the policy. The Secretary may enter into agreements for the transmittal of such information to entities electronically. The Secretary shall impose user fees for the transmittal of information under this subparagraph by a medicare administrative contractor, whether electronically or otherwise, and such user fees shall be collected and retained by the contractor.

(4) At the beginning of each year the Secretary shall publish directories (for appropriate local geographic areas) containing the name, address, and specialty of all participating physicians and suppliers (as defined in paragraph (1)) for that area for that year. Each directory shall be organized to make the most useful presentation of the information (as determined by the Secretary) for individuals enrolled under this part. Each participating physician directory for an area shall provide an alphabetical listing of all participating physicians practicing in the area and an alphabetical listing by locality and specialty of such physicians.

(5)(A) The Secretary shall promptly notify individuals enrolled under this part through an annual mailing of the participation program under this subsection and the publication and availability of the directories and shall make

So in original. Probably should be followed by "a".
the appropriate area directory or directories available in each district and branch office of the Social Security Administration, in the offices of medicare administrative contractors, and to senior citizen organizations.

(B) The annual notice provided under subparagraph (A) shall include—

(i) a description of the participation program,

(ii) an explanation of the advantages to beneficiaries of obtaining covered services through a participating physician or supplier,

(iii) an explanation of the assistance offered by medicare administrative contractors in obtaining the names of participating physicians and suppliers, and

(iv) the toll-free telephone number under paragraph (2)(A) for inquiries concerning the program and for requests for free copies of appropriate directories.

(6) The Secretary shall provide that the directories shall be available for purchase by the public. The Secretary shall provide that each appropriate area directory is sent to each participating physician located in that area and that an appropriate number of copies of each such directory is sent to hospitals located in the area. Such copies shall be sent free of charge.

(7) The Secretary shall provide that each explanation of benefits provided under this part for services furnished in the United States, in conjunction with the payment of claims under section 1395cc(j) of this title, shall include—

(A) a prominent reminder of the participating physician and supplier program established under this subsection (including the limitation on charges that may be imposed by such physicians and suppliers and a clear statement of any amounts charged for the particular items or services on the claim involved above the amount recognized under this part),

(B) the toll-free telephone number or numbers, maintained under paragraph (2), at which an individual enrolled under this part may obtain information on participating physicians and suppliers,

(C)(i) an offer of assistance to such an individual in obtaining the names of participating physicians of appropriate specialty and (ii) an offer to provide a free copy of the appropriate participating physician directory, and

(D) in the case of services for which the billed amount exceeds the limiting charge imposed under section 1395w–4(g) of this title, information regarding such applicable limiting charge (including information concerning the refund under section 1395w–4(g)(1)(A)(iv) of this title).

(8) The Secretary may refuse to enter into an agreement with a physician or supplier under this subsection, or may terminate or refuse to renew such agreement, in the event that such physician or supplier has been convicted of a felony under Federal or State law for an offense against the services is a participating physician under section 1395gg(f)(1) of this title.

(2) The term “participating physician” refers, with respect to the furnishing of services, to a physician who at the time of furnishing the services is a participating physician (under subsection (b)(1) of this section); the term “nonparticipating physician” refers, with respect to the furnishing of services, to a physician who at the time of furnishing the services is not a participating physician; and the term “nonparticipating supplier or other person” means a supplier or other person (excluding a provider of services) that is not a participating physician or supplier (as defined in subsection (b)(1) of this section).

(3) The term “percentage increase in the MEI” means, with respect to physicians’ services furnished in a year, the percentage increase in the medicare economic index (referred to in the fourth sentence of subsection (b)(3)(B)(ii) of this section, applicable to such services furnished as of the first day of that year.

(4) The term “primary care services” means physicians’ services which constitute office medical services, emergency department services, home medical services, skilled nursing, intermediate care, and long-term care medical services, or nursing home, boarding home, domiciliary, or custodial care medical services.

(j) Monitoring of charges of nonparticipating physicians; sanctions; restitution

(1)(A) In the case of a physician who is not a participating physician for items and services furnished during a period of the 30-month period beginning July 1, 1984, the Secretary shall monitor the physician’s actual charges to individuals enrolled under this part for physicians’ services during that portion of that period. If such physician knowingly and willfully bills individuals enrolled under this part for actual charges in excess of such physician’s actual charges for the calendar quarter beginning on April 1, 1984, the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(B)(i) During any period (on or after January 1, 1987, and before the date specified in clause (ii)), during which a physician is a nonparticipating physician, the Secretary shall monitor the actual charges of such physician for physicians’ services furnished to individuals enrolled.
under this part. If such physician knowingly and willfully bills on a repeated basis for such a service an actual charge in excess of the maximum allowable actual charge determined under subparagraph (C) for that service, the Secretary may apply sanctions against such physician in accordance with paragraph (2).

(ii) Clause (i) shall not apply to services furnished after December 31, 1990.

(C)(i) For a particular physicians’ service furnished by a nonparticipating physician to individuals enrolled under this part during a year, for purposes of subparagraph (B), the maximum allowable actual charge is determined as follows: If the physician’s maximum allowable actual charge for that service in the previous year was—

(I) less than 115 percent of the applicable percent (as defined in subsection (b)(4)(A)(iv) of this section) of the prevailing charge for the year and service involved, the maximum allowable actual charge for the year involved is the greater of the maximum allowable actual charge described in subclause (II) or the charge described in clause (ii), or

(II) equal to, or greater than, 115 percent of the applicable percent (as defined in subsection (b)(4)(A)(iv) of this section) of the prevailing charge for the year and service involved, the maximum allowable actual charge is 101 percent of the physician’s maximum allowable actual charge for the service for the previous year.

(ii) For purposes of clause (i)(I), the charge described in this clause for a particular physician’s service furnished in a year is the maximum allowable actual charge for the service of the physician for the previous year plus the product of (I) the applicable fraction (as defined in clause (iii)) and (II) the amount by which 115 percent of the prevailing charge for the year involved for such service furnished by nonparticipating physicians, exceeds the physician’s maximum allowable actual charge for the service for the previous year.

(iii) In clause (ii), the “applicable fraction” is—

(I) for 1987, ¾,

(II) for 1988, ⅞,

(III) for 1989, ⅜, and

(IV) for any subsequent year, 1.

(iv) For purposes of determining the maximum allowable actual charge under clauses (i) and (ii) for 1987, in the case of a physician’s service for which the physician has actual charges for the calendar quarter beginning on April 1, 1984, the “maximum allowable actual charge” for 1986 is the physician’s actual charge for such service furnished during such quarter.

For purposes of determining the maximum allowable actual charge under clauses (i) and (ii) for a year after 1986, in the case of a physician’s service for which the physician has no actual charges for the calendar quarter beginning on April 1, 1984, and for which a maximum allowable actual charge has not been previously established under this clause, the “maximum allowable actual charge” for the previous year shall be the 50th percentile of the customary charges for the service (weighted by frequency of the service) performed by nonparticipating physicians in the locality during the 12-month period ending June 30 of that previous year.

(vi) For purposes of this subparagraph, a “physician’s actual charge” for a physicians’ service furnished in a year or other period is the weighted average (or, at the option of the Secretary for a service furnished in the calendar quarter beginning April 1, 1984, the median) of the physician’s charges for such service furnished in the year or other period.

(vii) In the case of a nonparticipating physician who was a participating physician during a previous period, for the purpose of computing the physician’s maximum allowable actual charge during the physician’s period of nonparticipation, the physician shall be deemed to have had a maximum allowable actual charge during the period of participation, and such deemed maximum allowable actual charge shall be determined according to clauses (i) through (vi).

(viii) Notwithstanding any other provision of this subparagraph, the maximum allowable actual charge for a particular physician’s service furnished by a nonparticipating physician to individuals enrolled under this part during the 3-month period beginning on January 1, 1988, shall be the amount determined under this subparagraph for 1987. The maximum allowable actual charge for any such service otherwise determined under this subparagraph for 1988 shall take effect on April 1, 1988.

(ix) If there is a reduction under subsection (b)(13) of this section in the reasonable charge for medical direction furnished by a nonparticipating physician, the maximum allowable actual charge otherwise permitted under this subsection for such services shall be reduced in the same manner and in the same percentage as the reduction in such reasonable charge.

(D)(i) If an action described in clause (ii) results in a reduction in a reasonable charge for a physicians’ service or item and a nonparticipating physician furnishes the service or item to an individual entitled to benefits under this part after the effective date of such action, the physician may not charge the individual more than 125 percent of the reduced payment allowance (as defined in clause (iii)) plus (for services or items furnished during the 12-month period (or 9-month period in the case of an action described in clause (ii)(II)) beginning on the effective date of the action) ½ of the amount by which the physician’s maximum allowable actual charge for the service or item for the previous 12-month period exceeds such 125 percent level.

(ii) The first sentence of clause (i) shall apply to—

(I) an adjustment under subsection (b)(8)(B) of this section (relating to inherent reasonableness),

(II) a reduction under subsection (b)(10)(A) or (b)(14)(A) of this section (relating to certain overpriced procedures),

(III) a reduction under subsection (b)(11)(B) of this section (relating to certain cataract procedures),

(IV) a prevailing charge limit established under subsection (b)(11)(C)(i) or (b)(15)(A) of this section,
(V) a reasonable charge limit established under subsection (b)(11)(C)(ii) of this section, and

(VI) an adjustment under section 1395u(c)(3)(B) of this title (relating to physician supervision of certified registered nurse anesthetists).

(iii) In clause (i), the term "reduced payment allowance" means, with respect to an action—

(I) under subsection (b)(8)(B) of this section, the inherently reasonable charge established under subsection (b)(8) of this section;

(II) under subsection (b)(10)(A), (b)(11)(B), (b)(11)(C)(i), (b)(14)(A), or (b)(15)(A) of this section or under section 1395(l)(3)(B) of this title, the prevailing charge for the service after the action; or

(III) under subsection (b)(11)(C)(ii) of this section, the payment allowance established under such subsection.

(iv) If a physician knowingly and willfully bills in violation of clause (i) (whether or not such charge violates subparagraph (B)), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section.

(v) Clause (i) shall not apply to items and services furnished after December 31, 1990.

(2) Subject to paragraph (3), the sanctions which the Secretary may apply under this paragraph are—

(A) excluding a physician from participation in the programs under this chapter for a period not to exceed 5 years, in accordance with the procedures of subsections (c), (f), and (g) of section 1320a–7 of this title, or

(B) civil monetary penalties and assessments, in the same manner as such penalties and assessments are authorized under section 1320a–7a(a) of this title,

or both. The provisions of section 1320a–7a of this title (other than the first 2 sentences of subsection (a) and other than subsection (b)) shall apply to a civil money penalty and assessment under subparagraph (B) in the same manner as such provisions apply to a penalty, assessment, or proceeding under section 1320a–7a(a) of this title, except to the extent such provisions are inconsistent with subparagraph (A) or paragraph (3).

(3)(A) The Secretary may not exclude a physician pursuant to paragraph (2)(A) if such physician is a sole community physician or sole source of essential specialized services in a community.

(B) The Secretary shall take into account access of beneficiaries to physicians' services for which payment may be made under this part in determining whether to bar a physician from participation under paragraph (2)(A).

(4) The Secretary may, out of any civil monetary penalty or assessment collected from a physician pursuant to this subsection, make a payment to a beneficiary enrolled under this part in the nature of restitution for amounts paid by such beneficiary to such physician which was determined to be an excess charge under paragraph (1).

(k) Sanctions for billing for services of assistant at cataract operations

(1) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part for charges for services as an assistant at surgery for which payment may not be made by reason of section 1395y(a)(15) of this title, the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section in the case of surgery performed on or after March 1, 1987.

(2) If a physician knowingly and willfully presents or causes to be presented a claim or bills an individual enrolled under this part for charges that includes a charge for an assistant at surgery for which payment may not be made by reason of section 1395y(a)(15) of this title, the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section in the case of surgery performed on or after March 1, 1987.

(l) Prohibition of unassigned billing of services determined to be medically unnecessary by carrier

(1)(A) Subject to subparagraph (C), if—

(i) a nonparticipating physician furnishes services to an individual enrolled for benefits under this part,

(ii) payment for such services is not accepted on an assignment-related basis,

(iii) a medicare administrative contractor determines under part B of subchapter XI of this chapter that payment may not be made by reason of section 1395y(a)(1) of this title because a service otherwise covered under this subchapter is not reasonable and necessary under the standards described in that section or (II) payment under this subchapter for such services 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, and

(iv) the physician has collected any amounts for such services,

the physician shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts so collected.

(B) A refund under subparagraph (A) is considered to be on a timely basis only if—

(i) in the case of a physician who does not request reconsideration or seek appeal on a timely basis, the refund is made within 30 days after the date the physician receives a denial notice under paragraph (2), or

(ii) in the case in which such a reconsideration or appeal is taken, the refund is made within 15 days after the date the physician receives notice of an adverse determination on reconsideration or appeal.

(C) Subparagraph (A) shall not apply to the furnishing of a service by a physician to an individual in the case described in subparagraph (A)(ii)(I) if—

(i) the physician establishes that the physician did not know and could not reasonably have been expected to know that payment may not be made for the service by reason of section 1395y(a)(1) of this title, or

(ii) before the service was provided, the individual was informed that payment under this part may not be made for the specific service.
and the individual has agreed to pay for that service.

(2) Each medicare administrative contractor with a contract in effect under this section with respect to physicians and each peer review organization with a contract under part B of subchapter XI of this chapter shall send any notice of denial of payment for physicians’ services based on section 1395y(a)(1) of this title and for which payment is not requested on an assignment-related basis to the physician and the individual involved.

(3) If a physician knowingly and willfully fails to make refunds in violation of paragraph (1)(A), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section.

(m) Disclosure of information of unassigned claims for certain physicians’ services

(1) In the case of a nonparticipating physician who—

(A) performs an elective surgical procedure for an individual enrolled for benefits under this part and for which the physician’s estimated actual charge is at least $500, and

(B) does not accept payment for such procedure on an assignment-related basis,

the physician must disclose to the individual, in writing and in a form approved by the Secretary, the physician’s estimated actual charge for the procedure, the excess of the physician’s actual charge over the approved charge, and the coinsurance amount applicable to the procedure. The written estimate may not be used as the basis for, or evidence in, a civil suit.

(2) A physician who fails to make a disclosure required under paragraph (1) with respect to a procedure shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected for the procedure in excess of the charges recognized and approved under this part.

(3) If a physician knowingly and willfully fails to comply with paragraph (2), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section.

(n) Elimination of markup for certain purchased services

(1) If a physician’s bill or a request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1395x(s)(3) of this title (other than a clinical diagnostic laboratory test) for which the bill or request for payment does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or supervised the performance of the test, the amount payable with respect to the test shall be determined as follows:

(A) If the bill or request for payment indicates that the test was performed by a supplier, identifies the supplier, and indicates the amount the supplier charged the billing physician, payment for the test (less the applicable deductible and coinsurance amounts) shall be the actual acquisition costs (net of any discounts) or, if lower, the supplier’s reasonable charge (or other applicable limit) for the test.

(B) If the bill or request for payment (i) does not indicate who performed the test, or (ii) indicates that the test was performed by a supplier but does not identify the supplier or include the amount charged by the supplier, no payment shall be made under this part.

(2) A physician may not bill an individual enrolled under this part—

(A) any amount other than the payment amount specified in paragraph (1)(A) and any applicable deductible and coinsurance for a diagnostic test for which payment is made pursuant to paragraph (1)(A), or

(B) any amount for a diagnostic test for which payment may not be made pursuant to paragraph (1)(B).

(3) If a physician knowingly and willfully in repeated cases bills one or more individuals in violation of paragraph (2), the Secretary may apply sanctions against such physician in accordance with subsection (j)(2) of this section.

(o) Reimbursement for drugs and biologicals

(1) If a physician’s, supplier’s, or any other person’s bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological is equal to the following:

(A) In the case of any of the following drugs or biologicals, 95 percent of the average wholesale price:

(i) A drug or biological furnished before January 1, 2004.


(iii) A drug or biological furnished during 2004 that was not available for payment under this part as of April 1, 2003.

(iv) A vaccine described in subparagraph (A) or (B) of section 1395x(s)(10) of this title furnished on or after January 1, 2004.

(v) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.

(B) In the case of a drug or biological furnished during 2004 that is not described in—

(i) clause (ii), (iii), (iv), or (v) of subparagraph (A),

(ii) subparagraph (D)(i), or

(iii) subparagraph (F),

the amount determined under paragraph (4).

(C) In the case of a drug or biological that is not described in subparagraph (A)(iv), (D)(i), or (F) furnished on or after January 1, 2005, the amount provided under section 1395w–3 of this title, section 1395w–3a of this title, section 1395w–3b of this title, or section 1395rr(b)(13) of this title, as the case may be for the drug or biological.
(D)(i) Except as provided in clause (ii), in the case of infusion drugs furnished through an item of durable medical equipment covered under section 1395x(n) of this title on or after January 1, 2004, 95 percent of the average wholesale price for such drug in effect on October 1, 2003.

(ii) In the case of such infusion drugs furnished in a competitive acquisition area under section 1395w-3 of this title on or after January 1, 2007, the amount provided under section 1395w-3 of this title.

(E) In the case of a drug or biological, consisting of intravenous immune globulin, furnished—

(i) in 2004, the amount of payment provided under paragraph (4); and

(ii) in 2005 and subsequent years, the amount of payment provided under section 1395w-3a of this title.

(F) In the case of blood and blood products (other than blood clotting factors), the amount of payment shall be determined in the same manner as such amount of payment was determined on October 1, 2003.

(G) In the case of inhalation drugs or biologicals furnished through durable medical equipment covered under section 1395x(n) of this title that are furnished—

(i) in 2004, the amount provided under paragraph (4) for the drug or biological; and

(ii) in 2005 and subsequent years, the amount provided under section 1395w-3a of this title for the drug or biological.

(2) If payment for a drug or biological is made to a licensed pharmacy approved to dispense drugs or biologicals under this part, the Secretary may pay a dispensing fee (less the applicable deductible and coinsurance amounts) to the pharmacy. This paragraph shall not apply in the case of payment under paragraph (1)(C).

(3)(A) Payment for a charge for any drug or biological for which payment may be made under this part may be made only on an assignment-related basis.

(B) The provisions of subsection (b)(18)(B) of this section shall apply to charges for such drugs or biologicals in the same manner as they apply to services furnished by a practitioner described in subsection (b)(18)(C) of this section.

(4)(A) Subject to the succeeding provisions of this paragraph, the amount of payment for a drug or biological under this paragraph furnished in 2004 is equal to 85 percent of the average wholesale price (determined as of April 1, 2003) for the drug or biological.

(B) The Secretary shall substitute for the percentage under subparagraph (A) for a drug or biological the percentage that would apply to the drug or biological under the column entitled ‘‘Average of GAO and OIG data (percent)’’ in the table entitled ‘‘Table 3.—Medicare Part B Drugs in the Most Recent GAO and OIG Studies’’ published on August 20, 2003, in the Federal Register (68 Fed. Reg. 50445).

(C)(i) The Secretary may substitute for the percentage under subparagraph (A) a percentage that is based on data and information submitted by the manufacturer of the drug or biological by October 15, 2003.

(ii) The Secretary may substitute for the percentage under subparagraph (A) with respect to drugs and biologicals furnished during 2004 on or after April 1, 2004, a percentage that is based on data and information submitted by the manufacturer of the drug or biological after October 15, 2003, and before January 1, 2004.

(D) In no case may the percentage substituted under subparagraph (B) or (C) be less than 80 percent.

(5)(A) Subject to subparagraph (B), in the case of clotting factors furnished on or after January 1, 2005, the Secretary shall, after reviewing the January 2003 report to Congress by the Comptroller General of the United States entitled ‘‘Payment for Blood Clotting Factor Exceeds Providers Acquisition Cost’’, provide for a separate payment, to the entity which furnishes to the patient blood clotting factors, for items and services related to the furnishing of such factors in an amount that the Secretary determines to be appropriate. Such payment amount may take into account any or all of the following:

(i) The mixing (if appropriate) and delivery of factors to an individual, including special inventory management and storage requirements.

(ii) Ancillary supplies and patient training necessary for the self-administration of such factors.

(B) In determining the separate payment amount under subparagraph (A) for blood clotting factors furnished in 2005, the Secretary shall ensure that the total amount of payments under this part (as estimated by the Secretary) for such factors under paragraph (1)(C) and such separate payments for such factors does not exceed the total amount of payments that would have been made for such factors under this part (as estimated by the Secretary) if the amendments made by section 303 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 had not been enacted.

(C) The separate payment amount under this subparagraph for blood clotting factors furnished in 2006 or a subsequent year shall be equal to the separate payment amount determined under this paragraph for the previous year increased by the percentage increase in the consumer price index for medical care for the 12-month period ending with June of the previous year.

(6) In the case of an immunosuppressive drug described in subparagraph (J) of section 1395x(s)(2) of this title and an oral drug described in subparagraph (Q) or (T) of such section, the Secretary shall pay to the pharmacy a supplying fee for such a drug determined appropriate by the Secretary (less the applicable deductible and coinsurance amounts).

(7) There shall be no administrative or judicial review under section 1395f of this title, section 1395s of this title, or otherwise, of determinations of payment amounts, methods, or adjustments under paragraphs (4) through (6).

(p) Requiring submission of diagnostic information

(1) Each request for payment, or bill submitted, for an item or service furnished by a physician or practitioner specified in subsection
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(b)(18)(C) of this section for which payment may be made under this part shall include the appropriate diagnosis code (or codes) as established by the Secretary for such item or service.

(2) In the case of a request for payment for an item or service furnished by a physician or practitioner specified in subsection (b)(18)(C) of this section on an assignment-related basis which does not include the code (or codes) required under paragraph (1), payment may be denied under this part.

(3) In the case of a request for payment for an item or service furnished by a physician not submitted on an assignment-related basis and which does not include the code (or codes) required under paragraph (1)—

(A) if the physician knowingly and willfully fails to provide the code (or codes) promptly upon request of the Secretary or a Medicare administrative contractor, the physician may be subject to a civil money penalty in an amount not to exceed $2,000, and

(B) if the physician knowingly, willfully, and in repeated cases fails, after being notified by the Secretary of the obligations and requirements of this subsection, to include the code (or codes) required under paragraph (1), the physician may be subject to the sanction described in subsection (j)(2)(A) of this section.

The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (A) in the same manner as they apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(4) In the case of an item or service defined in paragraph (3), (6), (8), or (9) of subsection 1395m(a)(14)(J) of this title ordered by a physician or a practitioner in the same manner as they apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(q) Anesthesia services; counting actual time units

(1)(A) The Secretary, in consultation with groups representing physicians who furnish anesthesia services, shall establish by regulation a relative value guide for use in all localities in making payment for physician anesthesia services furnished under this part. Such guide shall be designed so as to result in expenditures under this subchapter for such services in an amount that would not exceed the amount of such expenditures which would otherwise occur.

(B) For physician anesthesia services furnished under this part during 1991, the prevailing charge conversion factor used in a locality under this subsection shall, subject to clause (iv), be reduced to the adjusted prevailing charge conversion factor for the locality determined as follows:

(i) The Secretary shall estimate the national weighted average of the prevailing charge conversion factors used under this subsection for services furnished during 1990 after March 31, using the best available data.

(ii) The national weighted average estimated under clause (i) shall be reduced by 7 percent.

(iii) The adjusted prevailing charge conversion factor for a locality is the sum of—

(I) the product of (a) the portion of the reduced national weighted average prevailing charge conversion factor computed under clause (ii) which is attributable to physician work and (b) the geographic work index value for the locality specified in Addendum C to the Model Fee Schedule for Physician Services (published on September 4, 1990, 55 Federal Register pp. 36238–36243)); and

(II) the product of (a) the remaining portion of the reduced national weighted average prevailing charge conversion factor computed under clause (ii) and (b) the geographic practice cost index value specified in subsection (b)(14)(C)(iv) of this section for the locality.

In applying this clause, 70 percent of the prevailing charge conversion factor shall be considered to be attributable to physician work.

(iv) The prevailing charge conversion factor to be applied to a locality under this subparagraph shall not be reduced by more than 15 percent below the prevailing charge conversion factor applied in the locality for the period during 1990 after March 31, but in no case shall the prevailing charge conversion factor be less than 60 percent of the national weighted average of the prevailing charge conversion factors (computed under clause (i)).

(2) For purposes of payment for anesthesia services (whether furnished by physicians or by certified registered nurse anesthetists) under this part, the time units shall be counted based on actual time rather than rounded to full time units.

(r) Establishment of physician identification system

The Secretary shall establish a system which provides for a unique identifier for each physician who furnishes services for which payment may be made under this subchapter. Under such system, the Secretary may impose appropriate fees on such physicians to cover the costs of investigation and recertification activities with respect to the issuance of the identifiers.

(s) Application of fee schedule

(1)(A) Subject to paragraph (3), the Secretary may implement a statewide or other area wide fee schedule to be used for payment of any item or service described in paragraph (2) which is paid on a reasonable charge basis.

(B) Any fee schedule established under this paragraph for such item or service shall be updated—

(i) for years before 2011—

(1) subject to subclause (II), by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year; and

(II) for items and services described in paragraph (2)(D) for 2009, section 1395m(a)(14)(J) of this title shall apply under
this paragraph instead of the percentage increase otherwise applicable; and

(ii) for 2011 and subsequent years—

(I) the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the previous year, reduced by—

(II) the productivity adjustment described in section 1395w(b)(3)(B)(x)(II) of this title.

The application of subparagraph (B)(ii)(II) may result in the update under this paragraph being less than 0.0 for a year, and may result in payment rates under any fee schedule established under this paragraph for a year being less than such payment rates for the preceding year.

(2) The items and services described in this paragraph are as follows:

(A) Medical supplies.

(B) Home dialysis supplies and equipment (as defined in section 1395rr(b)(8) of this title).

services for any previous year, the percentage increase computed under section 1395m(a)(14)(L)(i) of this title shall apply instead of the percentage increase otherwise applicable.

2008—Subsec. (b)(6)(D)(iii). Pub. L. 110–275, § 137, struck out “(before July 1, 2008)” after “or are provided”.

Subsec. (e)(1). Pub. L. 110–275, § 154(a)(2)(B), substituted “except that for items and services described in paragraph (2)(D)—” for “except that in no event shall a fee schedule for an item described in paragraph (2)(D) be updated before 2003.” and added subpars. (A) and (B).


Pub. L. 110–54 inserted “or are provided before (January 1, 2008) over a longer continuous period during all of which the first physician has been called or ordered to active duty as a member of a reserve component of the ‘armed forces’ after January 1, 2006” for “July 1, 2008”.


Subsec. (a). Pub. L. 108–173, § 911(c)(2), amended subsec. (a) generally. Prior to amendment, subsec. (a) authorized the Secretary to enter into contracts with carriers for the administration of benefits under this part, part D, and section 1395m.

Subsec. (b)(2)(A). Pub. L. 108–173, § 911(c)(3)(B)(i), struck out subpars. (A) and (B), which conditioned entering into contract on Secretary’s finding that carrier would perform obligations efficiently and effectively, provided for establishment and publication of standards and criteria for efficient and effective performance, and directed Secretary to establish standards for evaluating carriers’ performance of reviews of initial carrier determinations and of fair hearings under former paragraph (3)(C).


Subsec. (b)(2)(D). Pub. L. 108–173, § 911(c)(3)(B)(iii), struck out subpars. (D) and (E), which directed that carrier be subject to standards and criteria relating to the carrier’s success in recovering payments for items or services for which payment has or could be made under a primary plan and that Secretary could continue administration of claims for certain home health services through fiscal intermediaries under section 1395h of this title.


Pub. L. 108–173, § 911(c)(3)(C)(x), struck out “and shall contain such other terms and conditions not inconsistent with this section as the Secretary may find necessary or appropriate.” before “In determining” in concluding provisions.

Pub. L. 108–173, § 911(c)(3)(C)(ii), substituted “shall take such action” for “will take such action”.


Amendments

2010—Subsec. (b)(3). Pub. L. 111–148, § 4640(a)(2)(A)(ii), at end of concluding provisions, inserted “in applying subparagraph (B), the Secretary may specify exceptions to the 1 calendar year period specified in such subparagraph.”

Subsec. (b)(3)(B). Pub. L. 111–148, § 4640(a)(2)(A)(i), substituted “period ending 1 calendar year after the date of service” for “close of the calendar year following the date of service furnished in the last 3 months of any calendar year” in concluding provisions.


Subsec. (e)(1). Pub. L. 111–148, § 301(c), designated existing provisions as subpar. (A), added subpar. (B) and concluding provisions, and struck out former second sentence, which read as follows: “Any fee schedule established under this paragraph for such item or service shall contain such other terms and conditions not inconsistent with this section as the Secretary may find necessary or appropriate.”


Amendment of this section and sections 1395w–3a and 1395w–3b of this title, which enacted sections 1395w–3a and 1395w–3b of this title, and reenacted and amended this section and sections 1395w–4, 1395w–4a, 1395w–4b, and 1395w–4c of this title, and sections 1395x, 1395y, and 1396r–8 of this title, enacted provisions as subpars. (A), (B), (C), (D), (E), (F), (G), (H), (I), (J), (K), (L), (M), (N), (O), (P), (Q), (R), (S), (T), (U), (V), (W), (X), (Y), (Z), and (AA), and reenacted and amended this section and sections 1395w–3a and 1395w–3b of this title, and set out notes under this section and sections 1395x, 1395y, and 1396r–8 of this title, amended this section and sections 1395w–3a and 1395w–3b of this title, and set out notes under this section and sections 1395x, 1395y, and 1396r–8 of this title, and set out notes under this section and sections 1395w–3a and 1395w–3b of this title, and set out notes under this section and sections 1395w–3a and 1395w–3b of this title.
medicare administrative contractor” for “to the policyholders and subscribers of the carrier” in introductory provisions.

Subsec. (b)(3)(C) to (E). Pub. L. 108–173, § 911(c)(3)(C)(i), substituted “shall take such action” for “will take such action” in introductory provisions.

Subsec. (b)(3)(C) to (E). Pub. L. 108–173, § 911(c)(3)(C)(iv), struck out subpars. (C) to (E), which directed that each contract provide that the carrier would establish and maintain procedures for a fair hearing in any case where the amount in controversy was between $100 and $500, that the carrier would furnish to the Secretary such information and reports as he would find necessary in performing his functions under this part, and that the carrier would maintain such records and afford such access thereto as the Secretary would find necessary to assure the correctness and verification of the information and reports under former subpar. (D) and otherwise to carry out the purposes of this part.


Subsec. (b)(3)(I). Pub. L. 108–173, § 911(c)(3)(C)(vi), struck out subpar. (I), which directed that each contract would require the carrier to submit annual reports to the Secretary describing steps taken to recover payments made under this part for items or services for which payment had been or could have been made under a primary plan.


Subsec. (b)(5). Pub. L. 108–173, § 911(c)(3)(D), struck out par. (5), which provided that each contract under this section would provide for an employer or facility to charge for an item or service as described in clause (A) “except to an employer or facility under which any such facility submits the bill for such service.”.

Subsec. (b)(6)(A)(ii). Pub. L. 108–173, § 952(a), added cl. (i) and struck out former cl. (i) which read as follows: “(where the service was provided in a hospital, critical access hospital, clinic, or other facility) to the facility in which the service was provided if there is a contractual arrangement between such physician or other person and such facility under which such facility submits the bill for such service.”.


Subsec. (b)(7). Pub. L. 108–173, § 911(c)(3)(F), substituted “the Secretary” for “the carrier” in introductory provisions of subpar. (A), before “shall take into account” in subpar. (B)(i), in introductory provisions of subpar. (B)(ii), and before “shall provide” in subpar. (G).

Subsec. (c)(1). Pub. L. 108–173, § 911(c)(4)(A), struck out par. (1), which provided that any contract entered into with a carrier under this section would provide for advances of funds for the making of payments and for payment for necessary and proper cost of administration, and directed the Secretary to cause to be published in the Federal Register, by not later than Sept. 1 each year, data, standards, and methodology to be used to establish budgets for carriers and to cause to be published in the Federal Register for public comment, at least 90 days before Sept. 1, the data, standards, and methodology proposed to be used.

Subsec. (c)(2)(A). Pub. L. 108–173, § 911(c)(4)(B), substituted “contract under section 1395kk–1 of this title” for “contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B) of this section,” in introductory provisions.


Subsec. (c)(5). Pub. L. 108–173, § 911(c)(4)(E), struck out paras. (5) and (6), which provided that each contract would require the carrier to meet criteria to measure the timeliness of responses to requests for payment of claims described in section 1395m(a)(15)(C) of this title, and prohibited any carrier from carrying out any activity pursuant to a contract under the Medicare Integrity Program under section 1395ddl of this title.

Subsec. (d) to (f). Pub. L. 108–173, § 911(c)(5), struck out subsecs. (d) to (f), which provided that contracts under this section could require surety bonds and that certifying or disbursing officers or carriers would not be liable with respect to payments in the absence of gross negligence or intent to defraud and defined “carrier” for purposes of this part.

Subsec. (g). Pub. L. 108–173, § 911(c)(6), substituted “medicare administrative contractor or contractors” for “carrier or carriers”.

Subsec. (h)(2). Pub. L. 108–173, § 911(c)(7)(A), substituted “The Secretary” for “Each carrier having an agreement with the Secretary under subsection (a) of this section” in first sentence and for “Each such carrier” in last sentence.

Subsec. (h)(3)(A). Pub. L. 108–173, § 911(c)(7)(B)(i), which directed substitution of “‘such contractor’ for ‘such carrier’” was executed by making the substitution in two places to reflect the probable intent of Congress.

Pub. L. 108–173, § 911(c)(7)(B)(i), substituted “medicare administrative contractor having a contract under section 1395kk–1 of this title that provides for making payments under this part” for “a carrier having an agreement with the Secretary under subsection (a) of this section”.


Subsec. (i)(2). Pub. L. 108–173, § 796(b)(9), substituted “services, to a physician” for “services, a physician”.


Subsec. (k)(1). Pub. L. 108–173, § 905(a)(1), amended subparagraph (B) generally. Prior to amendment, subpar. (G) read as follows: “The provisions of subparagraphs (A) through (F) of this paragraph shall not apply to an inhalation drug or biological substance such as durable medical equipment covered under section 1395x(m) of this title.”
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Subsec. (o)(2). Pub. L. 108–173, § 303(b)(1), inserted at end “This paragraph shall not apply in the case of payment under paragraph (1)(C).”


Subsec. (s)(1). Pub. L. 108–173, § 302(d)(3)(A), substituted “Subject to paragraph (3), the Secretary” for “The Secretary”.


2000—Subsec. (b)(6)(C). Pub. L. 106–554, § 1(a)(a)(6) [title II, § 223(a)], struck out “for such services provided before January 1, 2005,” before “payment may be made” and substituted comma for semicolon at end.


Subsec. (t). Pub. L. 106–554, § 1(a)(a)(6) [title III, § 313(b)(2)], struck out “by a physician” before “to an individual” and “or of a part of a facility that includes a skilled nursing facility (as determined under regulations)” before “for which payment shall be made” and “(without regard to whether or not the item or service was furnished by the facility, by others under arrangement with them made by the facility, under any other contracting or consulting arrangement, or otherwise)” after “to the facility”.

1999—Subsec. (b)(6)(F). Pub. L. 106–113, § 1000(a)(6) [title III, § 305(a)], inserted “(including medical supplies described in section 1885(m)(5) of this title, but excluding durable medical equipment to the extent provided for in such section)” after “home health services”.

Subsec. (b)(8)(A)(1)(I). Pub. L. 106–113, § 1000(a)(6) [title II, § 225(c)], substituted “the application of this subsection to payment under this part” for “the application of this part”.


Subsec. (b)(6). Pub. L. 105–33, § 4512(c), inserted at end “For purposes of subparagraph (C) of the first sentence of this paragraph, an employment relationship may include any independent contractor arrangement, and employer status shall be determined in accordance with the law of the State in which the services described in such clause are performed.”


Subsec. (b)(6)(C). Pub. L. 105–33, § 4065(d)(1)(B), amended subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: “in the case of services described in clauses (i), (ii), or (iv) of section 1395x(s)(2)(K) of this title payment shall be made to the physician assistant or nurse practitioner involved, and”.


Subsec. (b)(8), (9). Pub. L. 105–33, § 4316(a), amended pars. (8) and (9) generally. Prior to amendment, par. (8) related to determination of reasonable charges for physician services, including factors to be considered, provision for increase or decrease of charge, consideration of resource costs, accounting for regional differences in prevailing charges, and impact of changes in reasonable charges, and par. (9) related to notice of proposed reasonable charges to be published in Federal Register, provision for comments on proposed changes, and publication of final determinations with respect to change in reasonable charges.

Subsec. (b)(12). Pub. L. 105–33, § 4512(b)(2), struck out par. (12) which read as follows: “(12) A With respect to services described in clauses (1), (i), or (iv) of section 1395x(s)(2)(K) of this title (relating to a physician assistant and nurse practitioners)—

‘‘(i) payment under this part may only be made on an assignment-related basis; and

‘‘(ii) the prevailing charges determined under paragraph (3) shall not exceed—

‘‘(I) 75 percent in the case of services performed as an assistant at surgery, 65 percent of the amount that would otherwise be recognized if performed by a physician who is serving as an assistant at surgery, or

‘‘(II) other applicable percentage (as defined in subparagraph (B)) of the prevailing charge rate determined for such services (or, for services furnished on or after January 1, 1992, the fee schedule amount specified in section 1395w–4–4 of this title) performed by physicians who are not specialists.

‘‘(B) In subparagraph (A)(i)(II), the term ‘applicable percentage means—

‘‘(i) 75 percent in the case of services performed (other than as an assistant at surgery) in a hospital, and

‘‘(ii) 85 percent in the case of other services.’’


Subsec. (b)(5). Pub. L. 105–33, § 4556(a), added subsec. (b).

Subsec. (p)(1)(2). Pub. L. 105–33, § 4317(a), inserted “or practitioner specified in subsection (b)(18)(C) of this section” after “by a physician”.


Subsec. (t). Pub. L. 104–191, § 221(b), inserted at end “Under such system, the Secretary may impose appropriate fees on such physicians to cover the costs of investigation and recertification activities with respect to the issuance of the identifiers.”


Subsec. (b)(3)(G). Pub. L. 103–432, § 1511(b)(3)(B)(i), which directed striking out “and” at end of subpar. (G), could not be executed because “and” did not appear at end of subpar. (G) subsequent to amendment by Pub. L. 103–432, § 1236(c)(2). See below.

Pub. L. 103–432, § 1236(c)(2), amended subpar. (G) generally. Prior to amendment, subpar. (G) read as follows: “will provide to each nonparticipating physician, at the beginning of each year, a list of the physician’s limiting charges established under section 1395w–4(g)(2) of this title for the year for the physicians’ services mostly commonly furnished by that physician; and”.

Subsec. (b)(3)(H). Pub. L. 103–432, § 1515(b)(1)(B)(ii), which directed striking out “and” at end of subpar. (H), could not be executed because “and” does not appear at end.

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Subsec. (b)(6)(D). Pub. L. 103–432, §125(b)(1), amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: “payment may be made to a physician who arranges for visit services (including emergency visits and related services) to be provided to an individual by a second physician on an occasional, reciprocal basis if (i) the first physician is unavailable to provide the visit services, (ii) the individual has arranged or seeks to receive the visit services from the first physician, (iii) the claim form submitted to the carrier includes the second physician’s unique identifier (provided under the system established under subsection (r) of this section) and indicates that the claim is for such a ‘covered visit service (and related services)’ to be provided to an individual by a second physician on an occasional, reciprocal basis and (iv) the visit services are not provided by the second physician over a continuous period of longer than 60 days.’’

Subsec. (b)(12)(C). Pub. L. 103–432, §123(b)(2)(B), struck out subpar. (C). Prior to amendment, subpar. (C) read as follows: ‘‘Except for deductible and coinsurance amounts applicable under section 1395f of this title, any person who knowingly and willfully presents, or causes to be presented, to an individual enrolled under this part a request for services described in clauses (i), (ii), or (iv) of section 1395k(a)(2)(K) of this title in violation of subparagraph (A)(i) is subject to a civil money penalty of not to exceed $2,000 for each such claim or request. The provisions of this subparagraph 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.’’

Subsec. (b)(16)(B)(iii). Pub. L. 103–432, §125(a)(1), struck out ‘‘simple and subcutaneous’’ after ‘‘Partial’’, substituted ‘‘injections and small joint’’ for ‘‘injections; small joint’’ and ‘‘femoral fracture and’’ for ‘‘femoral fracture treatments’’; struck out ‘‘lobectomy;’’ after ‘‘thoracostomy;’’ and ‘‘enterectomy; colostomy; cholecystectomy;’’ after ‘‘aneurysm repair;’’ substituted ‘‘fulguration and resection’’ for ‘‘fulguration; transurethral resection’’; and struck out ‘‘sacral laminectomy;’’ before ‘‘tympanoplasty’’. Subsec. (b)(17). Pub. L. 103–432, §126(e), redesignated par. (18), relating to payment for technical component of diagnostic tests, as (17) and inserted ‘‘tests specified in paragraph (14)(C)(i)’’, after ‘‘diagnostic laboratory tests’’.

Subsec. (b)(18). Pub. L. 103–432, §126(e), redesignated par. (18), relating to payment for technical component of diagnostic tests, as (17).

Pub. L. 103–432, §123(b)(1), added par. (18), relating to payment for service furnished by a practitioner deceased in subpar. (C).

Subsec. (c)(1). Pub. L. 103–432, §126(b)(2), struck out subpar. (A) designation before ‘‘Any contract entered into after ‘‘Partial’’, substituted ‘‘injections and small joint’’ for ‘‘injections; small joint’’ and ‘‘femoral fracture and’’ for ‘‘femoral fracture treatments’’; struck out ‘‘lobectomy;’’ after ‘‘thoracostomy;’’ and ‘‘enterectomy; colostomy; cholecystectomy;’’ after ‘‘aneurysm repair;’’ substituted ‘‘fulguration and resection’’ for ‘‘fulguration; transurethral resection’’; and struck out ‘‘sacral laminectomy;’’ before ‘‘tympanoplasty’’.


Subsec. (q)(1)(B). Pub. L. 103–432, §126(c)(2)(A), substituted ‘‘shall, subject to clause (iv), be reduced to the adjusted prevailing charge conversion factor for the locality determined as follows:’’ for ‘‘shall be determined as follows:’’ in introductory provisions. Subsec. (q)(1)(B)(iii). Pub. L. 103–432, §126(c)(2)(B), substituted ‘‘The adjusted prevailing charge conversion factor for’’ for ‘‘Subject to clause (iv), the prevailing charge conversion factor for’’.

1993—Subsec. (b)(4)(F). Pub. L. 103–66, §1351(a)(2), struck out subpar. (F) which related to prevailing charge or fee schedule amount in case of professional services of health care practitioners other than primary care services and other than services furnished in rural area designated as health professional shortage area furnished during practitioner’s first through fourth years of practice.

Subsec. (b)(13)(A). Pub. L. 103–66, §1351(a)(2)(A), added subpar. (A) and struck out former subpar. (A) which read as follows: ‘‘In determining the reasonable charge under paragraph (3) of a physician for medical direction of two or more nurse anesthetists performing, on or after April 1, 1988, and before January 1, 1996, anesthesia services in whole or in part concurrently, the number of base units which may be recognized with respect to such medical direction for each concurrent procedure (other than cataract surgery or an iridectomy) shall be reduced by—

‘‘(i) 10 percent, in the case of medical direction of 2 nurse anesthetists concurrently,

‘‘(ii) 25 percent, in the case of medical direction of 3 nurse anesthetists concurrently; and

‘‘(iii) 40 percent, in the case of medical direction of 4 nurse anesthetists concurrently.’’

Subsec. (b)(13)(B). Pub. L. 103–66, §1351(a)(2)(B), redesignated subpar. (C) as (B), substituted ‘‘subparagraph (A)’’ for ‘‘subparagraph (A) or (B)’’, and struck out former subpar. (B) which read as follows: ‘‘In determining the reasonable charge under paragraph (3) of a physician for medical direction of two or more nurse anesthetists performing, on or after January 1, 1989, and before January 1, 1996, anesthesia services in whole or in part concurrently, the number of base units which may be recognized with respect to such medical direction for each concurrent cataract surgery or iridectomy procedure shall be reduced by 10 percent.’’

Subsec. (c)(2)(B)(ii). Pub. L. 103–66, §13568(b), substituted ‘‘period ending on or before September 30, 1993’’ for ‘‘period in subcl. (IV) and added subcl. (V).’’

Subsec. (c)(3)(B). Pub. L. 103–66, §13568(a), added cls. (i) and (ii) and struck out former cls. (i) and (ii) which read as follows:

‘‘(i) with respect to claims received in the 3-month period beginning July 1, 1988, 10 days, and

‘‘(ii) with respect to claims received in the 12-month period beginning October 1, 1988, 14 days.’’

Subsec. (i)(2). Pub. L. 103–66, §13517(b), substituted ‘‘the term’’ for ‘‘, and the term’’ and inserted before period at end ‘‘, and the term which participating supplier or other person means a supplier or other person (excluding a provider of services) that is not a participating physician or supplier (as defined in subsection (h)(1) of this section).’’


Subsec. (b)(4)(F). Pub. L. 101–508, §4106(a)(1), amended subpar. (F) generally. Prior to amendment, subpar. (F) read as follows: ‘‘In determining the customary charges for physicians’ services furnished during a calendar
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year (other than primary care services and other than services furnished in a rural area (as defined in section 1395ww(d)(2)(D) of this title) that is designated, under section 1395w(a)(1)(A) of this title, as a health manpower shortage area) for which adequate actual charge data are not available because a physician has not yet been in practice for a sufficient period of time, the Secretary shall set the customary charge at a level no higher than 80 percent of the prevailing charge for a service. For the first calendar year during which the preceding sentence no longer applies, the Secretary shall set the customary charge for the service at a level no higher than 85 percent of the prevailing charge for the service."

Subsec. (b)(4)(F)(i). Pub. L. 101–508, § 4106(b)(2)(A), (B), substituted "professional services" for "physicians' services and professional services" and "practitioner's first" for "physician or practitioner's first".


Subsec. (b)(12)(A). Pub. L. 101–508, § 4155(c), substituted "clauses (i), (ii), or (iv) of section 1395x(s)(2)(K)" for "section 1395x(s)(2)(K)" in introductory provisions.

Subsec. (b)(12)(A)(ii)(II). Pub. L. 101–508, § 4118(b)(2)(C), struck out "as the case may be" after "section 1395w–4 of this title".


Subsec. (b)(12)(C). Pub. L. 101–508, § 4155(c), substituted "clauses (i), (ii), or (iv) of section 1395x(s)(2)(K)" for "section 1395x(s)(2)(K)" in introductory provisions.


Subsec. (b)(14)(B)(ii). Pub. L. 101–508, § 4118(b)(1)(A), which directed amendment of subcl. (I) by substituting "practice expense component (percent), divided by 100" for "physicians' service specified in clause (i), is the percent difference (but expressed as a positive number) specified for the service in the list" for "The 'percentage change' specified in this clause, for a physicians' service specified in clause (i), is the percent change specified for the service in table #2 in the Joint Explanatory Statement", was executed by making the substitution for "The 'percentage change' specified in this clause, for a physician's service specified in clause (i), is the percent change specified for the service in table #2 in the Joint Explanatory Statement" to reflect the probable intent of Congress.

Subsec. (b)(14)(C)(iv). Pub. L. 101–508, § 4118(a)(1)(E), which directed amendment of cl. (iv) by substituting "the Geographic Overhead Costs Index specified for the locality in table 1 of the September 1989 Supplement to the Geographic Medicare Economic Index: Alternative Approaches (prepared by the Urban Institute and the Center for Health Economics Research)" for "such value specified for the locality in table #3 in the Joint Explanatory Statement referred to in clause (i)", was executed by making the substitution for "such value specified for the locality in Table #3 in the Joint Explanatory Statement referred to in clause (i)" to reflect the probable intent of Congress.


Subsec. (q)(1). Pub. L. 101–508, § 4101(a), as amended by Pub. L. 103–432, § 126(c)(1), designated existing provisions as subpar. (A) and added subpar. (B).


1989—Subsec. (b)(2)(A). Pub. L. 101–239, § 6202(d)(2), inserted at end "The Secretary may not require, as a condition of entering into or renewing a contract under this section or under section 1396hh of this title, that a carrier match data obtained other than in its activities under this part with data used in the administration of this part for purposes of identifying situations in which section 1395(b) of this title may apply."

Pub. L. 101–234, § 201(a), repealed Pub. L. 100–360, § 3202(e)(3)(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. (b)(4)(F). Pub. L. 101–239, § 6106(a)(1), inserted "furnished during a calendar year after "physicians' services" and inserted at end "For the first calendar year during which the preceding sentence no longer applies, the Secretary shall set the customary charge at a level no higher than 85 percent of the prevailing charge for the service."


Subsec. (b)(12)(A). Pub. L. 101–239, § 6114(c)(1), inserted "or nurse practitioner" after "physician assistant".


Subsec. (b)(6)(C). Pub. L. 101–239, § 6114(c)(1), inserted "or nurse practitioner" after "physician assistant".

Subsec. (b)(6)(C). Pub. L. 101–239, § 6114(c)(1), inserted "or nurse practitioner" after "physician assistant".
(1) requiring notice that an individual has reached the part B catastrophic limit on out-of-pocket cost sharing for the year.

Subsec. (b)(3)(J). Pub. L. 100–360, § 202(e)(2), added subpar. (J) relating to requirements for determinations or payments with respect to covered outpatient drugs, to receive information and respond to requests by participating pharmacies.

Subsec. (b)(3)(K). Pub. L. 100–485, § 608(d)(5)(C), inserted “, including claims processing functions,” after “and for related functions”.

Pub. L. 100–360, § 202(e)(2), added subpar. (K) requiring contracts with organizations described in subsection (f)(3) of this section to implement and operate the electronic system established under subsection (e)(4) of this section for covered outpatient drugs.


adjusted by economic index data) equals or exceeds the prevailing charge level for the previous 12-month period exceeding the limiting charge.


2. Pub. L. 100–203, § 4046(a)(1)(A), redesignated former subpar. (C) as (D).

3. Subsec. (b)(11). Pub. L. 100–203, § 4045(c)(2)(B), added subpar. (A), struck out former cl. (i) designation before “In the case of” and substituted “the physician’s actual charge is subject to a limit under subsection (j)(1)(D) of this section.” for “(subject to clause (iv), the physician may not charge the individual more than the limiting charge (as defined in clause (ii)) plus (for services furnished during the 12-month period beginning on the effective date of the reduction) 1/3 of the amount by which the physician’s actual charges for the service for the previous 12-month period exceeds the limiting charge.”, and struck out former cls. (i) to (iv) which read as follows:

4. Subsec. (b)(14). Pub. L. 100–203, § 4046(a)(1)(A), (B), redesignated former subpar. (C) as (D) and substituted “paragraph (B) or (C)” for “paragraph (B)”.
Subsec. (i), Pub. L. 100–203, §4042(b)(1)(B), as added by Pub. L. 100–360, §411(f)(2)(C), transferred introductory provisions and par. (1) from former subsec. (h)(8).


(1)(B)]. Pub. L. 100–203, §4054(a)(1), (2), formerly §4053(a)(1), (2), as renumbered by Pub. L. 100–360, §411(f)(14), substituted the “actual charges of each such physician” for “such each physician’s actual charges” and “on a repeated basis for such a service an actual” for “for such a service a physician’s actual charges”.

(1)(C). Pub. L. 100–203, §4085(1)(7)(A), inserted “maximum allowable” after “If the physician’s”.

(1)(D). Pub. L. 100–203, §4042(c)(2), as added by Pub. L. 100–360, §411(f)(2)(F)(i), substituted “applicable percent” (as defined in subsection (b)(4)(A)(iv) of this section) of the prevailing charge for the year and service involved” for “prevailing charge for the year involved for such service furnished by nonparticipating physicians” in subcls. (I) and (II).


Pub. L. 99–272, §9301(d)(1)(B), (C), substituted “June 30 preceding the start of the calendar year” for “March 31 last preceding the start of the twelve-month period (beginning October 1 of each year)” in third sentence, and struck out “the twelve-month period beginning on October 1 in” before “any calendar year after 1974” in eighth sentence.

Subsec. (b)(3)(C). Pub. L. 99–509, §9341(a)(2), substituted “at least $100, but not more than $500” for “$100 or more”.


Subsec. (b)(4)(A)(II). Pub. L. 99–509, §9331(a)(1), added cl. (III) and struck out former cl. (II) which read as follows: “In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians’ services furnished during a 12-month period beginning on or after January 1, 1987, by a physician who is not a participating physician (as defined in subsection (b)(1) of this section) at the time of furnishing the services, the Secretary shall not set any level higher than the same level as was set for services furnished during the previous calendar year (without regard to clause (i)(II) for physicians who were participating physicians during that year.)”


Pub. L. 99–514, §1895(b)(14)(A), as amended by Pub. L. 99–509, §9307(c)(2)(A), struck out cl. (i) designation, and struck out cl. (ii) which read as follows: “In determining the prevailing charge levels under the third and fourth sentences of paragraph (3) for physicians’ services furnished during the periods beginning after December 31, 1986, by a physician who was not a participating physician on that date, the Secretary shall treat the level as set under subparagraph (A)(ii) as having been taken into account but for the limitations contained in subparagraph (A)(iii).”

Subsec. (b)(4)(D)(i) to (iii). Pub. L. 99–272, § 9301(b)(1)(D), designated existing provisions as cl. (i), substituted “In determining the customary charges for physicians’ services furnished during the 8-month period beginning May 1, 1986, or the 12-month period beginning January 1, 1987, by a physician who was not a participating physician (as defined in subsection (h)(1) of this section) on September 30, 1985” for “In determining the customary charges for physicians’ services furnished during the 12-month period beginning October 1, 1985, or October 1, 1986, by a physician who at no time for any services furnished during the 12-month period beginning October 1, 1984, was a participating physician (as defined in subsection (h)(1) of this section)”, and added cls. (ii) and (iii).


Subsec. (b)(6). Pub. L. 99–272, § 9303(c)(1)(A), redesignated existing provisions as subpar. (A), redesignated former subpars. (A) and (B) as cls. (i) and (ii), respectively, and added subpars. (B) and (C).


Former pars. (9) redesignated (11).

Pub. L. 99–272, § 9306(a), added part. (9).

Subsec. (b)(11). Pub. L. 99–272, § 9303(b)(3)(A), redesignated existing provisions as subpar. (A), redesignated former subpars. (A) and (B) as cls. (i) and (ii), respectively, and added subpars. (B) and (C).

Pub. L. 99–272, § 9303(b), redesignated former par. (9) as (11).


Subsec. (c). Pub. L. 99–272, § 9301(c)(1), designated existing provisions as par. (1) and added par. (2).

Subsec. (h)(1). Pub. L. 99–272, § 9301(d)(2), substituted “before the beginning of any year beginning with 1981” for “before October 1 of any year beginning with 1984”, “on an assignment-related basis” for “on the basis of an assignment described in subsection (b)(3)(B)(i) of this section, in accordance with subsection (b)(6)(B) of this section, or under the procedure described in section 1395gg(f)(1) of this title”, “during such year” for “during the 12-month period beginning on October 1 of such year”, “after the beginning of a year” for “after October 1 of a year”, and “during the remainder of the year” for “during the remainder of the 12-month period beginning on such October 1”.

Subsec. (h)(2). Pub. L. 99–272, § 9302(b)(1)(A), struck out period at end and substituted “and may request a copy of an appropriate directory published under paragraph (4). Each such carrier shall, without charge, mail a copy of such directory upon such a request.”

Subsec. (h)(4). Pub. L. 99–272, § 9302(b)(2), inserted at end “Each participating physician directory for an area shall provide an alphabetical listing of all participating physicians practicing in the area and an alphabetical listing by locality and specialty of such physicians.”

Pub. L. 99–272, § 9301(c)(3)(D), redesignated par. (2) of subsec. (i) as par. (6) of this subsection.

Subsec. (i)(5). Pub. L. 99–272, § 9302(b)(1)(B), substituted “the participation program under this subsection and the publication and availability of the directories” for “publication of the directories” and inserted at end “The Secretary shall include such notice in the mailing of appropriate benefit checks provided under subsection II of this chapter.”

Pub. L. 99–272, § 9306(b)(15)(A), struck out “such” before “the directories” and before “the appropriate area directory”.

Pub. L. 99–272, § 9301(c)(3)(D), redesignated par. (3) of subsec. (1) as par. (5) of this subsection.

Subsec. (h)(6). Pub. L. 99–272, § 9302(b)(1)(C), inserted before period at end of second sentence “and that an appropriate number of copies of each such directory is sent to hospitals located in the area” and inserted at end “Such copies shall be sent free of charge.”

Pub. L. 99–514, § 1895(b)(15)(B), substituted “the” for “the the” before “directories”.

Pub. L. 99–272, § 9301(c)(3)(D), redesignated par. (4) of subsec. (1) as par. (6) of this subsection.

Subsec. (h)(7), (8). Pub. L. 99–272, § 9301(c)(4), added pars. (7) and (8).

Subsec. (i)(1). Pub. L. 99–272, § 9301(c)(3)(A), struck out par. (1) which required the Secretary to publish a list containing the name, address, specialty, and percent of claims submitted with respect to each physician and supplier during preceding year that were paid on the basis of an assignment described in subsec. (b)(3)(B)(ii) of this section, in accordance with subsec. (b)(6)(B) of this section, or under procedure described in section 1395gg(f)(1) of this title.

Subsec. (i)(2). Pub. L. 99–272, § 9301(c)(3)(D), redesignated par. (2) of this subsection as par. (4) of subsec. (h).


Pub. L. 99–272, § 9301(c)(2)(A), (B), (3), substituted “shall publish directories (for appropriate local geographic areas)” for “shall publish a directory”, inserted “for that area” before “for that fiscal year”, substituted “Each directory shall” for “The directory shall”, and substituted “paragraph (1)” for “subsection (b)(1) of this section”.


Pub. L. 99–272, § 9301(c)(2)(C), (3)(C), struck out “directory” first place it appeared and inserted in lieu “the directories”, struck out “directory” second place it appeared and inserted in lieu “the appropriate area directory or directories”, and struck out “list and” wherever appearing.


Pub. L. 99–272, § 9301(c)(2)(D), (3)(C), struck out “list and” after “The Secretary shall provide that the in first sentence, substituted “the directories shall” for “directory shall”, and inserted provision requiring the Secretary to provide that each appropriate area directory be sent to each participating physician located in that area.

Subsec. (j)(1). Pub. L. 99–514, § 1895(b)(16)(A), inserted “presents or causes to be presented a claim or” in pars. (1) and (2).

Subsec. (c). Pub. L. 98–369, §2336(d)(2), inserted proviso that the Secretary, in determining a carrier’s necessary and proper cost of administration with respect to each contract, take into account the amount that is reasonable and adequate to meet the costs which must be incurred by an efficiently and economically operated carrier in carrying out the terms of its contract.
Subsecs. (i) and (j). Pub. L. 98–369, §2306(c), added subsecs. (i) and (j).
Subsec. (b)(3). Pub. L. 97–248, §194(a), in provisions following subpar. (F), inserted provisions that in determining the reasonable charge for outpatient services, the Secretary may limit such reasonable charge to a percentage of the amount of the prevailing charge for similar services furnished in a physician’s office, taking into account the extent to which overhead costs associated with such outpatient services have been included in the reasonable cost or charge of the facility.
Subsec. (b)(5)(D). Pub. L. 97–248, §113(a), added subpar. (D). Pub. L. 98–369, §2306(a), added par. (5) and redesignated former pars. (4) and (5) as (4) and (5), respectively.
Subsec. (b)(7). Pub. L. 98–369, §2306(a), redesignated par. (6) as (7).
Subsec. (b)(7)(A). Pub. L. 98–617, §3(b)(5)(B), struck out at end “If all the teaching physicians in a hospital agree to have payment made for all of their physicians’ services to the extent that the payments are based on a reasonable charge basis, the Secretary may be considered reasonable.”
Subsec. (b)(7)(B). Pub. L. 98–617, §3(a)(1), inserted “If all the teaching physicians in a hospital agree to have payment made for all of their physicians’ services to the extent that the payments are based on a reasonable charge basis, the Secretary may be considered reasonable.”
1981—Subsec. (b)(3). Pub. L. 97–35 inserted provision that the amount of any charges for outpatient services which shall be considered reasonable shall be subject to the limitations established by regulations issued by the Secretary pursuant to section 1395x(v)(1)(K) of this title.
1980—Subsec. (b)(3). Pub. L. 96–499, §546(a), in provisions following subpar. (F), substituted “service is rendered” for “bill is submitted or the request for payment is made”.
1977—Subsec. (b)(3). Pub. L. 95–216 provided that, with respect to power-operated wheelchairs for which payment may be made in accordance with section 1395k(a)(6) of this title, charges determined to be reasonable may not exceed the lowest charge at which power-operated wheelchairs are available in the locality.
Subsec. (b)(5). Pub. L. 95–142 inserted provisions relating to payments under a reassignment or power of attorney in cases other than direct payments to physicians or service providers.
1976—Subsec. (b)(3). Pub. L. 94–368 substituted “for the twelve-month period beginning on July 1 in any calendar year after 1974” for “for the fiscal year beginning July 1, 1975,” “prior to the start of the twelve-month period (beginning July 1, of each year) in which the bill is submitted or the request for payment is made” for “prior to the start of the fiscal year in which the bill is submitted or the request for payment is made”; and “for any twelve-month period (beginning after June 30, 1973) specified in clause (ii) of such sentence” for “for any fiscal year beginning after June 30, 1973.”
1972—Subsec. (a). Pub. L. 92–603, §227(e)(3), substituted which involve payments for physicians’ services on a reasonable charge basis for “which involve payments for physicians’ services”.
Subsec. (b)(3). Pub. L. 92–603, §§244(a), 258(a), inserted provisions relating to determination of reasonableness of physician charges, medical equipment and supplies, and for the extension of time for filing claims for supplementary medical insurance benefits
where the delay is due to administrative error, at end thereof.

Subsec. (b)(3)(B)(i). Pub. L. 92–603, §§211(c)(3), 281(d), 293, inserted a new subsection (b)(3), designated existing provisions as subcl. (i), added subcl. II, inserted exception in the case of services furnished as described in section 1395y(a)(4) of this title, other than for purposes of section 1395gg(f) of this title.

Subsec. (b)(3)(C). Pub. L. 102–460, §362(a), inserted provisions setting a $100 minimum amount on claims to establish entitlement to a hearing.


1968—Subsec. (b)(3)(B). Pub. L. 90–248 provided that payment be made on the basis of an itemized bill instead of a receipted bill as formerly required, and inserted "(except as otherwise provided in section 1395gg(f) of this title)" after "payment will".

CHANGE OF NAME

EFFECTIVE DATE OF 2010 AMENDMENT

Amendment by section 109–171, title V, §5114(c), Feb. 8, 2006, 120 Stat. 45, provided that: "The amendments made by this section [amending this section and section 1395ff of this title] shall apply to services furnished on or after Jan. 1, 2006."

Amendment by section 5202(a)(2) of Pub. L. 109–171 applicable to claims submitted on or after Jan. 1, 2006, see section 5202(b) of Pub. L. 109–171, set out as a note under section 1395f of this title.

EFFECTIVE DATE OF 2003 AMENDMENT
Amendment by section 627(b)(2) of Pub. L. 108–173 applicable to items furnished on or after Jan. 1, 2005, see section 627(c) of Pub. L. 108–173, set out as a note under section 1395f of this title.

Amendment by section 911(c) of Pub. L. 108–173 effective Oct. 1, 2005, except as otherwise provided, with transition rules authorizing Secretary of Health and Human Services to continue to enter into contracts under this section prior to such date, and provisions authorizing continuation of Medicare Integrity Program functions during the period that begins on Dec. 8, 2003, and ends on Oct. 1, 2011, see section 911(d) of Pub. L. 108–173, set out as an Effective Date; Transition Rule note under section 1395f of this title.

Pub. L. 108–173, title IX, §952(c), Dec. 8, 2003, 117 Stat. 2427, provided that: "The amendments made by this section [amending this section] shall apply to payments made on or after the date of the enactment of this Act [Dec. 8, 2003]."

EFFECTIVE DATE OF 2000 AMENDMENT
Amendment by section 1(a)(6) of Pub. L. 106–554 applicable to services furnished on or after Jan. 1, 2002, see section 1(a)(6) of Pub. L. 106–554, set out as a note under section 1395f of this title.

Pub. L. 106–554, §1(a)(6) [title I, §105(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–474, provided that: "The amendment made by subsection (a) [amending this section] shall apply to items furnished on or after Jan. 1, 2001."

Pub. L. 106–554, §1(a)(6) [title II, §222(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–487, provided that: "The amendments made by subsections (a) and (b) [amending this section and section 1395f of this title] shall apply to services furnished on or after Jan. 1, 2001."

Pub. L. 106–554, §1(a)(6) [title IV, §482(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–526, provided that: "The amendments made by this section [amending this section and sections 1395f and 1395q of this title] shall apply to services furnished on or after July 1, 2001."

EFFECTIVE DATE OF 1999 AMENDMENT
Pub. L. 106–113, div. B, §1000(a)(6) [title III, §305(e)], Nov. 29, 1999, 113 Stat. 1536, 1501A–362, provided that: "The amendments made by this section [amending this section and section 1395f of this title] shall apply to payments for services provided on or after the date of enactment of this Act [Nov. 29, 1999]."


EFFECTIVE DATE OF 1997 AMENDMENT
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.


Section 4302(c) of Pub. L. 105–33 provided that: "The amendments made by this section (amending this section and section 1395c of this title) shall take effect on the date of the enactment of this Act [Aug. 5, 1997] and apply to the entry and renewal of contracts on or after such date.

Amendment by section 4315(a) of Pub. L. 105–33, to the extent such amendment substitutes fee schedules for reasonable charges, applicable to particular services as of such date, to be considered to have begun as of such date, see section 4315(c) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Amendment by section 4316(a) of Pub. L. 105–33 effective Aug. 5, 1997, see section 4316(c) of Pub. L. 105–33, set out as a note under section 1395m of this title.

Section 4317(c) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section] shall apply to items and services furnished on or after January 1, 1998."

Amendment by section 4420(b)(2), (4) of Pub. L. 106–33 applicable to items and services furnished on or after July 1, 1998, see section 4420(d) of Pub. L. 105–33, set out as a note under section 1395l–3 of this title.

Amendment by section 4512(b)(2), (c) of Pub. L. 105–33 applicable with respect to services furnished and supplies provided on and after Jan. 1, 1998, see section 4512(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Amendment by section 4566(a) of Pub. L. 105–33 applicable to drugs and biologicals furnished on or after Jan. 1, 1998, see section 4566(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Amendment by section 4603(c)(2)(B)(i) of Pub. L. 105–33 applicable to cost reporting periods beginning on or after Oct. 1, 1998, except as otherwise provided, see section 4603(d) of Pub. L. 105–33, set out as an Effective Date note under section 1395fff of this title.

Amendment by section 4611(d) of Pub. L. 105–33 applicable to services furnished on or after Jan. 1, 1998, and for purposes of applying such amendment, any home health spell of illness that began, but did not end, before such date, to be considered to have begun as of such date, see section 4611(f) of Pub. L. 105–33, set out as a note under section 1395sk of this title.

**Effective Date of 1994 Amendment**


Amendment by section 13568(a), (b) of Pub. L. 103–66 applicable to claims received on or after Oct. 1, 1993, see section 13568(c) of Pub. L. 103–66, set out as a note under section 1395h of this title.

**Effective Date of 1995 Amendment**

Section 13515(d) of Pub. L. 103–66 provided that: "The amendments made by subsection (a) [amending this section and section 1395k–4 of this title] shall apply to services furnished on or after January 1, 1994."

Amendment by section 13568(a), (b) of Pub. L. 103–66 applicable to claims received on or after Oct. 1, 1993, see section 13568(c) of Pub. L. 103–66, set out as a note under section 1395h of this title.

**Effective Date of 1990 Amendment**


Section 4106(d) of Pub. L. 101–508 provided that:

(1) "(1) The amendments made by subsection (a) [amending this section and provisions set out below] apply to services furnished after 1990, except that—

(A) the provisions concerning the third and fourth years of practice apply only to physicians' services furnished after 1990 and 1991, respectively, and

(B) the provisions concerning the second, third, and fourth years of practice apply only to services of a health care practitioner furnished after 1991, 1992, and 1993, respectively.

(2) 'The amendments made by subsection (a) [amending this section and section 1395w–4 of this title] shall apply to services furnished after 1991."

Section 4106(b) of Pub. L. 101–508 provided that: "The amendment made by subsection (a) [amending this section] shall apply to tests and services furnished on or after January 1, 1991."

Section 4118(b) of Pub. L. 101–508 provided that: "The amendments made by paragraphs (1) and (2) [amending this section] apply to services furnished after March 1990."

Section 4118(b)(2)(A) of Pub. L. 101–508 provided that the amendment by that section is effective as if included in the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101–239.

Section 4118(b)(2)(B) of Pub. L. 101–508 provided that the amendment by that section is effective Jan. 1, 1991.

Amendment by section 4155(c) 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 1395sk of this title.

**Effective Date of 1989 Amendments**

Section 6102(c)(3) of Pub. L. 101–239 provided that the amendment made by that section is effective for physicians' services furnished on or after Jan. 1, 1992.

Section 6106(b) of Pub. L. 101–239 provided that: "The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after April 1, 1990."


(A) Subject to subparagraph (B), the amendments made by paragraph (1) [amending this section] apply to services furnished in 1990 or 1991 which were subject to the first sentence of section 1842(b)(4)(F) of the Social Security Act (subsec. (b)(4)(F) of this section) in 1989 or 1990.

"(B) The amendments made by paragraph (1) shall not apply to services furnished in 1990 before April 1,
1990. With respect to physicians' services furnished during 1990 on and after April 1, such amendments shall be applied as though any reference, in the matter inserted by such amendments, to the 'first calendar year during which the preceding sentence no longer applies' were deemed a reference to the remainder of 1990.'

Section 6101(b)(3) of Pub. L. 101–239 provided that: amendment made by subsection (a) of this section] apply to procedures performed after March 31, 1990.'

Section 611(f) of Pub. L. 101–239 provided that: 'The amendments made by this section [amending this section and section 1395x of this title] shall apply to services furnished on or after April 1, 1990.'

Amendment by section 6202(d)(2) of Pub. L. 101–239 applicable to agreements and contracts entered into or renewed on or after Dec. 19, 1989, see section 6202(d)(3) of Pub. L. 101–239, set out as a note under section 1395h 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 1393a–7a of this title.

Section 301(e) of Pub. L. 101–234 provided that: 'The provisions of this section [amending this section and sections 1395m, 1395cc, 1395f, and 1395ww of this title, enacting provisions set out as notes under section 1395m of this title, and repealing provisions set out as notes under sections 1395b, 1395b–1, 1395b–2, and 1395h of this title and section 8902 of Title 5, Government Organization and Employee] (other than subsections (c) and (d) [amending this section and sections 1395m, 1395cc, 1395f, and 1395ww of this title and enacting provisions set out as a note under section 1395m of this title]) shall take effect January 1, 1990, except that—

'[1] the repeal of section 421 of MCCA [Pub. L. 100–360, set out as a note under section 104 of Title 1, General Provisions.]

'[2] the amendments made by subsection (b) [amending this section and sections 1395m, 1395cc, 1395f, and 1395ww of this title] shall take effect on the date of the enactment of this Act [Dec. 13, 1989.]

**Effective Date of 1988 Amendments**


Section 202(m) of Pub. L. 100–360, as amended by Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 181, provided that:

'[1] (Repealed. Prior to repeal by Pub. L. 101–234, par. 1 as read as follows: 'CARRIERS.—The amendments made by subsection (e) [amending this section] shall take effect on January 1, 1990, but shall not be construed as requiring payment before February 1, 1991.')

'[2] (Repealed. Prior to repeal by Pub. L. 101–234, par. 2 as read as follows: 'TRUST FUND.—The amendment made by subsection (e) [amending this section] shall take effect on January 1, 1990, but shall not be construed as requiring payment before February 1, 1991.')

'[3] (Repealed. Prior to repeal by Pub. L. 101–234, par. 3 as read as follows: 'ENROLLMENTS.—The amendment made by subsection (f) [amending section 1395mm of this title] shall apply to enrollments effected on or after January 1, 1990.)

'[4] (Repealed. Prior to repeal by Pub. L. 101–234, par. 4 as read as follows: 'THE AMENDMENT.—The amendment made by subsection (g) [amending this section] shall apply to services furnished after March 31, 1989.

'[5] (Repealed. Prior to repeal by Pub. L. 101–234, par. 5 as read as follows: 'ADMINISTRATION.—With respect to administrative expenses (and costs of the Prescription Drug Payment Review Commission) for periods before January 1, 1990, amounts otherwise payable from the Federal Catastrophic Drug Insurance Trust Fund shall be payable from the Federal Supplementary Medical Insurance Trust Fund and shall also be treated as a debit to the Medicare Catastrophic Coverage Account.')

[Amendment of section 202(m) of Pub. L. 100–360, set out above, effective Jan. 1, 1990, see section 201(c) of Pub. L. 101–234, set out as an Effective Date of 1989 Amendment note under section 1320a–7a of this title.]

Section 223(d)(2), (3) of Pub. L. 100–360 provided that: 'The amendments made by subsection (c) [amending this section] shall first apply to explanations of benefits provided for items and services furnished on or after January 1, 1989.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(a)(3)(A), (C)(i), (f)(1)(A), (B), (2)–(4)(C), (5), (6)(B), (7), (9), (11)(A), (14), (g)(2)(A)–(C), (i)(1)(A), (2), (4)(C)(vi), and (j)(4)(A) 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 as amended by Pub. L. 100–203 effective Dec. 22, 1987, and applicable to budgets for fiscal years beginning with fiscal year 1989, see section 4035(a)(3) of Pub. L. 100–203, set out as a note under section 1395h of this title.

Section 404(b) of Pub. L. 100–203 provided that: 'The amendments made by subsection (a) [amending this section] shall apply to payment for physicians' services furnished on or after January 1, 1989.

Section 404(d) of Pub. L. 100–203 provided that: 'The amendments made by this section [amending this section and sections 1385i and 1395w–1 of this title and amending provisions set out below] shall apply to items and services furnished on or after April 1, 1988, except the amendment made by subsection (c)(2)(B) [amending this section] shall apply to services furnished on or after January 1, 1988.'

Section 404(b) of Pub. L. 100–203 provided that: 'The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after April 1, 1988.'

Section 404(b) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, § 411(f)(11)(B), July 1, 1988, 102 Stat. 779, provided that: 'The amendment made by subsection (a) [amending this section] shall apply to physicians who first furnish services to medicare beneficiaries on or after April 1, 1988.

Section 405(c) of Pub. L. 100–203 provided that: 'The amendment made by subsection (a) [amending this section] shall apply to diagnostic tests performed on or after April 1, 1988.

(2) The Secretary of Health and Human Services shall complete the review and make an appropriate adjustment of prevailing charge levels under subsection (b) [set out below] for items and services furnished no later than January 1, 1989.

(3) The amendments made by subsection (a) [amending this section] shall apply to items and services furnished on or after April 1, 1988, except the amendment made by subsection (c)(2)(B) [amending this section] shall apply to services furnished on or after January 1, 1988.

Section 405(b) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, § 411(f)(11)(B), July 1, 1988, 102 Stat. 779, provided that: 'The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1988.'

Section 405(b), formerly §405(b), of Pub. L. 100–203, as renumbered and amended by Pub. L. 100–360, title IV, §411(f)(11)(B), July 1, 1988, 102 Stat. 781, provided that: 'The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1988.'

Section 405(c), formerly §405(c), of Pub. L. 100–203, as renumbered and amended by Pub. L. 100–360, title IV, §411(f)(14), July 1, 1988, 102 Stat. 781, provided that: 'The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1988.'
shall apply to charges imposed for services furnished on or after April 1, 1986.

Amendment by section 4063(a) [amending this section] shall apply to contracts entered into or renewed on or after July 1, 1988, see section 4063(c) of Pub. L. 100–203, set out as a note under section 1395(f) of this title.

Section 4061(c)(1) of Pub. L. 100–203 provided that: "The amendments made by this subsection (a) [amending this section and enacting provisions set out as a note under this section] shall apply to contracts with carriers for claims for items and services furnished by participating physicians and suppliers on or after January 1, 1988." 

Section 4062(c)(3) of Pub. L. 100–203 provided that: "The amendments made by subsection (c) [amending this section] shall apply to carriers under contracts entered into or renewed on or after October 1, 1988.

Section 4085(a)(2) of Pub. L. 100–203 provided that: "The amendments made by this section [amending this section] shall apply to claims presented after the date of the enactment of this Act (Oct. 22, 1986)."

Amendment by section 1895(b)(14)(A), (15) of Pub. L. 99–514, title XVIII, §1895(b)(14)(B), Oct. 22, 1986, 100 Stat. 2634, provided that: "The amendments made by this subsection [amending this section and enacting provisions set out as a note under this section] shall apply to services furnished on or after May 1, 1986.

Amendment by section 9330(c) of Pub. L. 99–509 provided that: "The amendments made by this section [amending this section] shall apply to services furnished on or after January 1, 1987.

Amendment by section 9333(b), (c) of Pub. L. 99–509 applicable to services furnished on or after Jan. 1, 1987, see section 9333(c) of Pub. L. 99–509 set out as a note under section 1395x of this title.

Amendment by section 9341(a)(2) of Pub. L. 99–509 provided that: "The amendments made by this subsection [amending this section] shall apply to claims received on or after Nov. 1, 1985, with respect to services furnished on or after Jan. 1, 1986, see section 4096(d) of Pub. L. 100–203, set out as a note under section 1320c–3 of this title.

Amendment by Pub. L. 100–93 effective, except as otherwise provided, as if included in the enactment of Pub. L. 99–514, title XVIII, §1895(b)(14)(B), Oct. 22, 1986, 100 Stat. 2934, provided that: "Section 1895(b)(14)(A) of the Social Security Act [subsec. (h)(7) of this section], as added by this subsection, shall be effective as if it had been originally included in Public Law 98–611.

Amendment by section 9219(b)(2) of Pub. L. 99–272 provided that: "The amendments made by this subsection [amending this section and enacting provisions set out as a note under this section] shall apply to services furnished on or after April 1, 1986.

Amendment by section 9307(c) of Pub. L. 99–509 provided that: "The amendments made by this section [amending this section] shall apply to services furnished on or after November 1, 1985, with respect to items furnished on or after July 1, 1986, see section 4085(g)(2) of Pub. L. 100–203 provided that: "The amendments made by paragraph (1) [amending this section] shall apply to items and services furnished by participating physicians and suppliers on or after January 1, 1986, see section 4082(e)(3) of Pub. L. 100–203 provided that: "The amendments made by this section [amending this section] shall be effective as if included in section 9307(c) of the Consolidated Omnibus Budget Reconciliation Act of 1985 [Pub. L. 99–272].

Section 9319(b)(2) of Pub. L. 99–272 provided that: "The amendments made by paragraph (1) [amending this section] shall apply to items and services furnished on or after Jan. 1, 1987, see section 9319(b) of Pub. L. 99–272, set out as a note under section 1320c–3 of this title.
Section 2306(b)(2) of Pub. L. 98–369 provided that:

"The amendments made by paragraph (1) [amending this section] shall apply to items and services furnished on or after October 1, 1980."

Section 2307(a)(3) of Pub. L. 98–369 provided that:

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

Amendment by section 2326(d)(2) of Pub. L. 98–369 applicable to agreements and contracts entered into or renewed after Sept. 30, 1984, see section 2326(d)(3) of Pub. L. 98–369, set out as a note under section 1395f of this title.

Amendment by section 2354(b)(13), (14) 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(a)(1) of Pub. L. 98–369, set out as a note under section 1320a–1 of this title.

Amendment by section 2663(j)(2)(F)(iv) 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 2663(b)(b) of Pub. L. 98–369, set out as a note under section 401 of this title.

**Effective Date of 1982 Amendment**

Section 104(b) of Pub. L. 97–248, as amended by Pub. L. 97–448, title III, § 303(a)(2), Jan. 12, 1983, 96 Stat. 2408, provided that: "The amendments made by section 1395s of this title [amending this section and provisions set out as a note under section 401 of this title] shall become effective with respect to periods beginning after June 30, 1976, and before July 1, 1977, with a carrier designated pursuant to section 1842 of such Act [this section], and processed by such carrier after the appropriate changes were made pursuant to such section 3 in the prevailing charge levels for such twelve-month period beginning under the third and fourth sentences of section 1842(b)(3) of the Social Security Act [subsec. (b)(3) of this section]."

**Effective Date of 1974 Amendment**


**Effective Date of 1972 Amendment**

Amendment by section 211(c)(3) 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 262(b) of Pub. L. 92–603 provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to bills submitted and requests for payment made after the date of the enactment of this Act [Oct. 30, 1972]."

Section 4022(c)(2), (3) of Pub. L. 105–33, set out as a note under section 1395gg of this title.

Amendment by section 113(b)(1) of Pub. L. 97–248 provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to services performed on or after October 1, 1982."


**Effective Date of 1980 Amendment**

Section 918(a)(2) of Pub. L. 96–499 provided that: "The amendment made by paragraph (1) [amending this section] shall apply to bills submitted and requests for payment made on or after such date (not later than April 1, 1981) as the Secretary of Health and Human Services prescribes by a notice published in the Federal Register."

Section 946(c) of Pub. L. 96–499 provided that: "The amendments made by subsections (a) and (b) [amending this section] shall become effective with respect to bills submitted or requests for payment made on or after July 1, 1981."

Section 946(c)(2) of Pub. L. 96–499 provided that: "The amendment made by subsection (b) [amending this section] shall apply with respect to cost accounting periods beginning on or after January 1, 1981."

**Effective Date of 1977 Amendments**

Amendment by Pub. L. 95–216 effective in the case of items and services furnished after Dec. 30, 1977, see section 501(c) of Pub. L. 95–216, set out as a note under section 1395x of this title.

Amendment by Pub. L. 95–142 applicable with respect to care and services furnished on or after Oct. 25, 1977, see section 2(a)(4) of Pub. L. 95–142, set out as a note under section 1395f of this title.

**Effective Date of 1976 Amendment**

Section 4 of Pub. L. 94–368 provided that: "The amendments made by sections 2 and 3 of this Act [amending this section and provisions set out as a note under section 390e of Title 7, Agriculture] shall be effective with respect to periods beginning after June 30, 1976, except that, for the twelve-month period beginning July 1, 1976, the amendments made by section 3 [amending this section and provisions set out as a note under section 390e of Title 7, Agriculture] shall be applicable with respect to claims filed under part B of title XVIII of the Social Security Act [this part] (after June 30, 1976, and before July 1, 1977) with a carrier designated pursuant to section 1842 of such Act [this section], and processed by such carrier after the appropriate changes were made pursuant to such section 3 in the prevailing charge levels for such twelve-month period beginning under the third and fourth sentences of section 1842(b)(3) of the Social Security Act [subsec. (b)(3) of this section]."

**Effective Date of 1974 Amendment**


**Effective Date of 1972 Amendment**

Section 4 of Pub. L. 94–368 provided that: "The amendments made by sections 2 and 3 of this Act [amending this section and provisions set out as a note under section 390e of Title 7, Agriculture] shall be applicable with respect to periods beginning after June 30, 1976, and before July 1, 1977, with a carrier designated pursuant to section 1842 of such Act [this section], and processed by such carrier after the appropriate changes were made pursuant to such section 3 in the prevailing charge levels for such twelve-month period beginning under the third and fourth sentences of section 1842(b)(3) of the Social Security Act [subsec. (b)(3) of this section]."

**Effective Date of 1974 Amendment**


**Effective Date of 1972 Amendment**

Amendment by section 211(c)(3) 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 262(b) of Pub. L. 92–603 provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to bills submitted and requests for payment made after March 1968.

Section 263(b) of Pub. L. 92–603 provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to hearings requested (under the procedures established under section 1822(b)(3)(C) of the Social Security Act [subsec. (b)(3)(C) of this section]) after the date of the enactment of this Act [Oct. 30, 1972]."

Amendment by section 263(d)(5) of Pub. L. 92–603 with respect to collection of premiums applicable to premiums becoming due and payable after the fourth month following the month of enactment of Pub. L. 92–603 which was approved on Oct. 30, 1972, see section 263(3) of Pub. L. 92–603, set out as a note under section 1395s of this title.

Amendment by section 264(d) of Pub. L. 92–603 to apply in the case of notices sent to individuals after Oct. 30, 1972, see section 261(g) of Pub. L. 92–603, set out as a note under section 1395gg of this title.

**Effective Date of 1968 Amendment**

Section 129(b) of Pub. L. 90–248 provided that: "The amendments made by subsection (a) [amending this section] shall apply with respect to claims on which a final determination has not been made on or before the date of enactment of this Act [Jan. 2, 1968]."

**Transfer of Functions**

Physician Payment Review Commission (PPRC) was terminated and its assets and staff transferred to the Medicare Payment Advisory Commission (MedPAC) by section 462(c)(2), (3) of Pub. L. 105–33, set out as a note under section 1860h–6 of this title. Section 462(c)(2), (3) further provided that MedPAC was to be responsible for preparation and submission of reports required by law to be submitted by PPRC, and that, for that purpose, any reference in law to PPRC was to be deemed, after the appointment of MedPAC, to refer to MedPAC.

**Linkage of Revised Drug Payments and Increases for Drug Administration**

Human Services] shall not implement the revisions in payment amounts for drugs and biologicals administered by physicians as a result of the amendments made by subsection (b) [amending this section] with respect to 2004 unless the Secretary concurrently makes adjustments to the practice expense payment adjustment under the amendments made by subsection (a) [amending section 1395w-4 of this title]."

CONTINUATION OF PAYMENT METHODOLOGY FOR RADIOPHARMACEUTICALS
Pub. L. 108–173, title III, § 303(h), Dec. 8, 2003, 117 Stat. 2253, provided that: ‘‘Nothing in the amendments made by this section [enacting sections 1395w–3a and 1395w–3b of this title, amending this section and sections 1395l, 1395w–4, 1395x, 1396c, and 1396c–8 of this title, and repealing provisions set out as a note under this section] shall be construed as changing the payment methodology under part B of title XVIII of the Social Security Act [this part] for radiopharmaceuticals, including the use by carriers of invoice pricing methodology.’’

IMPLEMENTATION OF 2003 AMENDMENT
Pub. L. 108–173, title III, § 303(i)(5), Dec. 8, 2003, 117 Stat. 2255, provided that: ‘‘The provisions of chapter 8 of title 5, United States Code, shall not apply with respect to regulations implementing the amendments made by subsection (a), (b), and (e)(3) [sic] [amending this section and section 1395w–4 of this title], to regulations implementing section 304 [set out as a note under this subsection], and to regulations implementing the amendment made by section 305(a) [amending this section], insofar as such regulations apply in 2004.’’

APPLICATION OF 2003 AMENDMENT TO PHYSICIAN SPECIALTIES
Pub. L. 108–173, title III, § 303(j), Dec. 8, 2003, 117 Stat. 2255, provided that: ‘‘Insofar as the amendments made by this section [enacting sections 1395w–3a and 1395w–3b of this title, amending this section and sections 1395l, 1395w–4, 1395x, 1396c, and 1396c–8 of this title, and repealing provisions set out as a note under this section] apply to payments for drugs or biologicals and drug administration services furnished by physicians, such amendments shall only apply to physicians in the specialties of hematology, hematology/oncology, and medical oncology under title XVIII of the Social Security Act [this subchapter].’’

Pub. L. 108–173, title III, § 304, Dec. 8, 2003, 117 Stat. 2255, provided that: ‘‘Notwithstanding section 303(j) [set out above], the amendments made by section 303 [enacting sections 1395w–3a and 1395w–3b of this title, amending this section and sections 1395l, 1395w–4, 1395x, 1396c, and 1396c–8 of this title, and repealing provisions set out as a note under this section] shall also apply 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.’’

ISSUANCE OF TEMPORARY NATIONAL CODES

REvised PART B PAYMENT FOR DRUGS AND BIOLOGICAlS AND RELATED SERVICES
Pub. L. 106–554, § 1(a)(6) [title IV, ¶ 429], Dec. 21, 2000, 114 Stat. 2763, 2763A–522, provided that: ‘‘(a) RECOMMENDATIONS FOR REVISED PAYMENT METHODOLOGY FOR DRUGS AND BIOLOGICALS.—

‘‘(1) STUDY.—

‘‘(A) IN GENERAL.—The Comptroller General of the United States shall conduct a study on the reimbursement for drugs and biologicals under the current medicare payment methodology (provided under section 1842(o) of the Social Security Act (42 U.S.C. 1395u(o))) and for related services under part B of title XVIII of such Act (this part). In the study, the Comptroller General shall—

‘‘(i) identify the average prices at which such drugs and biologicals are acquired by physicians and other suppliers;

‘‘(ii) quantify the difference between such average prices and the reimbursement amount under such section; and

‘‘(iii) determine the extent to which (if any) payment under such part is adequate to compensate physicians, providers of services, or other suppliers of such drugs and biologicals for costs incurred in the administration, handling, or storage of such drugs or biologicals.

‘‘(B) CONSULTATION.—In conducting the study under subparagraph (A), the Comptroller General shall consult with physicians, providers of services, and suppliers of drugs and biologicals under the medicare program under title XVIII of such Act [this subchapter], as well as other organizations involved in the distribution of such drugs and biologicals to such physicians, providers of services, and suppliers.

‘‘(2) REPORT.—Not later than 9 months after the date of the enactment of this Act (Dec. 21, 2000), the Comptroller General shall submit to Congress and to the Secretary of Health and Human Services a report on the study conducted under this subsection, and shall include in such report recommendations for revised payment methodologies described in paragraph (3).

‘‘(3) RECOMMENDATIONS FOR REVISED PAYMENT METHODOLOGIES.—

‘‘(A) IN GENERAL.—The Comptroller General shall provide specific recommendations for revised payment methodologies for reimbursement for drugs and biologicals and for related services under the medicare program. The Comptroller General may include in the recommendations—

‘‘(i) proposals to make adjustments under subsection (c) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for the practice expense component of the physician fee schedule under such section for the costs incurred in the administration, handling, or storage of certain categories of such drugs and biologicals, if appropriate; and

‘‘(ii) proposals for new payments to providers of services or suppliers for such costs, if appropriate.

‘‘(B) ENSURING PATIENT ACCESS TO CARE.—In making recommendations under this paragraph, the Comptroller General shall ensure that any proposed revised payment methodology is designed to ensure that medicare beneficiaries continue to have appropriate access to health care services under the medicare program.

‘‘(C) MATTERS CONSIDERED.—In making recommendations under this paragraph, the Comptroller General shall consider—

‘‘(i) the method and amount of reimbursement for similar drugs and biologicals made by large group health plans;

‘‘(ii) as a result of any revised payment methodology, the potential for patients to receive inpatient or outpatient hospital services in lieu of services in a physician’s office; and

‘‘(iii) the effect of any revised payment methodology on the delivery of drug therapies by hospital outpatient departments.

‘‘(D) COORDINATION WITH BBRA STUDY.—In making recommendations under this paragraph, the Comptroller General shall conclude and take into account the results of the study provided for under section 213(a) of BBRA [Pub. L. 106–113, § 1000(a)(6) [title II, § 213(a)], set out as a note under section 1395 of this title] (119 Stat. 1583–350).

‘‘(b) IMPLEMENTATION OF NEW PAYMENT METHODOLOGY.—
"(1) IN GENERAL.—Notwithstanding any other provision of law, based on the recommendations contained in the report under subsection (a), the Secretary of Health and Human Services, subject to paragraph (2), shall revise the payment methodology under section 1842(o) of the Social Security Act (42 U.S.C. 1395u(o)) for drugs and biologicals furnished under part B of the medicare program [this part]. To the extent the Secretary determines appropriate, the Secretary may provide for the adjustments to payments amounts referred to in subsection (a)(3)(A)(i) or additional payments referred to in subsection (a)(3)(A)(ii).

"(2) LIMITATION.—In revising the payment methodology under paragraph (1), in no case may the estimated aggregate payments for drugs and biologicals under the revised system (including additional payments referred to in subsection (a)(3)(A)(i)) exceed the aggregate amount of payment for such drugs and biologicals that would have been made under the payment methodology in effect under such section 1842(o).

"(c) MORATORIUM ON DECREASES IN PAYMENT RATES.—Notwithstanding any other provision of law, effective for drugs and biologicals furnished on or after January 1, 2001, the Secretary may not directly or indirectly decrease the rates of reimbursement (in effect as of such date) for drugs and biologicals under the current medicare payment methodology (provided under section 1842(o) of the Social Security Act (42 U.S.C. 1395u(o))) until such time as the Secretary has reviewed the report submitted under subsection (a)(2).

IMPLEMENTATION OF INHERENT REASONABLENESS (IR) AUTHORITY


"(a) LIMITATION ON USE.—The Secretary of Health and Human Services may not use, or permit fiscal intermediaries or carriers to use, the inherent reasonableness authority provided under section 1842(b)(8) of the Social Security Act (42 U.S.C. 1395u(b)(8)) until after—

"(1) the Comptroller General of the United States releases a report pursuant to the request for such a report made on March 1, 1999, regarding the impact of the Secretary's, fiscal intermediaries', and carriers' use of such authority; and

"(2) the Secretary has published a notice of final rulemaking in the Federal Register that relates to such authority and that responds to such report and to comments received in response to the Secretary's interim final regulation relating to such authority that was published in the Federal Register on January 7, 1998.

"(b) REEVALUATION OF IR CRITERIA.—In promulgating the final regulation under subsection (a)(2), the Secretary shall—

"(1) reevaluate the appropriateness of the criteria included in such interim final regulation for identifying payments which are excessive or deficient; and

"(2) take appropriate steps to ensure the use of valid and reliable data when exercising such authority.

INITIAL BUDGET NEUTRALITY

Section 431(d) of Pub. L. 105–33 provided that: "The Secretary, in developing a fee schedule for particular services (under the amendments made by this section [amending this section and section 1385 of this title]), shall set amounts for the first year period to which the fee schedule applies at a level so that the total payments under title XVIII of the Social Security Act (42 U.S.C. 1390 et seq.) for those services for that year period shall be approximately equal to the estimated total payments if such fee schedule had not been implemented."

IMPROVEMENTS IN ADMINISTRATION OF LABORATORY TESTS

Section 455 of Pub. L. 105–33 provided that:

"(a) SELECTION OF REGIONAL CARRIERS.—

"(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the 'Secretary') shall—

"(A) divide the United States into no more than 5 regions, and

"(B) designate a single carrier for each such region, for the purpose of payment of claims under part B of title XVIII of the Social Security Act [this part] with respect to clinical diagnostic laboratory tests furnished on or after such date (not later than July 1, 1999) as the Secretary specifies.

"(2) DESIGNATION.—In designating such carriers, the Secretary shall consider, among other criteria—

"(A) a carrier's timeliness, quality, and experience in claims processing, and

"(B) a carrier's capacity to conduct electronic data interchange with laboratories and data matches with other carriers.

"(3) SINGLE DATA RESOURCE.—The Secretary shall select one of the designated carriers to serve as a central statistical resource for all claims information relating to such clinical diagnostic laboratory tests handled by all the designated carriers under such part.

"(4) ALLOCATION OF CLAIMS.—The allocation of claims for clinical diagnostic laboratory tests to particular designated carriers shall be based on whether a carrier serves the geographic area where the laboratory specimen was collected or other method specified by the Secretary.

"(5) SECRETARIAL EXCLUSION.—Paragraph (1) shall not apply with respect to clinical diagnostic laboratory tests furnished by physician office laboratories if the Secretary determines that such offices would be unduly burdened by the application of billing responsibilities with respect to more than one carrier.

"(b) ADOPTION OF NATIONAL POLICIES FOR CLINICAL LABORATORY TESTS.

"(1) IN GENERAL.—Not later than January 1, 1999, the Secretary shall first adopt, consistent with paragraph (2), national coverage and administrative policies for clinical diagnostic laboratory tests under part B of title XVIII of the Social Security Act [this part], using a negotiated rulemaking process under subchapter III of chapter 5 of title 5, United States Code.

"(2) CONSIDERATIONS IN DESIGN OF NATIONAL POLICIES.—The policies under paragraph (1) shall be designed to promote program integrity and national uniformity and simplify administrative requirements with respect to clinical diagnostic laboratory tests payable under such part in connection with the following:

"(A) Beneficiary information required to be submitted with each claim or order for laboratory tests.

"(B) The medical conditions for which a laboratory test is reasonable and necessary (within the meaning of section 1862(a)(1)(A) of the Social Security Act [section 1395y(a)(1)(A) of this title]).

"(C) The appropriate use of procedure codes in billing for a laboratory test, including the unbundling of laboratory services.

"(D) The medical documentation that is required by a medicare contractor at the time a claim is submitted for a laboratory test in accordance with section 1833(e) of the Social Security Act [section 1395(e) of this title].

"(E) Recordkeeping requirements in addition to any information required to be submitted with a claim, including physicians' obligations regarding such requirements.

"(F) Procedures for filing claims and for providing remittances by electronic media.

"(G) Limitation on frequency of coverage for the same tests performed on the same individual.

"(3) CHANGES IN LABORATORY POLICIES PENDING ADOPTION OF NATIONAL POLICY.—During the period that begins on the date of the enactment of this Act
[Aug. 5, 1997] and ends on the date the Secretary first implements national policies pursuant to regulations promulgated under this subsection, a carrier under such part may implement such national policies, the Secretary shall permit any carrier to develop and implement interim policies of the type described in paragraph (1), in accordance with guidelines established by the Secretary, in cases in which a uniform national policy has not been established under this subsection and there is a demonstrated need for a policy to respond to aberrant utilization or provision of unnecessary tests. Except as the Secretary specifically permits, no policy shall be implemented under this paragraph for a period of longer than 2 years.

(5) INTERIM NATIONAL POLICIES.—After the date the Secretary first designates regional carriers under subsection (a), the Secretary shall establish a process under which designated carriers can collectively develop and implement interim national policies of the type described in paragraph (1). No such policy shall be implemented under this paragraph for a period of longer than 2 years.

(6) BIENNIAL REVIEW PROCESS.—Not less often than once every 2 years, the Secretary shall solicit and review comments regarding changes in the national policies established under this subsection. As part of such biennial review process, the Secretary shall specifically review and consider whether to incorporate or supersede interim policies developed under paragraph (4) or (5). Based upon such review, the Secretary may provide for appropriate changes in the national policies previously adopted under this subsection.

(7) REQUIREMENT AND NOTICE.—The Secretary shall ensure that any policies adopted under paragraph (3), (4), or (5) shall apply to all laboratory claims payable under part B of title XVIII of the Social Security Act [this part], and shall provide for advance notice to interested parties and a 45-day period in which such parties may submit comments on the proposed change.

"(c) INCLUSION OF LABORATORY REPRESENTATIVE ON CARRIER ADVISORY COMMITTEES.—The Secretary shall direct that any advisory committee established by a carrier to advise such carrier with respect to coverage and administrative policies under part B of title XVIII of the Social Security Act [this part] shall include an individual to represent the independent clinical laboratories and such other laboratories as the Secretary deems appropriate. The Secretary shall consider recommendations from national and local organizations that represent independent clinical laboratories in such section.

WHOLESALE PRICE STUDY AND REPORT
Pub. L. 101–33, title IV, §4556(c), Aug. 5, 1997, 111 Stat. 463, which directed the Secretary of Health and Human Services to study the effect on the average wholesale price of drugs and biologicals of the amendments to this section by section 4556(a) of Pub. L. 101–33, and to report to Congress the result of such study not later than July 1, 1999, was repealed by Pub. L. 108–173, title III, §303(h), Dec. 8, 2003, 117 Stat. 2255.

BUDGET NEUTRALITY ADJUSTMENT
Section 1351(b) of Pub. L. 101–66 provided that: "Notwithstanding any other provision of law, the Secretary of Health and Human Services shall reduce the following values and amounts for 1994 (to be applied for that year and subsequent years) by such uniform percentage as the Secretary determines to be required to assure that the amendments made by subsection (a) (amending this section and section 1395w–4 of this title) will not result in expenditures under part B of title XVIII of the Social Security Act [this part] in 1994 that exceed the amount of such expenditures that would have been made if such amendments had not been made:

(1) The relative values established under section 1840(c) of such Act [sec. 1395w–4(c) of this title] for services other than anesthesia services and, in the case of anesthesia services, the conversion factor established under section 1848 of such Act for such services.

(2) The amounts determined under section 1842(b)(2)(A) of such Act.

(3) The prevailing charges or fee schedule amounts to be applied under such part for services of a health care practitioner (as defined in section 1842(b)(4)(F)(I)(I) of such Act [subsec. (b)(4)(F)(I)(I) of this section], as in effect before the date of the enactment of this Act [Aug. 10, 1993])."

PROCEDURE CODES

"(A) The codes for the procedures specified in clause (1) are as follows: Hospital inpatient medical services (HCPCS codes 90200 through 90292), consultations (HCPCS codes 90600 through 90661), other visits (HCPCS code 99069), emergency and urgent medical services (HCPCS codes 90750 through 90764), psychiatric services (HCPCS codes 90801 through 90962), emergency care facility services (HCPCS codes 99062 through 99065), and critical care services (HCPCS codes 99160 through 99174).

"(B) The codes for the procedures specified in clause (iii) are as follows: Partial mastectomy (HCPCS code 19160); tendon sheath injections and small joint arthrocentesis (HCPCS codes 20550, 20600, 20605, and 20610); femoral fracture and trochanteric fracture treatments (HCPCS codes 27230, 27232, 27234, 27238, 27240, 27242, 27246, and 27248); endotracheal intubation (HCPCS code 31500); thoracentesis (HCPCS code 32000); thoracotomy (HCPCS codes 32020, 32035, and 32065); aneurysm repair (HCPCS codes 35111); cystourethroscopy (HCPCS code 52340); transurethral fulguration and resection (HCPCS codes 52606 and 52620); tympanoplasty with mastoidectomy (HCPCS code 69645); and ophthalmoscopy (HCPCS codes 92250 and 92259)."

STUDY OF RELEASE OF PREPAYMENT MEDICAL REVIEW SCREEN PARAMETERS
Section 4111 of Pub. L. 101–368 directed Secretary of Health and Human Services to conduct a study of effect of release of medicare prepayment medical review screen parameters on physician billings for services to which the parameters apply, such study to be based upon the release of the screen parameters at a minimum of six carriers, with Secretary to report results of study to Congress not later than Oct. 1, 1992.

FREEZE IN CHARGES FOR PARENTERAL AND ENTERAL NUTRIENTS, SUPPLIES, AND EQUIPMENT
Section 13541 of Pub. L. 103–66 provided that: "In determining the amount of payment under part B of title XVIII of the Social Security Act [this part] with respect to parenteral and enteral nutrients, supplies, and equipment during 1994 and 1995, the charges determined to be reasonable with respect to such nutrients, supplies, and equipment were determined to be reasonable with respect to such nutrients, supplies, and equipment during 1981.

Section 4122 of Pub. L. 101–368 directed that: "In determining the amount of payment for such services of a health care practitioner (as defined in section 1842(b)(4)(F)(I)(I) of such Act [subsec. (b)(4)(F)(I)(I) of this section], as in effect before the date of the enactment of this Act [Aug. 10, 1993])."
PROHIBITION ON REGULATIONS CHANGING COVERAGE OF CONVENTIONAL EYEWEAR

Section 4153(b)(1) of Pub. L. 101–508 provides that:

“(A) Notwithstanding any other provision of law (except as provided in subparagraph (B)) the Secretary of Health and Human Services (referred to in this subsection as the ‘Secretary’) may not issue any regulation that changes the coverage of conventional eyewear furnished to individuals (enrolled under part B of title XVIII of the Social Security Act (this part)) following cataract surgery with insertion of an intraocular lens."

“(B) Paragraph (1) shall not apply to any regulation issued for the sole purpose of implementing the amendments made by paragraph (2).”

DIRECTORY OF UNIQUE PHYSICIAN IDENTIFIER NUMBERS

Section 4161(c) of Pub. L. 101–508, as amended by Pub. L. 103–432, title I, §147(c)(7)(B), Oct. 31, 1994, 108 Stat. 4432, provided that: “Not later than March 31, 1991, the Secretary of Health and Human Services shall publish, and shall periodically update, a directory of the unique physician identification numbers of all physicians providing services for which payment may be made under part B of title XVIII of the Social Security Act [this part], and shall include in such directory the names, provider numbers, and billing addresses (sic) of all listed physicians.”

TREATMENT OF CERTAIN EYE EXAMINATION VISITS AS PRIMARY CARE SERVICES

Section 6102(e)(10) of Pub. L. 101–230 provided that: “In applying section 1842(l)(4) of the Social Security Act [subsec. (l)(4) of this section] for services furnished on or after January 1, 1990, intermediate and comprehensive office visits for eye examinations and treatments (codes 92002 and 92004) shall be considered to be primary care services.”

DELAY IN UPDATE UNTIL APRIL 1, 1990, AND REDUCTION IN PERCENTAGE INCREASE IN MEDICARE ECONOMIC INDEX

Section 6107(a) of Pub. L. 101–230 provided that:

“(1) IN GENERAL.—Subject to the amendments made by this section [amending this section], any increase or adjustment in customary, prevailing, or reasonable charges, fee schedule amounts, maximum allowable actual charges, and other limits on actual charges with respect to physicians’ services and other items and services described in paragraph (2) under part B of title XVIII of the Social Security Act (this part) which would otherwise occur as of January 1, 1990, shall be delayed so as to occur as of April 1, 1990, and, notwithstanding any other provision of law, the amount of payment under such for such items and services which are furnished during the period beginning on January 1, 1990, and ending on March 31, 1990, shall be determined on the same basis as the amount of payment for such services furnished on December 31, 1989.

“(2) ITEMS AND SERVICES COVERED.—The items and services described in this paragraph are items and services (other than ambulance services and clinical diagnostic laboratory services) for which payment is made under part B of title XVIII of the Social Security Act on the basis of a reasonable charge or a fee schedule.

“(3) EXTENSION OF PARTICIPATION AGREEMENTS AND RELATED PROVISIONS.—Notwithstanding any other provision of law—

“(A) subject to the last sentence of this paragraph, each participation agreement in effect on December 31, 1989, under section 1842(h)(1) of the Social Security Act [subsec. (h)(1) of this section] shall remain in effect for the 3-month period beginning on January 1, 1990;

“(B) the effective period for such agreements under such section entered into for 1990 shall be the 9-month period beginning on April 1, 1990, and the Secretary of Health and Human Services shall provide an opportunity for participating physicians and suppliers to enroll as participating physicians and suppliers before April 1, 1990;

“(C) instead of publishing, under section 1842(h)(4) of the Social Security Act [subsec. (h)(4) of this section], at the beginning of 1990, directories of participating physicians and suppliers for 1990, the Secretary shall provide for such publication, at the beginning of the 9-month period beginning on April 1, 1990, of such directories of participating physicians and suppliers for such period and;

“(D) instead of providing to nonparticipating physicians under section 1842(b)(3)(G) of the Social Security Act [subsec. (b)(3)(G) of this section] at the beginning of 1990, a list of maximum allowable actual charges for 1990, the Secretary shall provide, at the beginning of the 9-month period beginning on April 1, 1990, such physicians such a list for such 9-month period.

An agreement with a participating physician or supplier described in subparagraph (A) in effect on December 31, 1989, under section 1842(h)(1) of the Social Security Act shall remain in effect for the period described in subparagraph (A) if the participating physician or supplier requests on or before December 31, 1989, that the agreement be terminated.”

STATE DEMONSTRATION PROJECTS ON APPLICATION OF LIMITATION ON VISITS PER MONTH PER RESIDENT ON AGGREGATE BASIS FOR A TEAM

Section 6114(e) of Pub. L. 101–239 provided that: “The Secretary of Health and Human Services shall provide for at least 1 demonstration project under which, in the application of section 1842(l)(2)(C) of the Social Security Act [subsec. (l)(2)(C) of this section] (as added by subsection (c)(2) of this section) in one or more States, the limitation on the number of visits per month per resident would be applied on an average basis over the aggregate total of residents receiving services from members of the team.”

APPLICATION OF DIFFERENT PERFORMANCE STANDARDS FOR ELECTRONIC SYSTEM FOR COVERED OUTPATIENT DRUGS


DELAY IN APPLICATION OF COORDINATION OF BENEFITS WITH PRIVATE HEALTH INSURANCE

Section 202(e)(4)(B) of Pub. L. 100–360, which provided that the provisions of section 1395u(h)(3) of this title not apply to covered outpatient drugs (other than drugs described in section 1395x(s)(2)(J) of this title as of July 1, 1988) dispensed before January 1, 1993, was repealed by Pub. L. 101–234, title II, §201(a), Dec. 13, 1989, 103 Stat. 1961.

EXTENSION OF PHYSICIAN PARTICIPATION AGREEMENTS AND RELATED PROVISIONS

Section 4041(a)(2) of Pub. L. 100–203 provided that: “Notwithstanding any other provision of law—

“(A) subject to the last sentence of this paragraph, each agreement with a participating physician in effect on December 31, 1987, under section 1842(h)(1) of the Social Security Act [subsec. (h)(1) of this section] shall remain in effect for the 3-month period beginning on January 1, 1988;

“(B) the effective period for such agreements under such section entered into for 1988 shall be the nine-month period beginning on April 1, 1988, and the Secretary shall provide an opportunity for physicians to enroll as participating physicians and suppliers prior to April 1, 1988;

“(C) instead of publishing, under section 1842(h)(4) of the Social Security Act [subsec. (h)(4) of this sec-
The Comptroller General shall report to Congress, by April 1, 1988, of such directories of participating physicians for such period; and

“(D) instead of providing to nonparticipating physicians, under section 1395b(3)(G) of the Social Security Act [subsec. (b)(3)(G) of this section] at the beginning of 1988, a list of maximum allowable actual charges for 1988, the Secretary shall provide, at the beginning of the 9-month period beginning on April 1, 1988, to such physicians such a list for such 9-month period.

An agreement with a participating physician in effect on December 31, 1987, under section 1842(b)(1) of the Social Security Act shall not remain in effect for the period described in subparagraph (A) if the participating physician requests on or before December 31, 1987, that the agreement be terminated.”

**Development of Uniform Relative Value Guide**

Section 4048(b) of Pub. L. 100–203, as amended by Pub. L. 101–508, title IV, § 4118(b)(1), Nov. 5, 1990, 104 Stat. 1388–70, provided that: “The Secretary of Health and Human Services, in consultation with groups representing physicians who furnish anesthesia services, shall establish by regulation a relative value guide for use in all carrier localities in making payment for physician anesthesia services furnished under part B of title XVIII of the Social Security Act [this part] on and after March 1, 1989. Such guide shall be designed so as to result in expenditures under such title [this subchapter] for such services in an amount that would not exceed the amount of such expenditures which would otherwise occur.”

Section 4118(b) of Pub. L. 100–508 provided that the amendment by that section to section 4048(b) of Pub. L. 100–203, set out above, is effective as if included in enactment of Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203.

**Study of Prevailing Charges for Anesthesia Services**

Section 4048(c) of Pub. L. 100–203, which required Secretary of Health and Human Services to study variations in conversion factors used by carriers under section 1395(b) of this title to determine prevailing charge for anesthesia services and to report results of study and make recommendations for appropriate adjustments in such factors not later than Jan. 1, 1989, was repealed by Pub. L. 101–508, title IV, § 4118(b)(2), Nov. 5, 1990, 104 Stat. 1388–70.

**Gao Studies**

Section 4048(d) of Pub. L. 100–203 provided that:

“(1) The Comptroller General shall conduct a study—

(A) to determine the average anesthesia times reported for medicare reimbursement purposes,

(B) to verify those times from patient medical records,

(C) to compare anesthesia times to average surgical times, and

(D) to determine whether the current payments for physician supervision of nurse anesthetists are excessive.

The Comptroller General shall report to Congress, by not later than January 1, 1989, on such study and in the report include recommendations regarding the appropriateness of the anesthesia times recognized by medicare for reimbursement purposes and recommendations regarding adjustments of payments for physician supervision of nurse anesthetists.

“(2) The Comptroller General shall conduct a study on the impact of the amendment made by subsection (a) [amending this section], and shall report to Congress on the results of such study by April 1, 1990.”

**Adjustment in Medicare Prevailing Charges**

Section 4051(b) of Pub. L. 100–203 provided that:

“(1) Review.—The Secretary of Health and Human Services shall review payment levels under part B of title XVIII of the Social Security Act [this part] for diagnostic tests (described in section 1840 of such Act) which are recognized by physicians, and billed by such physicians, in order to determine the reasonableness of payment amounts for such tests (and for associated professional services component of such tests). The Secretary may require physicians and suppliers to provide such information on the purchase or sale price (net of any discounts) for such tests as is necessary to complete the review and make the adjustments under this subsection. The Secretary shall also review the reasonableness of payment levels for comparable in-office diagnostic tests.

“(2) Establishment of Revised Payment Screens.—If, as a result of such review, the Secretary determines, after notice and opportunity for at least 60 days for public comment, that the current prevailing charge levels (under the third and fourth sentences of section 1842(b) of the Social Security Act [subsec. (b) of this section]) for any such tests or associated professional services are excessive, the Secretary shall establish such charge levels at levels which, consistent with assuring that the test is widely and consistently available to medicare beneficiaries, reflect a reasonable price for the test without any markup. Alternatively, the Secretary, pursuant to guidelines published after notice and opportunity of at least 60 days for public comment, may delegate to carriers with contracts under section 1842 of the Social Security Act the establishment of new prevailing charge levels under this paragraph. When such charge levels are established, the provisions of section 1842(b)(1)(D) of such Act shall apply in the same manner as they apply to a reduction under section 1842(b)(8)(A) of such Act.”

**Adjustment for Maximum Allowable Actual Charge**

Section 4054(b), formerly § 4053(b), of Pub. L. 100–203, as renumbered by Pub. L. 100–360, title IV, § 4111(f)(14), July 1, 1988, 102 Stat. 781, provided that: “In the case of a physician who did not have actual charges under title XVIII of the Social Security Act [this title] for the procedure performed on or before December 31, 1987, that physician shall be entitled to the payment amount otherwise provided under such title or otherwise (for the procedure performed prior to June 30, 1984, the carrier shall compute the maximum allowable actual charge under section 1842(b) and (c) of the Social Security Act [subsec. (j) of this section] for such procedure performed by such physician in 1988 based on such physician’s actual charges for the procedure.”

**Physician Payment Studies; Definitions of Medical and Surgical Procedures**

Section 4056(a), formerly § 4055(a), of Pub. L. 100–203, as renumbered and amended by Pub. L. 100–360, title IV, § 4111(f)(13)(A), (14), July 1, 1988, 102 Stat. 781; Pub. L. 101–508, title IV, § 4118(g)(4), Nov. 5, 1990, 104 Stat. 1388–70, provided that:

“(1) Report on Variations in Carrier Payment Practice.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall conduct a study of variations in payment practices for physicians’ services among the different carriers under section 1842 of the Social Security Act [this section]. Such study shall examine carrier variations in the services included in global fees and pre- and post-operative services included in payment for the operating room. The Secretary shall develop, in consultation with appropriate national medical specialty societies and by not later than July 1, 1989, definitions of physicians’ services (including appropriate classification scheme for procedures) which
could serve as the basis for making payments for such services under part B of title XVIII of the Social Security Act [this part]. In developing such definitions, to the extent practicable—

“(A) ancillary services commonly performed in conjunction with a major procedure would be included with the major procedure;

“(B) pre- and post-procedure services would be included in the procedure; and

“(C) similar procedures would be listed together if the procedures are similar in resource requirements.

Payments for Durable Medical Equipment, Prosthetic Devices, Orthotics, and Prosthetics; 1-Year Freeze on Charge Limitation

Section 4062(a) of Pub. L. 100–203 provided that:

“(1) in general.—In imposing limitations on allowable charges for items and services (other than physicians’ services) furnished in 1988 under part B of title XVIII of such Act [this part] and for which payment is made on the basis of the reasonable charge for the item or service, the Secretary of Health and Human Services shall not impose any limitation at a level higher than the same level as was in effect in December 1987.

“(2) transition.—The provisions of section 4041(a)(2) (other than subparagraph (D) thereof) of this subtitle [set out as a note above] shall apply to suppliers of items and services described in paragraph (1), and directories of participating suppliers of such items and services, in the same manner as such section applies to physicians furnishing physicians’ services, and directories of participating physicians.’’

Special Rule With Respect to Payment for Durable Medical Equipment, Prosthetic Devices, Orthotics, and Prosthetics

Section 4062(d) of Pub. L. 100–203 provided that: “With respect to the establishment of a reasonable charge limit under section 1842(b)(11)(C)(ii) of the Social Security Act [subsec. (b)(11)(C)(ii) of this section], in applying section 1842(b)(11)(C)(i) of such Act, the matter beginning with ‘plus’ shall be considered to have been deleted.’’

Study on Cost Effectiveness of Hearing Aid Prior to Hearing by Administrative Law Judge on Carrier Determinations; Report to Congress

Section 4062(d) of Pub. L. 100–203 provided that: “The Comptroller General shall conduct a study concerning the cost effectiveness of requiring hearings with a carrier under part B of title XVIII of the Social Security Act [this part] before having a hearing before an administrative law judge respecting carrier determinations under that part. The Comptroller General shall report to the Congress on the results of such study by not later than June 30, 1989.”

Capacity To Set Geographic Payment Limits

Section 4065(e) of Pub. L. 100–203 provided that: “The Secretary of Health and Human Services shall develop the capability to implement (for services furnished on or after January 1, 1989) geographic limits on charges and payments under part B of title XVIII of the Social Security Act [this part] for physicians’ services based on statewide, regional, or national average (or percentile) in a distribution of prevailing charges or payment amounts (weighted by frequency of services). Any such limits shall take into account adjustments for geographic differences in cost of practice and cost of living.”

Utilization Screens for Physician Services Provided to Patients in Rehabilitation Hospitals

Section 4114 of Pub. L. 101–508, as amended by Pub. L. 103–432, title I, §126(c)(4), Oct. 31, 1994, 108 Stat. 4146, provided that: “Not later than 180 days after the date of the enactment of this Act [Nov. 5, 1994], the Secretary of Health and Human Services shall issue guidelines to assure a uniform level of review of physician visits to patients of a rehabilitation hospital or unit after the medical review screen parameter established under section 1840(h) of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203, set out below] has been exceeded.”

Section 4085(h) of Pub. L. 100–203 provided that: “(1) The Secretary of Health and Human Services shall establish (in consultation with appropriate physician groups, including those representing rehabilitative medicine) a separate utilization screen for physician visits to patients in rehabilitation hospitals and rehabilitative units (and patients in long-term care hospitals receiving rehabilitation services) to be used by carriers under section 1842 of the Social Security Act [this section] in performing functions under subsection (a) of such section related to the utilization practices of physicians in such hospitals and units.

“(2) Not later than 12 months after the date of enactment of this Act [Dec. 22, 1987], the Secretary of Health and Human Services shall take appropriate steps to implement the utilization screen established under paragraph (1).”

Plan Amendments Not Required Until January 1, 1989

For provisions directing that if any amendments made by subtitle A or subtitle C of title XI [§§1101–1147 and 1171–1177] or title XVIII [§§1800–1899A] of Pub. L. 99–514 require an amendment to any plan, such plan amendment shall not be required to be made before the first plan year beginning on or after Jan. 1, 1989, see section 1140 of Pub. L. 99–514, as amended, set out as a note under section 401 of Title 26, Internal Revenue Code.

Amendments in Contracts and Regulations

The Secretary of Health and Human Services to provide for such timely amendments to contracts under this section, and regulations, to such extent as may be necessary to implement Pub. L. 99–509 on a timely basis, see section 9311(d)(3) of Pub. L. 99–509, set out as an Effective Date of 1986 Amendment note under section 1385a of this title.

Medicare Economic Index

Section 9311(c)(1), (2), (4)–(6) of Pub. L. 99–509 provided that:

“(1) For 1987.—Notwithstanding any other provision of law, for purposes of part B of title XVIII of the Social Security Act [this part] for physicians’ services furnished in 1987, the percentage increase in the MEI (as defined in section 1842(b)(4)(E)(ii) of the Social Security Act [subsec. (b)(4)(E)(ii) of this section]) shall be 3.2 percent.

“(2) Prohibiting Retroactive Adjustment of Medicare Economic Index.—The Secretary of Health and Human Services is not authorized to revise the MEI in a manner that provides, for any period before January 1, 1985, for the substitution of a rental equivalence or rental substitution factor for the housing component of the consumer price index.’’

“(4) Study.—The Secretary shall conduct a study of the extent to which the MEI appropriately and equitably reflects economic changes in the provision of the physicians’ services to medicare beneficiaries. In conducting such study the Secretary shall consult with appropriate experts.

“(5) Limitation on Changes in MEI Methodology.—The Secretary shall not change the methodology (including the basis and elements) used in the MEI from that in effect as of October 1, 1985, until completion of the study under paragraph (4). After the completion of the study, the Secretary may not change such methodology except after providing notice in the Federal Register and opportunity for public comment.

“(6) MEI Defined.—In this subsection, the term ‘MEI’ means the economic index services shall use referred to in the fourth sentence of section 1842(b)(3) of the Social Security Act [subsec. (b)(3) of this section].’’
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DEVELOPMENT AND USE OF HCFA COMMON PROCEDURE CODING SYSTEM

Section 9331(d) of Pub. L. 99–509 provided that:

"(1) Not later than July 1, 1986, the Secretary of Health and Human Services shall, under the Medicare program, publish a final regulation of the Secretary of Health and Human Services (in this subsection referred to as the 'Secretary'), after public notice and opportunity for public comment and after consultation with appropriate medical and other experts, to establish the standards and criteria under section 1842(b)(2) of the Social Security Act (subsec. (b) of this section) for contracts under that section, a system to measure a carrier's performance of the responsibilities described in sections 1842(b)(3)(H) and 1842(b)(2) of such Act and that, of the amounts appropriated for administrative activities to carry out part B of title XVIII of the Social Security Act (this part), the Secretary of Health and Human Services shall apply 20% to such performance measures (described in section 1842(h)(3) of that Act) for items and services furnished to the Secretary by carriers under those contracts, at the beginning of the respective period. At the beginning of each fiscal year, the Secretary shall publish a new directory (described in section 1842(h)(4) of that Act) for payment under those contracts, for the period beginning on October 1, 1986, and ending on December 31, 1986, shall be determined on the basis of the aggregate annual payments under such part with respect to the services rendered in the third fiscal year for which such contracts were in effect, and to have entered into such agreement for such 8-month period beginning May 1, 1986, or terminate such an agreement previously entered into for fiscal year 1986. In the case of a physician or supplier who entered into such an agreement for fiscal year 1986, the physician or supplier shall be deemed to have entered into such agreement for such 8-month period and for each succeeding year unless the physician or supplier terminates such agreements before the beginning of the respective period. At the beginning of such 8-month period, the Secretary shall publish a new directory (described in section 1842(h)(4) of this Act (subsec. (b)(4) of this section), as redesignated by subsection (c)(3)(D) of this section) of participating physicians and suppliers.

(T) TRANSITIONAL PROVISIONS FOR MEDICARE PART B PAYMENTS

Section 9301(d)(5) of Pub. L. 99–272 provided that: "Notwithstanding any other provision of law, for purposes of making payment under part B of title XVIII of the Social Security Act (this part), customary and prevailing charges (and the lowest charges determined under the sixth sentence of section 1842(b)(3) of such Act (subsec. (b)(3) of this section)) for items and services furnished during the period beginning on October 1, 1986, and ending on December 31, 1986, shall be determined on the same basis as for items and services furnished on September 30, 1986.

(2) COMPUTATION OF CUSTOMARY CHARGES FOR CERTAIN FORMER HOSPITAL-COMPENSATED PHYSICIANS

Section 9301(b) of Pub. L. 99–272 provided that: "(1) In applying section 1842(b) of the Social Security Act (subsec. (b) of this section) to payment for physi-

PAYMENT FOR PARENTERAL AND ENTERAL NUTRITION SUPPLIES AND EQUIPMENT

Section 9340 of Pub. L. 99–509 provided that: "The Secretary of Health and Human Services shall apply the sixth sentence of section 1842(b)(3) of the Social Security Act (this part) shall require hospitals, as a condition of payment for outpatient hospital services under that part, to report claims for payment for such services under such part using a HCFA Common Procedure Coding System."

PERIOD FOR ENTERING INTO PARTICIPATION AGREEMENTS

Section 9301(b)(3) of Pub. L. 99–272 provided that: "The Secretary of Health and Human Services shall provide, during the month of April 1986, that physicians and suppliers may enter into an agreement under section 1842(b)(1) of the Social Security Act (subsec. (b)(1) of this section) for the 8-month period beginning May 1, 1986, or terminate such an agreement previously entered into for fiscal year 1986. In the case of a physician or supplier who entered into such an agreement for fiscal year 1986, the physician or supplier shall be deemed to have entered into such agreement for such 8-month period and for each succeeding year unless the physician or supplier terminates such agreements before the beginning of the respective period. At the beginning of such 8-month period, the Secretary shall publish a new directory (described in section 1842(h)(4) of such Act (subsec. (b)(4) of this section), as redesignated by subsection (c)(3)(D) of this section) of participating physicians and suppliers.

Section 9332(a)(2), (3) of Pub. L. 99–509, as amended by Pub. L. 100–203, title IV, § 4041(a)(2)(B), Dec. 22, 1987, 101 Stat. 1330–133, which provided that the Secretary of Health and Human Services was to provide, in the standards and criteria established under section 1842(b)(2) of the Social Security Act (subsec. (b) of this section) for contracts under that section, a system to measure a carrier's performance of the responsibilities described in sections 1842(b)(3)(H) and 1842(b)(2) of such Act and that, of the amounts appropriated for administrative activities to carry out part B of title XVIII of the Social Security Act (this part), the Secretary of Health and Human Services was to provide payments, totaling 1 percent of the total payments to carriers for claims processing in any fiscal year, to carriers under section 1842 of such Act, to reward such carriers for their success in increasing the proportion of physicians in the carrier's service area who were participating in increasing the proportion of total payments for physicians' services which were payments for such services rendered by participating physicians, was repealed by Pub. L. 100–203, title IV, § 4041(a)(3)(B), Dec. 22, 1987, 101 Stat. 1330–84.

(B) PERFORMANCE MEASURES.—The Secretary of Health and Human Services shall provide for the establishment of the standards and criteria required under the last sentence of section 1842(b)(2) of the Social Security Act (subsec. (b) of this section) by not later than October 1, 1987, which shall apply to contracts as of October 1, 1987.

(C) CARRIER BONUSES.—From the amounts appropriated for each fiscal year (beginning with fiscal year 1986), the Secretary shall first provide for payments of bonuses to carriers under section 1842(c)(1)(H) of the Social Security Act (subsec. (c)(1) of this section) not later than September 30, 1988, to reflect performance of carriers during the enrollment period before April 1, 1988.

REVIEW OF PROCEDURES

Section 9333(c) of Pub. L. 99–509 provided that: "Not later than October 1, 1987, the Secretary of Health and Human Services shall review the inherent reasonableness of the reasonable charge for at least 10 of the most costly procedures with respect to which payment is made under part B of title XVIII of the Social Security Act (this part) (determined on the basis of the aggregate annual payments under such part with respect to each such procedure)."

RATIFICATION OF REGULATIONS


(2) PATIENT PROTECTIONS.—In the case of any reduction in the reasonable charge for physicians' services effected under the regulation described in paragraph (1), the provisions of section 1842(j)(1)(D) of the Social Security Act (subsec. (j)(1)(D) of this section) (added by the amendment made by subsection (a)(3) shall apply in the same manner and to the same extent as they apply to a reduction in the reasonable charge for a physicians' service effected under section 1842(b)(8) of such Act."
cians' services performed during the 8-month period beginning May 1, 1986, in the case of a physician who at anytime during the period beginning on October 31, 1982, and ending on January 31, 1983, was a hospital-compensated physician (as defined in paragraph (3)) but who, as of February 1, 1985, was no longer a hospital-compensated physician, the physician's customary charges shall be—

(A) be based upon the physician's actual charges billed during the 12-month period ending on March 31, 1985, and

(B) in the case of a physician who was not a participating physician (as defined in section 1842(b)(1) of the Social Security Act [subsec. (h)(1) of this section]) on September 30, 1985, and who is not such a physician on May 1, 1986, be determined to take into account the legislative freeze on actual charges for non-participating physicians' services) by multiplying the physician's customary charges by .85.

(2) In applying section 1842(b) of the Social Security Act [subsec. (b) of this section] to payment for physicians' services performed during the 8-month period beginning May 1, 1986, in the case of a physician who during the period beginning on February 1, 1985, and ending on December 31, 1986, changes from being a hospital-compensated physician to not being a hospital-compensated physician, the physician's customary charges shall be determined in the same manner if the physician were considered to be a new physician.

(3) In this subsection, the term 'hospital-compensated physician' means, with respect to services furnished to patients of a hospital, a physician who is compensated by the hospital for the furnishing of physicians' services for which payment may be made under this part.

**Extension of Medicare Physician Payment Provisions**

Period of 15 months referred to in subsec. (j)(1) of this section for monitoring the charges of nonparticipating physicians to include the period Oct. 1, 1985, to Mar. 14, 1986, see section 5(b) of Pub. L. 99–107, set out as a note under section 1395w of this title.

**Simplification of Procedures With Respect to Claims and Payments for Clinical Diagnostic Laboratory Tests**

Section 2303(b) of Pub. L. 98–369 provided that: "The Secretary of Health and Human Services shall simplify the procedures under section 1842 of the Social Security Act [this section] with respect to claims and payments for clinical diagnostic laboratory tests so as to reduce unnecessary paperwork while assuring that sufficient information is supplied to identify instances of fraud and abuse."

**Study of Amounts Billed for Physician Services and Paid by Carriers Under Subsection (b)(7) of This Section; Report to Congress**

Section 2307(c) of Pub. L. 98–369 directed Comptroller General to conduct a study of the amounts billed for physician services and paid by carriers under subsec. (b)(7) of this section to determine whether such payments were made only where the physician satisfied the requirements of subsec. (b)(7)(A)(i) of this section, and to submit to Congress a report on results of such study not later than 18 months after July 15, 1984.

**Replacement of Agency, Organization, or Carrier Processing Medicare Claims; Number of Agreements and Contracts Authorized for Fiscal Years 1985 Through 1993**

For provision authorizing two agreements under section 1395h of this title and two contracts under this section for replacement of an agency, organization, or carrier in the lowest 20th percentile, see section 2326(a) of Pub. L. 98–369, as amended, set out as a note under section 1395h of this title.

**Rules and Regulations**

Section 113(b)(2) 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 the amendment made by subsection (a) (amending this section) on a timely basis. If such regulations are promulgated on an interim final basis, the Secretary shall take such steps as may be necessary to provide opportunity for public comment, and provide appropriate revision based thereon, so as to provide that such regulations are not on an interim basis later than January 31, 1983."

**Report on Reimbursement of Clinical Laboratories**

Section 918(a)(3) of Pub. L. 96–169 provided that not later than 24 months after an effective date (not later than Apr. 1, 1981) which was to have been prescribed by the Secretary of Health and Human Services, the Secretary was to report to the Congress (A) the proportion of bills and requests for payment submitted (during the 18-month period beginning on such effective date) under this subchapter for laboratory tests which did not identify who performed the tests, (B) the proportion of bills and requests for payment submitted during such period for laboratory tests with respect to which the amount paid under this subchapter was less than the amount that would otherwise have been payable in the absence of subsec. (b) of this section, (C) with respect to requests for payment described in subparagraph (B) which were submitted by patients, the average additional cost per laboratory test to patients resulting from reductions in payment that would otherwise have been made for such tests in the absence of such subsec. (b), and (D) with respect to bills described in subparagraph (B) which were submitted by physicians, the average reduction in payment per laboratory test to physicians resulting from the application of such subsec. (b).

**Prevailing Charge Levels for Fiscal Year Beginning July 1, 1975**

Section 101(b) of Pub. L. 94–182 provided that: "The amendment made by subsection (a) (amending subsec. (b)(3) of this section) shall be applicable with respect to claims filed under part B of title XVIII of the Social Security Act [this part] with a carrier designated pursuant to section 1842 of such Act [this section] and processed by such carrier after the appropriate changes were made in the prevailing charge levels for the fiscal year beginning July 1, 1975, on the basis of economic index data under the third and fourth sentence of section 1842(b)(3) of such Act [subsec. (b)(3) of this section]; except that (1) if less than the correct amount was paid (after the application of subsection (a) of this section) on any claim processed prior to the enactment of this section [Dec. 31, 1975], the correct amount shall be paid by such carrier at such time (not exceeding 6 months after the date of the enactment of this section) [Dec. 31, 1976] as is administratively feasible, and (2) no such payment shall be made on any claim where the difference between the amount paid and the correct amount due is less than $1."

**Report on Health Insurance Benefits Advisory Council on Methods of Reimbursement of Physicians for Their Services**

Section 224(b) of Pub. L. 92–603 directed Health Insurance Benefits Advisory Council to conduct a study of methods of reimbursement for physicians' services under Medicare with respect to fees, extent of assignments accepted by physicians, and share of physician fee costs which Medicare program does not pay and submit such study to Congress by Jan. 1, 1973.
§ 1395v. Agreements with States

(a) Duty of Secretary; enrollment of eligible individuals

The Secretary shall, at the request of a State made before January 1, 1970, or during 1981 or after 1988, enter into an agreement with such State pursuant to which all eligible individuals in either of the coverage groups described in subsection (b) of this section (as specified in the agreement) will be enrolled under the program established by this part.

(b) Coverage of groups to which applicable

An agreement entered into with any State pursuant to subsection (a) of this section may be applicable to either of the following coverage groups:

(1) individuals receiving money payments under the plan of such State approved under subchapter I of this chapter or subchapter XVI of this chapter; or
(2) individuals receiving money payments under all of the plans of such State approved under subchapters I, X, XIV, and XVI of this chapter, and part A of subchapter IV of this chapter.

Except as provided in subsection (g) of this section, there shall be excluded from any coverage group any individual who is entitled to monthly insurance benefits under subchapter II of this chapter or who is entitled to receive an annuity under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.]. Effective January 1, 1974, and subject to section 1396a(f) of this title, the Secretary shall, at the request of any State not eligible to participate in the State plan program established under subchapter XVI of this chapter, continue in effect the agreement entered into under this section with such State subject to such modifications as the Secretary may by regulations provide to take account of the termination of any plans of such State approved under subchapters I, X, XIV, and XVI of this chapter and the establishment of the supplemental security income program under subchapter XVI of this chapter.

(c) Eligible individuals

For purposes of this section, an individual shall be treated as an eligible individual only if he is an eligible individual (within the meaning of section 1395o of this title) on the date an agreement covering him is entered into under subsection (a) of this section or he becomes an eligible individual (within the meaning of such section) at any time after such date; and he shall be treated as receiving money payments described in subsection (b) of this section if he receives such payments for the month in which the agreement is entered into or any month thereafter.

(d) Monthly premiums; coverage periods

In the case of any individual enrolled pursuant to this section—

(1) the monthly premium to be paid by the State shall be determined under section 1395r of this title (without any increase under subsection (b) thereof); and
(2) his coverage period shall begin on whichever of the following is the latest:

(A) July 1, 1966; or
(B) the first day of the third month following the month in which the State agreement is entered into; or
(C) the first day of the first month in which he is both an eligible individual and a member of a coverage group specified in the agreement under this section; or
(D) such date as may be specified in the agreement; and

(3) his coverage period attributable to the agreement with the State under this section shall end on the last day of whichever of the following first occurs:

(A) the month in which he is determined by the State agency to have become ineligible both for money payments of a kind specified in the agreement and (if there is in effect a modification entered into under subsection (b) of this section) for medical assistance, or
(B) the month preceding the first month for which he becomes entitled to monthly benefits under subchapter II of this chapter or to an annuity or pension under the Railroad Retirement Act of 1974 [45 U.S.C. 231 et seq.].

(e) Subsection (d)(3) terminations deemed resulting in section 1395p enrollment

Any individual whose coverage period attributable to the State agreement is terminated pursuant to subsection (d)(3) of this section shall be deemed for purposes of this part (including the continuation of his coverage period under this part) to have enrolled under section 1395p of this title in the initial general enrollment period provided by section 1385(c) of this title. The coverage period under this part of any such individual who (in the last month of his coverage period attributable to the State agreement or in any of the following six months) files notice that he no longer wishes to participate in the insurance program established by this part, shall terminate at the close of the month in which the notice is filed.

(f) “Carrier” as including State agency; provisions facilitating deductions, coinsurance, etc., and leading to economy and efficiency of operation

With respect to eligible individuals receiving money payments under the plan of a State approved under subchapter I, X, XIV, or XVI of this chapter, or part A of subchapter IV of this chapter, or eligible to receive medical assistance under the plan of such State approved under subchapter XIX of this chapter, if the agreement entered into under this section so provides, the term “carrier” as defined in section 1395a(f) of this title also includes the State agency, specified in such agreement, which administers or supervises the administration of the plan of such State approved under subchapter I, XVI, or XIX of this chapter. The agreement shall also contain such provisions as will facilitate the financial transactions of the State and the carrier with respect to deductions, coinsurance, and otherwise, and as will lead to economy and effi-

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1 See References in Text note below.
ciency of operation, with respect to individuals receiving money payments under plans of the State approved under subchapters I, X, XIV, and XVI of this chapter, and part A of subchapter IV of this chapter, and individuals eligible to receive medical assistance under the plan of the State approved under subchapter XIX of this chapter.

(g) Subsection (b) exclusions from coverage groups

(1) The Secretary shall, at the request of a State made before January 1, 1970, or during 1981 or after 1988, enter into a modification of an agreement entered into with such State pursuant to subsection (a) of this section under which the second sentence of subsection (b) of this section shall not apply with respect to such agreement.

(2) In the case of any individual who would (but for this subsection) be excluded from the applicable coverage group described in subsection (b) of this section by the second sentence of such subsection—

(A) subsections (c) and (d)(2) of this section shall be applied as if such subsections referred to the modification under this subsection (in lieu of the agreement under subsection (a) of this section), and

(B) subsection (d)(3)(B) of this section shall not apply so long as there is in effect a modification entered into by the State under this subsection.

(h) Modifications respecting subsection (b) coverage groups

(1) The Secretary shall, at the request of a State made before January 1, 1970, or during 1981 or after 1988, enter into a modification of an agreement entered into with such State pursuant to subsection (a) of this section under which the coverage group described in subsection (b) of this section and specified in such agreement is broadened to include (A) individuals who are eligible to receive medical assistance under the plan of such State approved under subchapter XIX of this chapter, or (B) qualified medicare beneficiaries (as defined in section 1396d(p)(1) of this title).

(2) For purposes of this section, an individual shall be treated as eligible to receive medical assistance under the plan of the State approved under subchapter XIX of this chapter if, for the month in which the modification is entered into under this subsection or for any month thereafter, he has been determined to be eligible to receive medical assistance under such plan. In the case of any individual who would (but for this subsection) be excluded from the agreement, subsections (c) and (d)(2) of this section shall be applied as if they referred to the modification under subsection (a) of this section, and subsection (d)(2)(C) of this section shall be applied (except in the case of qualified medicare beneficiaries, as defined in section 1396d(p)(1) of this title) by substituting "second month following the first month" for "first month".

(3) In this subsection, the term "qualified medicare beneficiary" also includes an individual described in section 1396a(a)(10)(E)(ii) of this title.

(i) Enrollment of qualified medicare beneficiaries

For provisions relating to enrollment of qualified medicare beneficiaries under part A of this subchapter, see section 1395l–2(g) of this title.


REFERENCES IN TEXT
Part A of subchapter IV of this chapter, referred to in subsecs. (b) and (f), is classified to section 601 et seq. of this title.


Part A of this subchapter, referred to in subsec. (i), is classified to section 1395c et seq. of this title.

AMENDMENTS
Pub. L. 100–360, §301(e)(1)(B), as added by Pub. L. 100–485, §608(d)(4)(H)(ii), inserted (A) designation after “include” and added cl. (B).
Subsec. (h)(2). Pub. L. 100–360, §301(e)(1)(C), as added by Pub. L. 100–485, §608(d)(4)(H)(ii), inserted “(except in the case of qualified medicare beneficiaries, as defined in section 1396d(p)(1) of this title)” after “shall be applied”.
1983—Subsec. (d)(1). Pub. L. 98–21 substituted “without any increase under subsection (b) thereof” for “without any increase under subsection (c) thereof”.
Subsec. (e). Pub. L. 96–499, §947(a), inserted provision that the coverage period under this part of any individual who filed notice that he no longer wished to participate in the insurance program established by this part was to terminate at the close of the month in which the notice was filed.
Subsec. (g)(1), Pub. L. 96–499, §945(e), inserted “or during 1981,” after “January 1, 1970.”.
§ 1395w. Appropriations to cover Government contributions and contingency reserve (a) In general

There are authorized to be appropriated from time to time, out of any moneys in the Treasury...
not otherwise appropriated, to the Federal Supplementary Medical Insurance Trust Fund—

(1)(A) a Government contribution equal to the aggregate premiums payable for a month for enrollees age 65 and over under this part and deposited in the Trust Fund, multiplied by the ratio of—

(i) twice the dollar amount of the actuarially adequate rate per enrollee age 65 and over as determined under section 1395r(a)(1) of this title for such month minus the dollar amount of the premium per enrollee for such month, as determined under section 1395r(a)(3) of this title, to

(ii) the dollar amount of the premium per enrollee for such month, plus

(B) a Government contribution equal to the aggregate premiums payable for a month for enrollees under age 65 under this part and deposited in the Trust Fund, multiplied by the ratio of—

(i) twice the dollar amount of the actuarially adequate rate per enrollee age 65 as determined under section 1395r(a)(4) of this title for such month minus the dollar amount of the premium per enrollee for such month, as determined under section 1395r(a)(3) of this title, to

(ii) the dollar amount of the premium per enrollee for such month; minus

(C) the aggregate amount of additional premium payments attributable to the application of section 1395r(1) of this title; plus

(2) such sums as the Secretary deems necessary to place the Trust Fund, at the end of any fiscal year occurring after June 30, 1967, in the same position in which it would have been at the end of such fiscal year if (A) a Government contribution representing the excess of the premiums deposited in the Trust Fund during the fiscal year ending June 30, 1967, over the Government contribution actually appropriated to the Trust Fund during such fiscal year had been appropriated to it on June 30, 1967, and (B) the Government contribution for premiums deposited in the Trust Fund after June 30, 1967, had been appropriated to it when such premiums were deposited; plus

(3) a Government contribution equal to the amount of payment incentives payable under sections 1395w–4(e) and 1395w–23(h)(3) of this title.

(b) Contingency reserve

In order to assure prompt payment of benefits provided under this part and the administrative expenses thereunder during the early months of the program established by this part, and to provide a contingency reserve, there is also authorized to be appropriated, out of any moneys in the Treasury not otherwise appropriated, to remain available through the calendar year 1969 for repayable advances (without interest) to the Trust Fund, an amount equal to $18 multiplied by the number of individuals (as estimated by the Secretary) who could be covered in July 1966 by the insurance program established by this part if they had theretofore enrolled under this part.

(c) Election under section 1395w–24

The Secretary shall determine the Government contribution under subparagraphs (A) and (B) of subsection (a)(1) of this section without regard to any premium reduction resulting from an election under section 1395w–24(f)(1)(E) of this title or any credits provided under section 1395w–24(b)(1)(C)(ii) of this title and without regard to any premium adjustment effected under sections 1395r(h) and 1395w–29(f) of this title and without regard to any premium adjustment under section 1395r(c) of this title.


REFERENCES IN TEXT


AMENDMENTS

2000—Subsec. (a)(2), (3). Pub. L. 111–5 in par. (2) substituted ‘‘; plus’’ for period at end and added par. (3).


Subsec. (c). Pub. L. 108–173, §811(b)(2)(B), inserted ‘‘and without regard to any premium adjustment under section 1395r(c) of this title’’ before period at end.

Pub. L. 108–173, §241(b)(2)(B), inserted ‘‘and without regard to any premium adjustment effected under sections 1395r(h) and 1395w–29(f) of this title’’ before period at end.

Pub. L. 108–173, §222(b)(2)(C), inserted ‘‘or any credits provided under section 1395w–24(b)(1)(C)(iv) of this title’’ after ‘‘section 1395w–24(f)(1)(E) of this title’’.


1997—Subsec. (a)(1)(A)(i), (B)(i). Pub. L. 105–33 substituted ‘‘section 1395r(a)(3) of this title’’ for ‘‘section 1395r(a)(3) or 1395r(e) of this title, as the case may be’’.

1969—Subsec. (a). Pub. L. 101–234 inserted Pub. L. 100–360, §211(c)(2), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1968 Amendment note below.

1988—Subsec. (a). Pub. L. 100–360 inserted at end ‘‘In computing the amount of aggregate premiums and pre-

1See References in Text note below.
mums per enrollee under paragraph (1), there shall not be taken into account premiums attributable to section 1395r(g) of this title or section 59B of the Internal Revenue Code of 1986.''


1983—Subsec. (a)(1)(A)(ii). Pub. L. 98–21, § 606(a)(3)(F), substituted ‘‘section 1395(a)(1)’’ for ‘‘section 1395(c)(1)’’ and ‘‘section 1395r(a)(3) or 1395r(e)’’ for ‘‘section 1395r(c)(3) or 1395r(g)’’.

Subsec. (a)(3)(B)(ii). Pub. L. 98–21, § 606(a)(3)(G), substituted ‘‘1395r(a)(4)’’ for ‘‘1395r(c)(4)’’ and ‘‘1395r(a)(3) or 1395r(e)’’ for ‘‘1395r(c)(3) or 1395r(g)’’.

1982—Subsec. (a)(1)(A)(i), (B)(i). Pub. L. 97–248 substituted ‘‘section 1395r(c)(3) or 1395r(g)’’ of this title, as the case may be, for ‘‘section 1395r(c)(3) of this title’’.


(b) Subsec. (b). Pub. L. 90–248, § 147(a), designated existing provisions as par. (1), inserted provision for deposit of Government contribution in Trust Fund, and added par. (2).


**Effective Date of 2003 Amendment**


**Effective Date of 2000 Amendment**

Amendment by Pub. L. 106–554 applicable to years beginning with 2003, see section 1(a)(6) [title VI, § 606(b)] of Pub. L. 106–554, set out as a note under section 1395r of this title.

**Effective Date of 1989 Amendment**


**Effective Date of 1988 Amendment**

Amendment by Pub. L. 100–303 applicable, except as otherwise specified in such amendment, to monthly premiums for months beginning with January 1989, see section 211(d) of Pub. L. 100–303, set out as a note under section 1396r 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 2534(c)(1) of Pub. L. 98–369, set out as a note under section 1395r of this title.

**Effective Date of 1983 Amendment; Transitional Rule**

Amendment by Pub. L. 98–369 applicable for months beginning with January 1984, but for months after June 1983 and before January 1984, the amount of Government contributions under subsec. (a)(1) of this section shall be computed with the actuarially adequate rate which would have been in effect but for the amendments made by this section and using the amount of the premium in effect for June 1983, see section 606(c) of Pub. L. 98–21, set out as a note under section 1395r of this title.

**Effective Date of 1972 Amendment**

Section 203(e) of Pub. L. 92–603 provided that the amendment made by that section is effective with respect to enrollee premiums payable for months after June 1973.


**Effective Date of Repeal**

Repeal 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 1393–6 of this title.

§ 1395w–2. Intermediate sanctions for providers or suppliers of clinical diagnostic laboratory tests

(a) If the Secretary determines that any provider or clinical laboratory approved for participation under this subchapter no longer substantially meets the conditions of participation or for coverage specified under this subchapter with respect to the provision of clinical diagnostic laboratory tests under this part, the Secretary may (for a period not to exceed one year) impose intermediate sanctions developed pursuant to subsection (b) of this section, in lieu of terminating immediately the provider agreement or cancelling immediately approval of the clinical laboratory.

(b)(1) The Secretary shall develop and implement—

(A) a range of intermediate sanctions to apply to providers or clinical laboratories under the conditions described in subsection (a), 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) directed plans of correction,

(ii) civil money penalties in an amount not to exceed $10,000 for each day of substantial noncompliance,

(iii) payment for the costs of onsite monitoring by an agency responsible for conducting surveys, and

(iv) suspension of all or part of the payments to which a provider or clinical laboratory would otherwise be entitled under this subchapter with respect to clinical diagnostic laboratory tests furnished on or after the date on which the Secretary determines that intermediate sanctions should be imposed pursuant to 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 (ii) in the
same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a)(1) of this title.

(B) The sanctions specified in subparagraph (A) in addition to sanctions otherwise available under State or Federal law.


AMENDMENTS

1990—Pub. L. 101–508 substituted “providers or suppliers of” for “of” in section catchline.

1989—Pub. L. 101–234 repealed Pub. L. 100–360, § 203(e)(4), 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.


Pub. L. 100–360, § 411(g)(3)(G)(ii)(I), inserted “or that a clinical laboratory tests”.

Pub. L. 100–360, § 203(e)(4)(B), inserted “and services or those items and services that”.

Subsec. (b)(1)(A), Pub. L. 100–360, § 411(g)(3)(G)(ii), struck out “‘certified’ before “clinical laboratories”.

Subsec. (b)(2)(A), Pub. L. 100–360, § 411(g)(3)(G)(iv), inserted at end “‘The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (ii) in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.””

Subsec. (b)(2)(A)(II). Pub. L. 100–360, § 411(g)(3)(G)(iii), substituted “civil money penalties in an amount not to exceed $10,000 for each day of substantial noncompliance for “civil fines and penalties”.


Subsec. (b)(2)(A)(IV). Pub. L. 100–360, § 411(g)(3)(G)(iv), (vi), struck out “certified” before “clinical laboratory” and substituted “furnished on or after the date on for “furnished on or after the date in”.

Pub. L. 100–360, § 203(e)(4)(C), inserted “or home intravenous drug therapy services” after “clinical diagnostic laboratory tests”.

Subsec. (b)(3). Pub. L. 100–360, § 411(g)(3)(G)(vii), substituted “any penalties” for “any fines” and “severe penalties” for “severe fines”.

EFFECTIVE DATE OF 1990 AMENDMENT


EFFECTIVE DATE OF 1989 AMENDMENT

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 608(g)(1) of Pub. L. 100–485, set out as a note under section 704 of this title.

Amendment by section 203(e)(4) of Pub. L. 100–360 applicable to items and services furnished on or after Jan. 1, 1990, see section 203(g) of Pub. L. 100–360, set out as a note under section 1320c–3 of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(g)(3)(G) 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

Section 4064(d)(2) of Pub. L. 100–203 provided that: “The amendment made by paragraph (1) (enacting this section) shall become effective on January 1, 1990.”

§ 1395w–3. Competitive acquisition of certain items and services

(a) Establishment of competitive acquisition programs

(1) Implementation of programs

(A) In general

The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

(B) Phased-in implementation

The programs—

(i) shall be phased in among competitive acquisition areas in a manner consistent with subparagraph (D) so that the competition under the programs occurs in—

(I) 10 of the largest metropolitan statistical areas in 2007;

(II) an additional 91 of the largest metropolitan statistical areas in 2011; and

(III) additional areas after 2011 (or, in the case of national mail order for items and services, after 2010); and

(ii) may be phased in first among the highest cost and highest volume items and services or those items and services that the Secretary determines have the largest savings potential.
(C) Waiver of certain provisions

In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) Changes in competitive acquisition programs

(i) Round 1 of competitive acquisition program

Notwithstanding subparagraph (B)(i)(I) and in implementing the first round of the competitive acquisition programs under this section—

(I) the contracts awarded under this section before July 15, 2008, are terminated, no payment shall be made under this subchapter on or after July 15, 2008, based on such a contract, and, to the extent that any damages may be applicable as a result of the termination of such contracts, such damages shall be payable from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title;

(ii) the Secretary shall conduct the competition for such round in a manner so that it occurs in 2009 with respect to the same items and services and the same areas, except as provided in subclauses (III) and (IV);

(III) the Secretary shall exclude Puerto Rico so that such round of competition covers 9, instead of 10, of the largest metropolitan statistical areas; and

(IV) there shall be excluded negative pressure wound therapy items and services.

Nothing in subclause (I) shall be construed to provide an independent cause of action or right to administrative or judicial review with regard to the termination provided under such subclause.

(ii) Round 2 of competitive acquisition program

In implementing the second round of the competitive acquisition programs under this section described in subparagraph (B)(i)(II)—

(I) the metropolitan statistical areas to be included shall be those metropolitan statistical areas selected by the Secretary for such round as of June 1, 2008; and

(II) the Secretary shall conduct the competition for such round in a manner so that it occurs in 2009 with respect to the same items and services and the same areas, except as provided in subclauses (III) and (IV); and

(III) the Secretary may subdivide metropolitan statistical areas with populations (based upon the most recent data from the Census Bureau) of at least 8,000,000 into separate areas for competitive acquisition purposes.

(iii) Exclusion of certain areas in subsequent rounds of competitive acquisition programs

In implementing subsequent rounds of the competitive acquisition programs under this section, including under subparagraph (B)(i)(III), for competitions occurring before 2015, the Secretary shall exempt from the competitive acquisition program (other than national mail order) the following:

(I) Rural areas.

(II) Metropolitan statistical areas not selected under round 1 or round 2 with a population of less than 250,000.

(III) Areas with a low population density within a metropolitan statistical area that is otherwise selected, as determined for purposes of paragraph (3)(A).

(E) Verification by OIG

The Inspector General of the Department of Health and Human Services shall, through post-award audit, survey, or otherwise, assess the process used by the Centers for Medicare & Medicaid Services to conduct competitive bidding and subsequent pricing determinations under this section that are the basis for pivotal bid amounts and single payment amounts for items and services in competitive bidding areas under rounds 1 and 2 of the competitive acquisition programs under this section and may continue to verify such calculations for subsequent rounds of such programs.

(F) Supplier feedback on missing financial documentation

(i) In general

In the case of a bid where one or more covered documents in connection with such bid have been submitted not later than the covered document review date specified in clause (ii), the Secretary—

(I) shall provide, by not later than 45 days (in the case of the first round of the competitive acquisition programs as described in subparagraph (B)(i)(I)) or 90 days (in the case of a subsequent round of such programs) after the covered document review date, for notice to the bidder of all such documents that are missing as of the covered document review date; and

(II) may not reject the bid on the basis that any covered document is missing or has not been submitted on a timely basis, if all such missing documents identified in the notice provided to the bidder under subclause (I) are submitted to the Secretary not later than 10 business days after the date of such notice.

(ii) Covered document review date

The covered document review date specified in this clause with respect to a competitive acquisition program is the later of—

(I) the date that is 30 days before the final date specified by the Secretary for submission of bids under such program; or
(ii) the date that is 30 days after the first date specified by the Secretary for submission of bids under such program.

(iii) Limitations of process

The process provided under this subparagraph—

(I) applies only to the timely submission of covered documents;

(II) does not apply to any determination as to the accuracy or completeness of covered documents submitted or whether such documents meet applicable requirements;

(III) shall not prevent the Secretary from rejecting a bid based on any basis not described in clause (I)(II); and

(IV) shall not be construed as permitting a bidder to change bidding amounts or to make other changes in a bid submission.

(iv) Covered document defined

In this subparagraph, the term "covered document" means a financial, tax, or other document required to be submitted by a bidder as part of an original bid submission under a competitive acquisition program in order to meet required financial standards. Such term does not include other documents, such as the bid itself or accreditation documentation.

(2) Items and services described

The items and services referred to in paragraph (1) are the following:

(A) Durable medical equipment and medical supplies

Covered items (as defined in section 1395m(a)(13) of this title) for which payment would otherwise be made under section 1395m(a) of this title, including items used in infusion and drugs (other than inhalation drugs) and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and excluding certain complex rehabilitative power wheelchairs recognized by the Secretary as classified within group 3 or higher (and related accessories when furnished in connection with such wheelchairs).

(B) Other equipment and supplies

Items and services described in section 1395u(s)(2)(D) of this title, other than parenteral nutrients, equipment, and supplies.

(C) Off-the-shelf orthotics

Orthotics described in section 1395x(s)(9) of this title for which payment would otherwise be made under section 1395m(h) of this title which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.

(3) Exception authority

In carrying out the programs under this section, the Secretary may exempt—

(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and

(B) items and services for which the application of competitive acquisition is not likely to result in significant savings.

(4) Special rule for certain rented items of durable medical equipment and oxygen

In the case of a covered item for which payment is made on a rental basis under section 1395m(a) of this title and in the case of payment for oxygen under section 1395m(a)(5) of this title, the Secretary shall establish a process by which rental agreements for the covered items and supply arrangements with oxygen suppliers entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1395m(a) of this title.

(5) Physician authorization

(A) In general

With respect to items or services included within a particular HCPCS code, the Secretary may establish a process for certain items and services under which a physician may prescribe a particular brand or mode of delivery of an item or service within such code if the physician determines that use of the particular item or service would avoid an adverse medical outcome on the individual, as determined by the Secretary.

(B) No effect on payment amount

A prescription under subparagraph (A) shall not affect the amount of payment otherwise applicable for the item or service under the code involved.

(6) Application

For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) of this section shall be substituted for the payment basis otherwise applied under section 1395m(a) of this title, section 1395m(h) of this title, or section 1395u(s) of this title, as appropriate.

(7) Exemption from competitive acquisition

The programs under this section shall not apply to the following:

(A) Certain off-the-shelf orthotics

Items and services described in paragraph (2)(C) if furnished—

(i) by a physician or other practitioner (as defined by the Secretary) to the physician’s or practitioner’s own patients as part of the physician’s or practitioner’s professional service; or

(ii) by a hospital to the hospital’s own patients during an admission or on the date of discharge.

(B) Certain durable medical equipment

Those items and services described in paragraph (2)(A)—
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(b) Program requirements

(1) In general

The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) of this section for each competitive acquisition area in which the program is implemented under subsection (a) of this section with respect to such items and services.

(2) Conditions for awarding contract

(A) In general

The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

(i) The entity meets applicable quality standards specified by the Secretary under section 1395m(a)(20) of this title.

(ii) The entity meets applicable financial standards specified by the Secretary, taking into account the needs of small providers.

(iii) The total amounts to be paid to contractors in a competitive acquisition area are expected to be less than the total amounts that would otherwise be paid.

(iv) Access of individuals to a choice of multiple suppliers in the area is maintained.

(B) Timely implementation of program

Any delay in the implementation of quality standards under section 1395m(a)(20) of this title or delay in the receipt of advice from the program oversight committee established under subsection (c) of this section shall not delay the implementation of the competitive acquisition program under this section.

(3) Contents of contract

(A) In general

A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

(B) Term of contracts

The Secretary shall recompete contracts under this section not less often than once every 3 years.

(C) Disclosure of subcontractors

(i) Initial disclosure

Not later than 10 days after the date a supplier enters into a contract with the Secretary under this section, such supplier shall disclose to the Secretary, in a form and manner specified by the Secretary, the information on—

(I) each subcontracting relationship that such supplier has in furnishing items and services under the contract; and

(II) whether each such subcontractor meets the requirement of section 1395m(a)(20)(F)(i) of this title, if applicable to such subcontractor.

(ii) Subsequent disclosure

Not later than 10 days after such a supplier subsequently enters into a subcontracting relationship described in clause (i)(II), such supplier shall disclose to the Secretary, in such form and manner, the information described in subclauses (I) and (II) of clause (i).

(4) Limit on number of contractors

(A) In general

The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of individuals for such items or services in the geographic area covered under the contract on a timely basis.

(B) Multiple winners

The Secretary shall award contracts to multiple entities submitting bids in each area for an item or service.

(5) Payment

(A) In general

Payment under this part for competitively priced items and services described in subsection (a)(2) of this section shall be based on bids submitted and accepted under this section for such items and services. Based on such bids the Secretary shall determine a single payment amount for each item or service in each competitive acquisition area.

(B) Reduced beneficiary cost-sharing

(i) Application of coinsurance

Payment under this section for items and services shall be in an amount equal to 80 percent of the payment basis described in subparagraph (A).

(ii) Application of deductible

Before applying clause (i), the individual shall be required to meet the deductible described in section 1395l(b) of this title.

(C) Payment on assignment-related basis

Payment for any item or service furnished by the entity may only be made under this section on an assignment-related basis.

(D) Construction

Nothing in this section shall be construed as precluding the use of an advanced beneficiary notice with respect to a competitively priced item and service.

1 So in original. Probably should be “a”.
(6) Participating contractors

(A) In general

Except as provided in subsection (a)(4) of this section, payment shall not be made for items and services described in subsection (a)(2) of this section furnished by a contractor and for which competition is conducted under this section unless—

(i) the contractor has submitted a bid for such items and services under this section; and

(ii) the Secretary has awarded a contract to the contractor for such items and services under this section.

(B) Bid defined

In this section, the term “bid” means an offer to furnish an item or service for a particular price and time period that includes, where appropriate, any services that are attendant to the furnishing of the item or service.

(C) Rules for mergers and acquisitions

In applying subparagraph (A) to a contractor, the contractor shall include a successor entity in the case of a merger or acquisition, if the successor entity assumes such contract along with any liabilities that may have occurred thereunder.

(D) Protection of small suppliers

In developing procedures relating to bids and the awarding of contracts under this section, the Secretary shall take appropriate steps to ensure that small suppliers of items and services have an opportunity to be considered for participation in the program under this section.

(7) Consideration in determining categories for bids

The Secretary may consider the clinical efficiency and value of specific items within codes, including whether some items have a greater therapeutic advantage to individuals.

(8) Authority to contract for education, monitoring, outreach, and complaint services

The Secretary may enter into contracts with appropriate entities to address complaints from individuals who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such individuals and monitoring of quality of services with respect to the program.

(9) Authority to contract for implementation

The Secretary may contract with appropriate entities to implement the competitive bidding program under this section.

(10) Special rule in case of competition for diabetic testing strips

(A) In general

With respect to the competitive acquisition program for diabetic testing strips conducted after the first round of the competitive acquisition programs, if an entity does not demonstrate to the Secretary that its bid covers types of diabetic testing strip products that, in the aggregate and taking into account volume for the different products, cover 50 percent (or such higher percentage as the Secretary may specify) of all such types of products, the Secretary shall reject such bid. The volume for such types of products may be determined in accordance with such data (which may be market based data) as the Secretary recognizes.

(B) Study of types of testing strip products

Before 2011, the Inspector General of the Department of Health and Human Services shall conduct a study to determine the types of diabetic testing strip products by volume that could be used to make determinations pursuant to subparagraph (A) for the first competition under the competitive acquisition program described in such subparagraph and submit to the Secretary a report on the results of the study. The Inspector General shall also conduct such a study and submit such a report before the Secretary conducts a subsequent competitive acquisition program described in subparagraph (A).

(11) No administrative or judicial review

There shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of—

(A) the establishment of payment amounts under paragraph (5);

(B) the awarding of contracts under this section;

(C) the designation of competitive acquisition areas under subsection (a)(1)(A) and the identification of areas under subsection (a)(1)(D)(iii);

(D) the phased-in implementation under subsection (a)(1)(B) and implementation of subsection (a)(1)(D);

(E) the selection of items and services for competitive acquisition under subsection (a)(2) of this section;

(F) the bidding structure and number of contractors selected under this section; or

(G) the implementation of the special rule described in paragraph (10).

(c) Program Advisory and Oversight Committee

(1) Establishment

The Secretary shall establish a Program Advisory and Oversight Committee (hereinafter in this section referred to as the “Committee”)

(2) Membership; terms

The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify.

(3) Duties

(A) Advice

The Committee shall provide advice to the Secretary with respect to the following functions:

(i) The implementation of the program under this section.

(ii) The establishment of financial standards for purposes of subsection (b)(2)(A)(ii) of this section.

2So in original. Probably should be “acquisition.”
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PRIOR PROVISIONS


AMENDMENTS


(f) Competitive acquisition ombudsman

The Secretary shall provide for a competitive acquisition ombudsman within the Centers for Medicare & Medicaid Services in order to respond to complaints and inquiries made by suppliers and individuals relating to the application of the competitive acquisition program under this section. The ombudsman may be within the office of the Medicare Beneficiary Ombudsman appointed under section 1395b–9(c) of this title.

The ombudsman shall submit to Congress an annual report on the activities under this subsection, which report shall be coordinated with the report provided under section 1395b–9(c)(2)(C) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, §1847, as added Pub. L. 105–33, title III, §1302(c), Oct. 24, 1997, 111 Stat. 481, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.)

REFERENCES IN TEXT

§ 1395w–3a. Use of average sales price payment methodology

(a) Application

(1) In general

Except as provided in paragraph (2), this section shall apply to payment for drugs and biologicals that are described in section 1395w(a)(1)(C) of this title and that are furnished on or after January 1, 2005.

(2) Election

This section shall not apply in the case of a physician who elects under subsection (a)(1)(A)(i) of section 1395w–3b of this title for that section to apply instead of this section for the payment for drugs and biologicals.

(b) Payment amount

(1) In general

Subject to paragraph (7) and subsections (d)(3)(C) and (e) of this section, the amount of payment determined under this section for the billing and payment code for a drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C) of this section), 106 percent of the amount determined under paragraph (3) for a multiple source drug furnished before April 1, 2008, or 106 percent of the amount determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008; or

(B) in the case of a single source drug or biological (as defined in subsection (c)(6)(D) of this section), 106 percent of the amount determined under paragraph (4); or

(C) in the case of a biosimilar biological product (as defined in subsection (c)(6)(H)), the amount determined under paragraph (8).

(2) Specification of unit

(A) Specification by manufacturer

The manufacturer of a drug or biological shall specify the unit associated with each National Drug Code (including package size) as part of the submission of data under section 13966–8(b)(3)(A)(iii) of this title.

(B) Unit defined

In this section, the term “unit” means, with respect to each National Drug Code (including package size) associated with a drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference to volume measures pertaining to liquids. For years after 2004, the Secretary may establish the unit for a manufacturer to report and methods for counting units as the Secretary determines appropriate to implement this section.
(3) Multiple source drug
For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1395w–8(b)(3)(A)(iii) of this title determined by—

(A) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(i) the manufacturer’s average sales price (as defined in subsection (c) of this section); and

(ii) the total number of units specified under paragraph (2) sold; and

(B) dividing the sum determined under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all National Drug Codes assigned to such drug products.

(4) Single source drug or biological
The amount specified in this paragraph for a single source drug or biological is the lesser of the following:

(A) Average sales price
The average sales price as determined using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(B) Wholesale acquisition cost (WAC)
The wholesale acquisition cost (as defined in subsection (c)(6)(B) of this section) using the methodology applied under paragraph (3) for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008, for all National Drug Codes assigned to such drug or biological product.

(5) Basis for payment amount
The payment amount shall be determined under this subsection based on information reported under subsection (f) of this section and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(6) Use of volume-weighted average sales prices in calculation of average sales price
(A) In general
For all drug products included within the same multiple source drug billing and payment code, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1395w–8(b)(3)(A)(iii) of this title determined by—

(i) computing the sum of the products (for each National Drug Code assigned to such drug products) of—

(I) the manufacturer’s average sales price (as defined in subsection (c)), determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code; and

(II) the total number of units specified under paragraph (2) sold; and

(ii) dividing the sum determined under clause (i) by the sum of the products (for each National Drug Code assigned to such drug products) of—

(I) the total number of units specified under paragraph (2) sold; and

(II) the total number of billing units for the National Drug Code for the billing and payment code.

(B) Billing unit defined
For purposes of this subsection, the term “billing unit” means the identifiable quantity associated with a billing and payment code, as established by the Secretary.

(7) Special rule
Beginning with April 1, 2008, the payment amount for—

(A) each single source drug or biological described in section 1395u(o)(1)(G) of this title that is treated as a multiple source drug because of the application of subsection (c)(6)(C)(ii) is the lower of—

(i) the payment amount that would be determined for such drug or biological applying such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied; and

(B) a multiple source drug described in section 1395u(o)(1)(G) of this title (excluding a drug or biological that is treated as a multiple source drug because of the application of such subsection) is the lower of—

(i) the payment amount that would be determined for such drug or biological taking into account the application of such subsection; or

(ii) the payment amount that would have been determined for such drug or biological if such subsection were not applied.

(8) Biosimilar biological product
The amount specified in this paragraph for a biosimilar biological product described in paragraph (1)(O) is the sum of—

(A) the average sales price as determined using the methodology described under paragraph (6) applied to a biosimilar biological product for all National Drug Codes assigned to such product in the same manner as such paragraph is applied to drugs described in such paragraph; and

(B) 6 percent of the amount determined under paragraph (4) for the reference biological product (as defined in subsection (c)(6)(I)).

(c) Manufacturer’s average sales price
(1) In general
For purposes of this section, subject to paragraphs (2) and (3), the manufacturer’s “average sales price” means, of a drug or biological for
a National Drug Code for a calendar quarter for a manufacturer for a unit—

(A) the manufacturer’s sales to all purchasers (excluding sales exempted in paragraph (2)) in the United States for such drug or biological in the calendar quarter; divided by

(B) the total number of such units of such drug or biological sold by the manufacturer in such quarter.

(2) Certain sales exempted from computation

In calculating the manufacturer’s average sales price under this subsection, the following sales shall be excluded:

(A) Sales exempt from best price

Sales exempt from the inclusion in the determination of “best price” under section 1396r–8(c)(1)(C)(i)(I) of this title.

(B) Sales at nominal charge

Such other sales as the Secretary identifies as sales to an entity that are merely nominal in amount (as applied for purposes of section 1396r–8(c)(1)(C)(ii)(III) of this title, except as the Secretary may otherwise provide).

(3) Sale price net of discounts

In calculating the manufacturer’s average sales price under this subsection, such price shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1396r–8 of this title). For years after 2004, the Secretary may include in such price other price concessions, which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.

(4) Payment methodology in cases where average sales price during first quarter of sales is unavailable

In the case of a drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not sufficiently available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological based on—

(A) the wholesale acquisition cost; or

(B) the methodologies in effect under this part on November 1, 2003, to determine payment amounts for drugs or biologicals.

(5) Frequency of determinations

(A) In general on a quarterly basis

The manufacturer’s average sales price, for a drug or biological of a manufacturer, shall be calculated by such manufacturer under this subsection on a quarterly basis. In making such calculation insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks. For years after 2004, the Secretary may establish a uniform methodology under this subparagraph to estimate and apply such costs.

(B) Updates in payment amounts

The payment amounts under subsection (b) of this section shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer’s average sales price calculated for the most recent calendar quarter for which data is available.

(C) Use of contractors; implementation

The Secretary may contract with appropriate entities to calculate the payment amount under subsection (b) of this section. Notwithstanding any other provision of law, the Secretary may implement, by program instruction or otherwise, any of the provisions of this section.

(6) Definitions and other rules

In this section:

(A) Manufacturer

The term “manufacturer” means, with respect to a drug or biological, the manufacturer (as defined in section 1396r–8(k)(5) of this title).

(B) Wholesale acquisition cost

The term “wholesale acquisition cost” means, with respect to a drug or biological, the manufacturer’s list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

(C) Multiple source drug

(i) In general

The term “multiple source drug” means, for a calendar quarter, a drug for which there are 2 or more drug products which—

(I) are rated as therapeutically equivalent (under the Food and Drug Administration’s most recent publication of “Approved Drug Products with Therapeutic Equivalence Evaluations”),

(II) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

(III) are sold or marketed in the United States during the quarter.

(ii) Exception

With respect to single source drugs or biologicals that are within the same billing and payment code as of October 1, 2003, the Secretary shall treat such single source drugs or biologicals as if the single source drugs or biologicals were multiple source drugs.

(D) Single source drug or biological

The term “single source drug or biological” means—
(i) a biological; or
(ii) a drug which is not a multiple source drug and which is produced or distributed under a new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application.

(E) Exception from pharmaceutical equivalence and bioequivalence requirement

Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

(F) Determination of pharmaceutical equivalence and bioequivalence

For purposes of this paragraph—
(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and
(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they are shown to meet an appropriate standard of bioequivalence.

(G) Inclusion of vaccines

In applying provisions of section 1396r–8 of this title under this section, “other than a vaccine” is deemed deleted from section 1396r–8(k)(2)(B) of this title.

(H) Biosimilar biological product

The term “biosimilar biological product” means a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 262 of this title.

(I) Reference biological product

The term “reference biological product” means the biological product licensed under such section 262 of this title that is referred to in the application described in subparagraph (H) of the biosimilar biological product.

(d) Monitoring of market prices

(1) In general

The Inspector General of the Department of Health and Human Services shall conduct studies, which may include surveys, to determine the widely available market prices of drugs and biologicals to which this section applies, as the Inspector General, in consultation with the Secretary, determines to be appropriate.

(2) Comparison of prices

Based upon such studies and other data for drugs and biologicals, the Inspector General shall compare the average sales price under this section for drugs and biologicals with—
(A) the widely available market price for such drugs and biologicals (if any); and
(B) the average manufacturer price (as determined under section 1396r–8(k)(1) of this title) for such drugs and biologicals.

(3) Limitation on average sales price

(A) In general

The Secretary may disregard the average sales price for a drug or biological that exceeds the widely available market price or the average manufacturer price for such drug or biological by the applicable threshold percentage (as defined in subparagraph (B)).

(B) Applicable threshold percentage defined

In this paragraph, the term “applicable threshold percentage” means—
(i) in 2005, in the case of an average sales price for a drug or biological that exceeds widely available market price or the average manufacturer price, 5 percent; and
(ii) in 2006 and subsequent years, the percentage applied under this subparagraph subject to such adjustment as the Secretary may specify for the widely available market price or the average manufacturer price, or both.

(C) Authority to adjust average sales price

If the Inspector General finds that the average sales price for a drug or biological exceeds such widely available market price or average manufacturer price for such drug or biological by the applicable threshold percentage, the Inspector General shall inform the Secretary (at such times as the Secretary may specify to carry out this subparagraph) and the Secretary shall, effective as of the next quarter, substitute for the amount of payment otherwise determined under this section for such drug or biological the lesser of—
(i) the widely available market price for the drug or biological (if any); or
(ii) 103 percent of the average manufacturer price (as determined under section 1396r–8(k)(1) of this title) for the drug or biological.

(4) Civil money penalty

(A) In general

If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of the manufacturer’s average sales price for a drug or biological, the Secretary may apply a civil money penalty in an amount of up to $10,000 for each such price misrepresentation and for each day in which such price misrepresentation was applied.

(B) Procedures

The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to civil money penalties under subparagraph (B) in the same manner as they apply to a penalty or proceeding under section 1320a–7a(a) of this title.
(5) Widely available market price
(A) In general
In this subsection, the term “widely available market price” means the price that a prudent physician or supplier would pay for the drug or biological. In determining such price, the Inspector General shall take into account the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers for such drugs or biologicals.

(B) Considerations
In determining the price under subparagraph (A), the Inspector General shall consider information from one or more of the following sources:
(i) Manufacturers.
(ii) Wholesalers.
(iii) Distributors.
(iv) Physician supply houses.
(v) Specialty pharmacies.
(vi) Group purchasing arrangements.
(vii) Surveys of physicians.
(viii) Surveys of suppliers.
(ix) Information on such market prices from insurers.
(x) Information on such market prices from private health plans.

(e) Authority to use alternative payment in response to public health emergency
In the case of a public health emergency under section 247d of this title in which there is a documented inability to access drugs and biologicals, and a concomitant increase in the price, of a drug or biological which is not reflected in the manufacturer’s average sales price for one or more quarters, the Secretary may use the wholesale acquisition cost (or other reasonable measure of drug or biological price) instead of the manufacturer’s average sales price for such quarters and for subsequent quarters until the price and availability of the drug or biological has stabilized and is substantially reflected in the applicable manufacturer’s average sales price.

(f) Quarterly report on average sales price
For requirements for reporting the manufacturer’s average sales price (and, if required to make payment, the manufacturer’s wholesale acquisition cost) for the drug or biological under this section, see section 1395w–3(a)(2) of this title.

(g) Judicial review
There shall be no administrative or judicial review under section 1395w–3(h)(1) of this title, section 1395w–7 of this title, or otherwise, of—
(1) determinations of payment amounts under this section, including the assignment of National Drug Codes to billing and payment codes;
(2) the identification of units (and package size) under subsection (b)(2) of this section;
(3) the method to allocate rebates, chargebacks, and other price concessions to a quarter if specified by the Secretary;
(4) the manufacturer’s average sales price when it is used for the determination of a payment amount under this section; and
(5) the disclosure of the average manufacturer price by reason of an adjustment under subsection (d)(3)(C) or (e) of this section.


AMENDMENTS
2007—Subsec. (b)(1). Pub. L. 110–173, §112(b)(1), inserted “paragraph (7) and” after “Subject to” in introductory provisions.
Subsec. (b)(1)(A). Pub. L. 110–173, §112(a)(1), inserted “for a multiple source drug furnished before April 1, 2008, or 106 percent of the amount determined under paragraph (6) for a multiple source drug furnished on or after April 1, 2008” after “paragraph (3)”. Subsec. (b)(1)(A), (B). Pub. L. 110–173, §112(a)(2), inserted “for single source drugs and biologicals furnished before April 1, 2008, and using the methodology applied under paragraph (6) for single source drugs and biologicals furnished on or after April 1, 2008,” after “paragraph (3)”.

EFFECTIVE DATE OF 2010 AMENDMENT
Pub. L. 111–148, title III, §3139(b), Mar. 23, 2010, 124 Stat. 440, provided that: “The amendments made by subsection (a) (amending this section) shall apply to payments for biosimilar biological products beginning with the first day of the second calendar quarter after enactment of legislation providing for a biosimilar pathway (as determined by the Secretary [probably means the Secretary of Health and Human Services]).”

REPORT ON SALES TO PHARMACY BENEFIT MANAGERS
“(A) STUDY.—The Secretary [of Health and Human Services] shall conduct a study on sales of drugs and biologicals to large volume purchasers, such as pharmacy benefit managers and health maintenance organizations, for purposes of determining whether the price at which such drugs and biologicals are sold to such purchasers does not represent the price such drugs and biologicals are made available for purchase to prudent physicians.
“(B) REPORT.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the study conducted under paragraph (1), and shall include recommendations on whether such sales to large volume purchasers should be excluded from the computation of a manufacturer’s average sales price under section 1847A of the Social Security Act [this section], as added by paragraph (1).”

INSPECTOR GENERAL REPORT ON ADEQUACY OF REIMBURSEMENT RATE UNDER AVERAGE SALES PRICE METHODOLOGY
“(A) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study on the ability of physician practices in the specialties of hematology, hematologic/oncology, and medical oncology of different sizes, especially particularly

1 So in original. The comma probably should not appear.
large practices, to obtain drugs and biologicals for the treatment of cancer patients at 106 percent of the average sales price for the drugs and biologicals. In conducting the study, the Inspector General shall conduct an audit of a representative sample of such practices to determine the adequacy of reimbursement under section 1847A of the Social Security Act [this section], as added by paragraph (1).

"(B) REPORT.—Not later October 1, 2005, the Inspector General shall submit to Congress a report on the study conducted under subparagraph (A), and shall include recommendations on the adequacy of reimbursement for such drugs and biologicals under such section 1847A [this section]."

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 303 of Pub. L. 108–173, set out as a note under section 1395u of this title.

§ 1395w–3b. Competitive acquisition of outpatient drugs and biologicals

(a) Implementation of competitive acquisition

(1) Implementation of program

(A) In general

The Secretary shall establish and implement a competitive acquisition program under which—

(i) competitive acquisition areas are established for contract award purposes for acquisition of and payment for categories of competitively biddable drugs and biologicals (as defined in paragraph (2)) under this part;

(ii) each physician is given the opportunity annually to elect to obtain drugs and biologicals under the program, rather than under section 1395w–3a of this title; and

(iii) each physician who elects to obtain drugs and biologicals under the program makes an annual selection under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part.

This section shall not apply in the case of a physician who elects section 1395w–3a of this title to apply.

(B) Implementation

For purposes of implementing the program, the Secretary shall establish categories of competitively biddable drugs and biologicals. The Secretary shall phase in the program with respect to those categories beginning in 2006 in such manner as the Secretary determines to be appropriate.

(C) Waiver of certain provisions

In order to promote competition, in carrying out the program the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) Exclusion authority

The Secretary may exclude competitively biddable drugs and biologicals (including a class of such drugs and biologicals) from the competitive bidding system under this section if the application of competitive bidding to such drugs or biologicals—

(i) is not likely to result in significant savings; or

(ii) is likely to have an adverse impact on access to such drugs or biologicals.

(2) Competitively biddable drugs and biologicals and program defined

For purposes of this section—

(A) Competitively biddable drugs and biologicals defined

The term "competitively biddable drugs and biologicals" means a drug or biological described in section 1395u(o)(1)(C) of this title and furnished on or after January 1, 2006.

(B) Program

The term "program" means the competitive acquisition program under this section.

(C) Competitive acquisition area; area

The terms "competitive acquisition area," and "area" mean an appropriate geographic region established by the Secretary under the program.

(D) Contractor

The term "contractor" means an entity that has entered into a contract with the Secretary under this section.

(3) Application of program payment methodology

(A) In general

With respect to competitively biddable drugs and biologicals which are supplied under the program in an area and which are prescribed by a physician who has elected this section to apply—

(i) the claim for such drugs and biologicals shall be submitted by the contractor that supplied the drugs and biologicals;

(ii) collection of amounts of any deductible and coinsurance applicable with respect to such drugs and biologicals shall be the responsibility of such contractor and shall not be collected unless the drug or biological is administered to the individual involved; and

(iii) the payment under this section (and related amounts of any applicable deductible and coinsurance) for such drugs and biologicals shall be made only to such contractor upon receipt of a claim for a drug or biological supplied by the contractor for administration to a beneficiary.

(B) Process for adjustments

The Secretary shall provide a process for adjustments to payments in the case in
which payment is made for drugs and biologicals which were billed at the time of dispensing but which were not actually administered.

(C) Information for purposes of cost-sharing

The Secretary shall provide a process by which physicians submit information to contractors for purposes of the collection of any applicable deductible or coinsurance amounts under subparagraph (A)(ii).

(D) Post-payment review process

The Secretary shall establish (by program instruction or otherwise) a post-payment review process (which may include the use of statistical sampling) to assure that payment is made for a drug or biological under this section only if the drug or biological has been administered to a beneficiary. The Secretary may provide and with respect to which the program applies unless—

(i) Capacity to supply competitively bidable drug or biological within category

(I) In general

The entity has sufficient arrangements to acquire and to deliver competitively biddable drugs and biologicals within such category in the area specified in the contract.

(II) Shipment methodology

The entity has arrangements in effect for the shipment at least 5 days each week of competitively biddable drugs and biologicals under the contract and for the prompt response and resolution of complaints of physicians and individuals and of inquiries regarding the shipment of competitively biddable drugs and biologicals; and

(ii) Quality, service, financial performance and solvency standards

The entity meets quality, service, financial performance, and solvency standards specified by the Secretary, including—

(I) the establishment of procedures for the prompt response and resolution of complaints of physicians and individuals and of inquiries regarding the shipment of competitively biddable drugs and biologicals; and

(II) a grievance and appeals process for the resolution of disputes.

(B) Additional considerations

The Secretary may refuse to award a contract under this section, and may terminate such a contract, with an entity based upon—

(i) the suspension or revocation, by the Federal Government or a State government, of the entity’s license for the dis-
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See References in Text note below.

(3) Awarding multiple contracts for a category and area.

The Secretary may limit (but not below 2) the number of qualified entities that are awarded such contracts for any category and area. The Secretary shall select among qualified entities based on the following:

(A) The bid prices for competitively biddable drugs and biologicals within the category and area.

(B) Bid price for distribution of such drugs and biologicals.

(C) Ability to ensure product integrity.

(D) Customer service.

(E) Past experience in the distribution of drugs and biologicals, including controlled substances.

(F) Such other factors as the Secretary may specify.

(4) Terms of contracts

(A) In general

A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify consistent with this section.

(B) Period of contracts

A contract under this section shall be for a term of 3 years, but may be terminated by the Secretary or the entity with appropriate, advance notice.

(C) Integrity of drug and biological distribution system

A contractor (as defined in subsection (a)(2)(D) of this section) shall—

(i) acquire all drug and biological products it distributes directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer; and

(ii) comply with any product integrity safeguards as may be determined to be appropriate by the Secretary.

Nothing in this subparagraph shall be construed to relieve or exempt any contractor from the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] that relate to the wholesale distribution of prescription drugs or biologicals.

(D) Compliance with code of conduct and fraud and abuse rules

Under the contract—

(i) the contractor shall comply with a code of conduct, specified or recognized by the Secretary, that includes standards relating to conflicts of interest; and

(ii) the contractor shall comply with all applicable provisions relating to prevention of fraud and abuse, including compliance with applicable guidelines of the Department of Justice and the Inspector General of the Department of Health and Human Services.

(E) Direct delivery of drugs and biologicals to physicians

Under the contract the contractor shall only supply competitively biddable drugs and biologicals directly to the selecting physicians and not directly to individuals, except under circumstances and settings where an individual currently receives a drug or biological in the individual’s home or other non-physician office setting as the Secretary may provide. The contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. This section does not—

(i) require a physician to submit a prescription for each individual treatment; or

(ii) change a physician’s flexibility in terms of writing a prescription for drugs or biologicals for a single treatment or a course of treatment.

(5) Permitting access to drugs and biologicals

The Secretary shall establish rules under this section under which drugs and biologicals which are acquired through a contractor under this section may be used to resupply inventories of such drugs and biologicals which are administered consistent with safe drug practices and with adequate safeguards against fraud and abuse. The previous sentence shall apply if the physicians can demonstrate to the Secretary all of the following:

(A) The drugs or biologicals are required immediately.

(B) The physician could not have reasonably anticipated the immediate requirement for the drugs or biologicals.

(C) The contractor could not deliver to the physician the drugs or biologicals in a timely manner.

(D) The drugs or biologicals were administered in an emergency situation.

(6) Construction

Nothing in this section shall be construed as waiving applicable State requirements relating to licensing of pharmacies.

(c) Bidding process

(1) In general

In awarding a contract for a category of drugs and biologicals in an area under the program, the Secretary shall consider with respect to each entity seeking to be awarded a contract the bid price and the other factors referred to in subsection (b)(3) of this section.

(2) Bid defined

In this section, the term “bid” means an offer to furnish a competitively biddable drug...
or biological for a particular price and time period.

(3) Bidding on a national or regional basis

Nothing in this section shall be construed as precluding a bidder from bidding for contracts in all areas of the United States or as requiring a bidder to submit a bid for all areas of the United States.

(4) Uniformity of bids within area

The amount of the bid submitted under a contract offer for any competitively biddable drug or biological for an area shall be the same for that drug or biological for all portions of that area.

(5) Confidentiality of bids

The provisions of subparagraph (D) of section 1396r–8(b)(3) of this title shall apply to periods during which a bid is submitted with respect to a competitively biddable drug or biological under this section in the same manner as it applies to information disclosed under such section, except that any reference—

(A) in that subparagraph to a “manufacturer or wholesaler” is deemed a reference to a “bidder” under this section;

(B) in that section to “prices charged for drugs” is deemed a reference to a “bid” submitted under this section; and

(C) in clause (i) of that section to “this section”, is deemed a reference to “part B of subchapter XVIII of this chapter”.

(6) Inclusion of costs

The bid price submitted in a contract offer for a competitively biddable drug or biological shall—

(A) include all costs related to the delivery of the drug or biological to the selecting physician (or other point of delivery); and

(B) include the costs of dispensing (including shipping) of such drug or biological and management fees, but shall not include any costs related to the administration of the drug or biological, or wastage, spillage, or spoilage.

(7) Price adjustments during contract period; disclosure of costs

Each contract awarded shall provide for—

(A) disclosure to the Secretary the contractor’s reasonable, net acquisition costs for periods specified by the Secretary, not more often than quarterly, of the contract; and

(B) appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a contractor’s reasonable, net acquisition costs, as so disclosed.

(d) Computation of payment amounts

(1) In general

Payment under this section for competitively biddable drugs or biologicals shall be based on bids submitted and accepted under this section for such drugs or biologicals in an area. Based on such bids the Secretary shall determine a single payment amount for each competitively biddable drug or biological in the area.

(2) Special rules

The Secretary shall establish rules regarding the use under this section of the alternative payment amount provided under section 1395w–3a of this title to the use of a price for specific competitively biddable drugs and biologicals in the following cases:

(A) New drugs and biologicals

A competitively biddable drug or biological for which a payment and billing code has not been established.

(B) Other cases

Such other exceptional cases as the Secretary may specify in regulations.

(e) Cost-sharing

(1) Application of coinsurance

Payment under this section for competitively biddable drugs and biologicals shall be in an amount equal to 80 percent of the payment basis described in subsection (d)(1) of this section.

(2) Deductible

Before applying paragraph (1), the individual shall be required to meet the deductible described in section 1395(b) of this title.

(3) Collection

Such coinsurance and deductible shall be collected by the contractor that supplies the drug or biological involved. Subject to subsection (a)(3)(B) of this section, such coinsurance and deductible may be collected in a manner similar to the manner in which the coinsurance and deductible are collected for durable medical equipment under this part.

(f) Special payment rules

(1) Use in exclusion cases

If the Secretary excludes a drug or biological (or class of drugs or biologicals) under subsection (a)(1)(D) of this section, the Secretary may provide for payment to be made under this part for such drugs and biologicals (or class) using the payment methodology under section 1395w–3a of this title.

(2) Application of requirement for assignment

For provision requiring assignment of claims for competitively biddable drugs and biologicals, see section 1395u(o)(3) of this title.

(3) Protection for beneficiary in case of medical necessity denial

For protection of individuals against liability in the case of medical necessity determinations, see section 1395w–3b of this title.

(g) Judicial 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 establishment of payment amounts under subsection (d)(1) of this section;

(2) the awarding of contracts under this section; and

(3) the establishment of competitive acquisition areas under subsection (a)(2)(C) of this section.
§ 1395w–4. Payment for physicians’ services
(a) Payment based on fee schedule

(1) In general
Effective for all physicians’ services (as defined in subsection (j)(3) of this section) furnished under this part during a year (beginning with January 1, 2007) for which payment is otherwise made on the basis of a reasonable charge or on the basis of a fee schedule under section 1395m(b) of this title, payment under this part shall instead be based on the lesser of—
(A) the actual charge for the service, or
(B) subject to the succeeding provisions of this subsection, the amount determined under the fee schedule established under subsection (b) of this section for services furnished during that year (in this subsection referred to as the “fee schedule amount”).

(2) Transition to full fee schedule

(A) Limiting reductions and increases to 15 percent in 1992

(i) Limit on increase

In the case of a service in a fee schedule area (as defined in subsection (j)(2) of this section) for which the adjusted historical payment basis (as defined in subparagraph (D)) is less than 85 percent of the fee schedule amount for services furnished in 1992, there shall be substituted for the fee schedule amount an amount equal to the adjusted historical payment basis plus 15 percent of the fee schedule amount otherwise established (without regard to this paragraph).

(ii) Limit in reduction

In the case of a service in a fee schedule area for which the adjusted historical payment basis exceeds 115 percent of the fee schedule amount for services furnished in 1992, there shall be substituted for the fee schedule amount an amount equal to the adjusted historical payment basis minus 15 percent.


 EFFECTIVE DATE OF 2006 AMENDMENT

(1) requiring the conduct of any additional competition under subsection (b)(1) of section 1874B of the Social Security Act (42 U.S.C. 1395w–3b)—

‘‘(i) on or after April 1, 2007; and

‘‘(ii) on or after July 1, 2006, and before April 1, 2007, for claims that are unpaid as of April 1, 2007.’’

CONSTRUCTION OF 2006 AMENDMENT
Pub. L. 109–432, div. B, title I, § 108(b), Dec. 20, 2006, 120 Stat. 2983, provided that: ‘‘Not later than July 1, 2006, the Secretary of Health and Human Services shall submit to Congress a report on the program conducted under section 1874B of the Social Security Act [this section], as added by paragraph (1). Such report shall include information on savings, reductions in cost-sharing, access to competitively biddable drugs and biologicals, the range of choices of contractors available to physicians, the satisfaction of physicians and of individuals enrolled under this part [probably means part B of title XVIII of the Social Security Act, which is classified to this part], and information comparing prices for drugs and biologicals under such section and section 1847A of such Act [section 1395w–3a of this title], as added by subsection (c).’’

APPLICATION OF 2003 AMENDMENT TO PHYSICIAN SPECIALTIES

Amendment by section 303 of Pub. L. 109–432, 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 subsection, see section 303(j) of Pub. L. 109–432, set out as a note under section 1395w et seq. of this title.

Notwithstanding section 303(j) of Pub. L. 109–432 (see note above), amendment by section 303 of Pub. L. 109–432 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. 109–432, set out as a note under section 1395w et seq. of this title.

§ 1395w–4. Payment for physicians’ services (a) Payment based on fee schedule

(1) In general

Effective for all physicians’ services (as defined in subsection (j)(3) of this section) furnished under this part during a year (beginning with January 1, 2007) for which payment is otherwise made on the basis of a reasonable charge or on the basis of a fee schedule under section 1395m(b) of this title, payment under this part shall instead be based on the lesser of—

(A) the actual charge for the service, or

(B) subject to the succeeding provisions of this subsection, the amount determined under the fee schedule established under subsection (b) of this section for services furnished during that year (in this subsection referred to as the “fee schedule amount”).

(2) Transition to full fee schedule

(A) Limiting reductions and increases to 15 percent in 1992

(i) Limit on increase

In the case of a service in a fee schedule area (as defined in subsection (j)(2) of this section) for which the adjusted historical payment basis (as defined in subparagraph (D)) is less than 85 percent of the fee schedule amount for services furnished in 1992, there shall be substituted for the fee schedule amount an amount equal to the adjusted historical payment basis plus 15 percent of the fee schedule amount otherwise established (without regard to this paragraph).

(ii) Limit in reduction

In the case of a service in a fee schedule area for which the adjusted historical payment basis exceeds 115 percent of the fee schedule amount for services furnished in 1992, there shall be substituted for the fee schedule amount an amount equal to the adjusted historical payment basis minus 15 percent.
provide for a transition in the same manner under subparagraph (B). With respect to services (including radiologist services, as defined in section 1395m(b)(6) of this title), but excluding nuclear medicine services that are subject to section 6105(b) of the Omnibus Budget Reconciliation Act of 1989, there shall be substituted for the weighted average prevailing charge the amount provided under section 6105(b) of the Omnibus Budget Reconciliation Act of 1989.

(3) Incentives for participating physicians and suppliers

In applying paragraph (1)(B) in the case of a nonparticipating physician or a nonparticipating supplier or other person, the fee schedule amount shall be 95 percent of such amount otherwise applied under this subsection (without regard to this paragraph). In the case of physicians’ services (including services which the Secretary excludes pursuant to subsection (j)(3) of this section) of a nonparticipating physician, supplier, or other person for which payment is made under this part on a basis other than the fee schedule amount, the payment shall be based on 95 percent of the payment basis for such services furnished by a participating physician, supplier, or other person.

(4) Special rule for medical direction

(A) In general

With respect to physicians’ services furnished on or after January 1, 1994, and consisting of medical direction of two, three, or four concurrent anesthesia cases, except as provided in paragraph (5), the fee schedule amount to be applied shall be equal to one-half of the amount described in subparagraph (B).

(B) Amount

The amount described in this subparagraph, for a physician’s medical direction of the performance of anesthesia services, is the following percentage of the fee schedule amount otherwise applicable under this section if the anesthesia services were personally performed by the physician alone:

(i) For services furnished during 1994, 120 percent.
(ii) For services furnished during 1995, 115 percent.
(iii) For services furnished during 1996, 110 percent.
(iv) For services furnished during 1997, 105 percent.
(v) For services furnished after 1997, 100 percent.

(5) Incentives for electronic prescribing

(A) Adjustment

Subject to subparagraph (B) and subsection (m)(2)(B), with respect to covered professional services furnished by an eligible professional during 2012, 2013 or 2014, if the eligible professional is not a successful electronic prescriber for the reporting period for the year (as determined under subsection (m)(3)(B)), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection (determined after application of paragraph (3) but without regard to this paragraph).

(ii) Applicable percent

For purposes of clause (i), the term “applicable percent” means—
(I) for 2012, 99 percent;
(II) for 2013, 98.5 percent; and
(III) for 2014, 98 percent.

(B) Significant hardship exception

The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a successful electronic prescriber would result in a significant hardship, such as in the case of an eligible professional who practices in a rural area without sufficient Internet access.

(C) Application

(i) Physician reporting system rules

Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this paragraph in the same manner as they apply for purposes of such subsection.

(ii) Incentive payment validation rules

Clauses (ii) and (iii) of subsection (m)(5)(D) shall apply for purposes of this paragraph in a similar manner as they apply for purposes of such subsection.

(D) Definitions

For purposes of this paragraph:

(i) Eligible professional; covered professional services

The terms “eligible professional” and “covered professional services” have the meanings given such terms in subsection (k)(3).

(ii) Physician reporting system

The term “physician reporting system” means the system established under subsection (k).

(iii) Reporting period

The term “reporting period” means, with respect to a year, a period specified by the Secretary.

(6) Special rule for teaching anesthesiologists

With respect to physicians’ services furnished on or after January 1, 2010, in the case of teaching anesthesiologists involved in the training of physician residents in a single anesthesia case or two concurrent anesthesia cases, the fee schedule amount to be applied shall be 100 percent of the fee schedule amount otherwise applicable under this section if the anesthesia services were personally performed by the teaching anesthesiologist alone and paragraph (4) shall not apply if—

(A) the teaching anesthesiologist is present during all critical or key portions of the anesthesia service or procedure involved; and

(B) the teaching anesthesiologist (or another anesthesiologist with whom the teaching anesthesiologist has entered into an arrangement) is immediately available to furnish anesthesia services during the entire procedure.

(7) Incentives for meaningful use of certified EHR technology

(A) Adjustment

(i) In general

Subject to subparagraphs (B) and (D), with respect to covered professional services furnished by an eligible professional during 2015 or any subsequent payment year, if the eligible professional is not a meaningful EHR user (as determined under paragraph (k)) for an EHR reporting period for the year, the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection (determined after application of paragraph (3) but without regard to this paragraph).

(ii) Applicable percent

Subject to clause (iii), for purposes of clause (i), the term “applicable percent” means—
(I) for 2015, 99 percent (or, in the case of an eligible professional who was subject to the application of the payment adjustment under subsection (a)(5) for 2014, 98 percent);
(II) for 2016, 98 percent; and
(III) for 2017 and each subsequent year, 97 percent.

(iii) Authority to decrease applicable percentage for 2018 and subsequent years

For 2018 and each subsequent year, if the Secretary finds that the proportion of eligible professionals who are meaningful EHR users (as determined under subsection (o)(2)) is less than 75 percent, the
applicable percent shall be decreased by 1 percentage point from the applicable percent in the preceding year, but in no case shall the applicable percent be less than 95 percent.

(B) Significant hardship exception
The Secretary may, on a case-by-case basis, exempt an eligible professional from the application of the payment adjustment under subparagraph (A) if the Secretary determines, subject to annual renewal, that compliance with the requirement for being a meaningful EHR user would result in a significant hardship, such as in the case of an eligible professional who practices in a rural area without sufficient Internet access. In no case may an eligible professional be granted an exemption under this subparagraph for more than 5 years.

(C) Application of physician reporting system rules
Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this paragraph in the same manner as they apply for purposes of such subsection.

(D) Non-application to hospital-based eligible professionals
No payment adjustment may be made under subparagraph (A) in the case of hospital-based eligible professionals (as defined in subsection (o)(1)(C)(ii)).

(E) Definitions
For purposes of this paragraph:

(i) Covered professional services
The term “covered professional services” has the meaning given such term in subsection (k)(3).

(ii) EHR reporting period
The term “EHR reporting period” means, with respect to a year, a period (or periods) specified by the Secretary.

(iii) Eligible professional
The term “eligible professional” means a physician, as defined in section 1395x(r) of this title.

(8) Incentives for quality reporting

(A) Adjustment

(i) In general
With respect to covered professional services furnished by an eligible professional during 2015 or any subsequent year, if the eligible professional does not satisfactorily submit data on quality measures for covered professional services for the quality reporting period for the year (as determined under subsection (m)(3)(A)), the fee schedule amount for such services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services under this subsection (determined after application of paragraphs (3), (5), and (7), but without regard to this paragraph).

(ii) Applicable percent
For purposes of clause (i), the term “applicable percent” means—

(I) for 2015, 98.5 percent; and

(II) for 2016 and each subsequent year, 98 percent.

(B) Application

(i) Physician reporting system rules
Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this paragraph in the same manner as they apply for purposes of such subsection.

(ii) Incentive payment validation rules
Clauses (ii) and (iii) of subsection (m)(5)(D) shall apply for purposes of this paragraph in a similar manner as they apply for purposes of such subsection.

(C) Definitions
For purposes of this paragraph:

(i) Eligible professional; covered professional services
The terms “eligible professional” and “covered professional services” have the meanings given such terms in subsection (k)(3).

(ii) Physician reporting system
The term “physician reporting system” means the system established under subsection (k).

(iii) Quality reporting period
The term “quality reporting period” means, with respect to a year, a period specified by the Secretary.

(b) Establishment of fee schedules

(1) In general
Before November 1 of the preceding year, for each year beginning with 1998, subject to subsection (p), the Secretary shall establish, by regulation, fee schedules that establish payment amounts for all physicians’ services furnished in all fee schedule areas (as defined in subsection (j)(2) of this section) for the year. Except as provided in paragraph (2), each such payment amount for a service shall be equal to the product of—

(A) the relative value for the service (as determined in subsection (c)(2) of this section),

(B) the conversion factor (established under subsection (d) of this section) for the year, and

(C) the geographic adjustment factor (established under subsection (e)(2) of this section) for the service for the fee schedule area.

(2) Treatment of radiology services and anesthesia services

(A) Radiology services
With respect to radiology services (including radiologist services, as defined in section 1395m(b)(6) of this title), the Secretary shall base the relative values on the relative value
scale developed under section 1395m(b)(1)(A) of this title, with appropriate modifications of the relative values to assure that the relative values established for radiology services which are similar or related to other physicians' services are consistent with the relative values established for those similar or related services.

(B) Anesthesia services

In establishing the fee schedule for anesthesia services for which a relative value guide has been established under section 4048(b) of the Omnibus Budget Reconciliation Act of 1987, the Secretary shall, to the extent practicable, adjust the relative value guide, with appropriate adjustment of the conversion factor, in a manner to assure that the fee schedule amounts for anesthesia services are consistent with the fee schedule amounts for other services determined by the Secretary to be of comparable value. In applying the previous sentence, the Secretary shall adjust the conversion factor by geographic adjustment factors in the same manner as such adjustment is made under paragraph (1)(C).

(C) Consultation

The Secretary shall consult with the Physician Payment Review Commission and organizations representing physicians or suppliers who furnish radiology services and anesthesia services in applying subparagraphs (A) and (B).

(3) Treatment of interpretation of electrocardiograms

The Secretary—

(A) shall make separate payment under this section for the interpretation of electrocardiograms performed or ordered to be performed as part of or in conjunction with a visit to or a consultation with a physician, and

(B) shall adjust the relative values established for visits and consultations under subsection (c) of this section so as not to include relative value units for interpretations of electrocardiograms in the relative value for visits and consultations.

(4) Special rule for imaging services

(A) In general

In the case of imaging services described in subparagraph (B) furnished on or after January 1, 2007, if—

(i) the technical component (including the technical component portion of a global fee) of the service established for a year under the fee schedule described in paragraph (1) without application of the geographic adjustment factor described in paragraph (1)(C), exceeds

(ii) the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of section 1395(t) of this title for such service for such year, determined without regard to geographic adjustment under paragraph (2)(D) of such section,

the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor described in paragraph (1)(C), for the fee schedule amount for such technical component for such year.

(B) Imaging services described

For purposes of subparagraph (A), imaging services described in this subparagraph are imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography, and for 2010 and 2011, dual-energy x-ray absorptiometry services (as described in paragraph (6)).

(C) Adjustment in imaging utilization rate

With respect to fee schedules established for 2011 and subsequent years, in the methodology for determining practice expense relative value units for expensive diagnostic imaging equipment under the final rule published by the Secretary in the Federal Register on November 25, 2009 (42 CFR 410 et al.), the Secretary shall use a 75 percent assumption instead of the utilization rates otherwise established in such final rule.

(D) Adjustment in technical component discount on single-session imaging involving consecutive body parts

For services furnished on or after July 1, 2010, the Secretary shall increase the reduction in payments attributable to the multiple procedure payment reduction applicable to the technical component for imaging under the final rule published by the Secretary in the Federal Register on November 21, 2005 (part 405 of title 42, Code of Federal Regulations) from 25 percent to 50 percent.

(5) Treatment of intensive cardiac rehabilitation program

(A) In general

In the case of an intensive cardiac rehabilitation program described in section 1395x(eee)(4) of this title, the Secretary shall substitute the Medicare OPD fee schedule amount established under the prospective payment system for hospital outpatient department services under paragraph (3)(D) of section 1395(t) of this title for cardiac rehabilitation (under HCPCS codes 93797 and 93798 for calendar year 2007, or any succeeding HCPCS codes for cardiac rehabilitation).

(B) Definition of session

Each of the services described in subparagraphs (A) through (E) of section 1395x(eee)(3) of this title, when furnished for one hour, is a separate session of intensive cardiac rehabilitation.

(C) Multiple sessions per day

Payment may be made for up to 6 sessions per day of the series of 72 one-hour sessions of intensive cardiac rehabilitation services described in section 1395x(eee)(4)(B) of this title.
(6) Determination of relative values for physicians' services

For dual-energy x-ray absorptiometry services (identified in 2006 by HCPCS codes 76075 and 76077 (and any succeeding codes)) furnished during 2010 and 2011, instead of the payment amount that would otherwise be determined under this section for such years, the payment amount shall be equal to 70 percent of the product of—

(A) the relative value for the service (as determined in subsection (c)(2)) for 2006;

(B) the conversion factor (established under subsection (d)) for 2006; and

(C) the geographic adjustment factor (established under subsection (e)(2)) for the service for the fee schedule area for 2010 and 2011, respectively.

(7) Adjustment in discount for certain multiple therapy services

In the case of therapy services furnished on or after January 1, 2011, and for which payment is made under fee schedules established under this section, instead of the 25 percent multiple procedure payment reduction specified in the final rule published by the Secretary in the Federal Register on November 29, 2010, the reduction percentage shall be 20 percent.

(c) Determination of relative values for physicians' services

(1) Division of physicians' services into components

In this section, with respect to a physicians' service:

(A) "Work component" defined

The term "work component" means the portion of the resources used in furnishing the service that reflects physician time and intensity in furnishing the service. Such portion shall—

(i) include activities before and after direct patient contact, and

(ii) be defined, with respect to surgical procedures, to reflect a global definition including pre-operative and post-operative physicians' services.

(B) "Practice expense component" defined

The term "practice expense component" means the portion of the resources used in furnishing the service that reflects the general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising practice expenses.

(C) "Malpractice component" defined

The term "malpractice component" means the portion of the resources used in furnishing the service that reflects malpractice expenses in furnishing the service.

(2) Determination of relative values

(A) In general

(i) Combination of units for components

The Secretary shall develop a methodology for combining the work, practice expense, and malpractice relative value units, determined under subparagraph (C), for each service in a manner to produce a single relative value for that service. Such relative values are subject to adjustment under subparagraph (F)(i) and section 13515(b) of the Omnibus Budget Reconciliation Act of 1993.

(ii) Extrapolation

The Secretary may use extrapolation and other techniques to determine the number of relative value units for physicians' services for which specific data are not available and shall take into account recommendations of the Physician Payment Review Commission and the results of consultations with organizations representing physicians who provide such services.

(B) Periodic review and adjustments in relative values

(i) Periodic review

The Secretary, not less often than every 5 years, shall review the relative values established under this paragraph for all physicians' services.

(ii) Adjustments

(I) In general

The Secretary shall, to the extent the Secretary determines to be necessary and subject to subclause (II), adjust the number of such units to take into account changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures. The Secretary shall publish an explanation of the basis for such adjustments.

(II) Limitation on annual adjustments

Subject to clauses (iv) and (v), the adjustments under subclause (I) for a year may not cause the amount of expenditures under this part for the year to differ by more than $29,000,000 from the amount of expenditures under this part that would have been made if such adjustments had not been made.

(iii) Consultation

The Secretary, in making adjustments under clause (ii), shall consult with the Medicare Payment Advisory Commission and organizations representing physicians.

(iv) Exemption of certain additional expenditures from budget neutrality

The additional expenditures attributable to—

(I) subparagraph (H) shall not be taken into account in applying clause (ii)(II) for 2004;

(II) subparagraph (I) insofar as it relates to a physician fee schedule for 2005 or 2006 shall not be taken into account in applying clause (ii)(II) for drug administration services under the fee schedule for such year for a specialty described in subparagraph (I)(ii)(II);

(III) subparagraph (J) insofar as it relates to a physician fee schedule for 2005
or 2006 shall not be taken into account in applying clause (i)(II) for drug administration services under the fee schedule for such year; and

(IV) subsection (b)(6) shall not be taken into account in applying clause (i)(II) for 2010 or 2011.

(v) Exemption of certain reduced expenditures from budget-neutrality calculation

The following reduced expenditures, as estimated by the Secretary, shall not be taken into account in applying clause (i)(II):

(I) Reduced payment for multiple imaging procedures

Effective for fee schedules established beginning with 2007, reduced expenditures attributable to subsection (b)(4).

(II) OPD payment cap for imaging services

Effective for fee schedules established beginning with 2007, reduced expenditures attributable to subsection (b)(4).

(III) Change in utilization rate for certain imaging services

Effective for fee schedules established beginning with 2011, reduced expenditures attributable to the change in the utilization rate applicable to 2011, as described in subsection (b)(4)(C).


(VI) Additional reduced payment for multiple imaging procedures

Effective for fee schedules established beginning with 2011, reduced expenditures attributable to the change in the multiple procedure payment reduction for imaging under the final rule published by the Secretary in the Federal Register on November 21, 2005 (42 CFR 405, et al.) insofar as it relates to the physician fee schedules for 2006 and 2007.

(ii) Practice expense relative value units

The Secretary shall determine a number of practice expense relative value units for the service for years before 1999 equal to the product of—

(I) the base allowed charges (as defined in subparagraph (D)) for the service, and

(II) the practice expense percentage for the service (as determined under paragraph (3)(C)(ii)),

and for years beginning with 1999 based on the relative practice expense resources involved in furnishing the service. For 1999, such number of units shall be determined based 75 percent on such product and based 25 percent on the relative practice expense resources involved in furnishing the service. For 2000, such number of units shall be determined based 50 percent on such product and based 50 percent on such relative practice expense resources. For 2001, such number of units shall be determined based 50 percent on such product and based 50 percent on such relative practice expense resources. For a subsequent year, such number of units shall be determined based entirely on such relative practice expense resources.

(iii) Malpractice relative value units

The Secretary shall determine a number of malpractice relative value units for the service for years before 2000 equal to the product of—

(I) the base allowed charges (as defined in subparagraph (D)) for the service, and

(II) the malpractice percentage for the service (as determined under paragraph (3)(C)(iii)),

and for years beginning with 2000 based on the malpractice expense resources involved in furnishing the service.

(D) “Base allowed charges” defined

In this paragraph, the term “base allowed charges” means, with respect to a physician’s service, the national average allowed charges for the service under this part for services furnished during 1991, as estimated by the Secretary using the most recent data available.

(E) Reduction in practice expense relative value units for certain services

(i) In general

Subject to clause (ii), the Secretary shall reduce the practice expense relative value
units applied to services described in clause (iii) furnished in—
(I) 1994, by 25 percent of the number by which the number of practice expense relative value units (determined for 1994 without regard to this subparagraph) exceeds the number of work relative value units determined for 1994,
(II) 1995, by an additional 25 percent of such excess, and
(III) 1996, by an additional 25 percent of such excess.

(ii) Floor on reductions
The practice expense relative value units for a physician’s service shall not be reduced under this subparagraph to a number less than 128 percent of the number of work relative value units.

(iii) Services covered
For purposes of clause (i), the services described in this clause are physicians’ services that are not described in clause (ii) and for which—
(I) there are work relative value units, and
(II) the number of practice expense relative value units (determined for 1994) exceeds 128 percent of the number of work relative value units (determined for such year).

(iv) Excluded services
For purposes of clause (iii), the services described in this clause are services which the Secretary determines at least 75 percent of which are provided under this subchapter in an office setting.

(F) Budget neutrality adjustments
The Secretary—
(i) shall reduce the relative values for all services (other than anesthesia services) established under this paragraph (and, in the case of anesthesia services, the conversion factor established by the Secretary for such services) by such percentage as the Secretary determines to be necessary so that, beginning in 1996, the amendment made by section 13514(a) of the Omnibus Budget Reconciliation Act of 1993 would not result in expenditures under this section that exceed the amount of such expenditures that would have been made if such amendment had not been made, and
(ii) shall reduce the amounts determined under subsection (a)(2)(B)(ii)(I) of this section by such percentage as the Secretary determines to be required to assure that, taking into account the reductions made under clause (i), the amendment made by section 13514(a) of the Omnibus Budget Reconciliation Act of 1993 would not result in expenditures under this section in 1994 that exceed the amount of such expenditures that would have been made if such amendment had not been made.

(G) Adjustments in relative value units for 1998

(i) In general
The Secretary shall—
(I) subject to clauses (iv) and (v), reduce the practice expense relative value units applied to any services described in clause (ii) furnished in 1998 to a number equal to 110 percent of the number of work relative value units, and
(II) increase the practice expense relative value units for office visit procedure codes during 1998 by a uniform percentage which the Secretary estimates will result in an aggregate increase in payments for such services equal to the aggregate decrease in payments by reason of subclause (I).

(ii) Services covered
For purposes of clause (i), the services described in this clause are physicians’ services that are not described in clause (iii) and for which—
(I) there are work relative value units, and
(II) the number of practice expense relative value units (determined for 1998) exceeds 110 percent of the number of work relative value units (determined for such year).

(iii) Excluded services
For purposes of clause (ii), the services described in this clause are services which the Secretary determines at least 75 percent of which are provided under this subchapter in an office setting.

(iv) Limitation on aggregate reallocation
If the application of clause (i)(I) would result in an aggregate amount of reductions under such clause in excess of $390,000,000, such clause shall be applied by substituting for 110 percent such greater percentage as the Secretary estimates will result in the aggregate amount of such reductions equaling $390,000,000.

(v) No reduction for certain services
Practice expense relative value units for a procedure performed in an office or in a setting out of an office shall not be reduced under clause (i) if the in-office or out-of-office practice expense relative value, respectively, for the procedure would increase under the proposed rule on resource-based practice expenses issued by the Secretary on June 18, 1997 (62 Federal Register 33153 et seq.).

(H) Adjustments in practice expense relative value units for certain drug administration services beginning in 2004

(i) Use of survey data
In establishing the physician fee schedule under subsection (b) of this section with respect to payments for services furnished on or after January 1, 2004, the Secretary shall, in determining practice expense relative value units under this subsection, utilize a survey submitted to the Secretary as of January 1, 2003, by a physician specialty organization pursuant to section 212 of the Medicare, Medicaid, and SCHIP Balanced Budget Reconciliation Act of 1999 if the survey—
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(I) covers practice expenses for oncology drug administration services; and

(II) meets criteria established by the Secretary for acceptance of such surveys.

(ii) Pricing of clinical oncology nurses in practice expense methodology

If the survey described in clause (i) includes data on wages, salaries, and compensation of clinical oncology nurses, the Secretary shall utilize such data in the methodology for determining practice expense relative value units for such year.

(iii) Work relative value units for certain drug administration services

In establishing the relative value units under this paragraph for drug administration services described in clause (iv) furnished on or after January 1, 2004, the Secretary shall establish work relative value units equal to the work relative value units for a level 1 office medical visit for an established patient.

(iv) Drug administration services described

The drug administration services described in this clause are physicians’ services—

(I) which are classified as of October 1, 2003, within any of the following groups of procedures: therapeutic or diagnostic infusions (excluding chemotherapy); chemotherapy administration services; and therapeutic, prophylactic, or diagnostic injections;

(II) for which there are no work relative value units assigned under this subsection as of such date; and

(III) for which national relative value units have been assigned under this subsection as of such date.

(I) Adjustments in practice expense relative value units for certain drug administration services beginning with 2005

(i) In general

In establishing the physician fee schedule under subsection (b) of this section with respect to payments for services furnished on or after January 1, 2005 or 2006, the Secretary shall adjust the practice expense relative value units for such year consistent with clause (ii).

(ii) Use of supplemental survey data

(I) In general

Subject to subclause (II), if a specialty submits to the Secretary by not later than March 1, 2004, for 2005, or March 1, 2005, for 2006, data that includes expenses for the administration of drugs and biologicals for which the payment amount is determined pursuant to section 1395u(a) of this title, the Secretary shall use such supplemental survey data in adjusting this subparagraph for the years involved insofar as they are collected and provided by entities and organizations consistent with the criteria established by the Secretary pursuant to section 212(a) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999.

(II) Limitation on specialty

Subclause (I) shall apply to a specialty only insofar as not less than 40 percent of payments for the specialty under this subchapter in 2002 are attributable to the administration of drugs and biologicals, as determined by the Secretary.

(III) Application

This clause shall not apply with respect to a survey to which subparagraph (H)(i) applies.

(j) Provisions for appropriate reporting and billing for physicians’ services associated with the administration of covered outpatient drugs and biologicals

(i) Evaluation of codes

The Secretary shall promptly evaluate existing drug administration codes for physicians’ services to ensure accurate reporting and billing for such services, taking into account levels of complexity of the administration and resource consumption.

(ii) Use of existing processes

In carrying out clause (i), the Secretary shall use existing processes for the consideration of coding changes and, to the extent coding changes are made, shall use such processes in establishing relative values for such services.

(iii) Implementation

In carrying out clause (i), the Secretary shall consult with representatives of physician specialties affected by the implementation of section 1395w–3a of this title or section 1395w–3b of this title, and shall take such steps within the Secretary’s authority to expedite such considerations under clause (ii).

(iv) Subsequent, budget neutral adjustments permitted

Nothing in subparagraph (H) or (I) or this subparagraph shall be construed as preventing the Secretary from providing for adjustments in practice expense relative value units under (and consistent with) subparagraph (B) for years after 2004, 2005, or 2006, respectively.

(K) Potentially misvalued codes

(i) In general

The Secretary shall—

(I) periodically identify services as being potentially misvalued using criteria specified in clause (ii); and

(II) review and make appropriate adjustments to the relative values established under this paragraph for services identified as being potentially misvalued under subclause (I).

(ii) Identification of potentially misvalued codes

For purposes of identifying potentially misvalued services pursuant to clause
(i) The Secretary shall examine (as the Secretary determines to be appropriate) codes (and families of codes as appropriate) for which there has been the fastest growth; codes (and families of codes as appropriate) that have experienced substantial changes in practice expenses; codes for new technologies or services within an appropriate period (such as 3 years) after the relative values are initially established for such codes; multiple codes that are frequently billed in conjunction with furnishing a single service; codes with low relative values, particularly those that are often billed multiple times for a single treatment; codes which have not been subject to review since the implementation of the RBRVS (the so-called "Harvard-valued codes"); and such other codes determined to be appropriate by the Secretary.

(ii) Practice expense percentage

The work percentage for a service (or class of services) performed by physicians in that specialty (determined under subparagraph (B)) multiplied by

(b) The provisions of subparagraph (B)(ii)(II) shall apply to adjustments to relative value units made pursuant to this subparagraph using methods described in subclauses (I) through (V) of subparagraph (K)(iii) as the Secretary determines to be appropriate.

(v) Adjustments

The Secretary shall make appropriate adjustments to the work relative value units under the fee schedule under subsection (b). The provisions of subparagraph (B)(ii)(II) shall apply to adjustments to relative value units made pursuant to this subparagraph in the same manner as such provisions apply to adjustments under subparagraph (B)(ii)(II).

(3) Component percentages

For the purposes of paragraph (2), the Secretary shall determine a work percentage, a practice expense percentage, and a malpractice percentage for each physician's service as follows:

(A) Division of services by specialty

For each physician's service or class of physicians' services, the Secretary shall determine the average percentage of each such service or class of services that is performed, nationwide, under this part by physicians in each of the different physician specialties (as identified by the Secretary).

(B) Division of specialty by component

The Secretary shall determine the average percentage division of resources, among the work component, the practice expense component, and the malpractice component, used by physicians in each of such specialties in furnishing physicians' services. Such percentages shall be based on national data that describe the elements of physician practice costs and revenues, by physician specialty. The Secretary may use extrapolation and other techniques to determine practice costs and revenues for specialties for which adequate data are not available.

(C) Determination of component percentages

(i) Work percentage

The work percentage for a service (or class of services) is equal to the sum (for all physician specialties) of—

(I) the average percentage division for the work component for each physician specialty (determined under subparagraph (B)), multiplied by

(II) the proportion (determined under subparagraph (A)) of such service (or services) performed by physicians in that specialty.

(ii) Practice expense percentage

For years before 2002, the practice expense percentage for a service (or class of
services) is equal to the sum (for all physician specialties) of—
(I) the average percentage division for the practice expense component for each physician specialty (determined under subparagraph (B)), multiplied by
(II) the proportion (determined under subparagraph (A)) of such service (or services) performed by physicians in that specialty.

(iii) Malpractice percentage
For years before 1999, the malpractice percentage for a service (or class of services) is equal to the sum (for all physician specialties) of—
(I) the average percentage division for the malpractice component for each physician specialty (determined under subparagraph (B)), multiplied by
(II) the proportion (determined under subparagraph (A)) of such service (or services) performed by physicians in that specialty.

(D) Periodic recomputation
The Secretary may, from time to time, provide for the recomputation of work percentages, practice expense percentages, and malpractice percentages determined under this paragraph.

(4) Ancillary policies
The Secretary may establish ancillary policies (with respect to the use of modifiers, local codes, and other matters) as may be necessary to implement this section.

(5) Coding
The Secretary shall establish a uniform procedure coding system for the coding of all physicians’ services. The Secretary shall provide for an appropriate coding structure for visits and consultations. The Secretary may incorporate the use of time in the coding for visits and consultations. The Secretary, in establishing such coding system, shall consult with the Physician Payment Review Commission and other organizations representing physicians.

(6) No variation for specialists
The Secretary may not vary the conversion factor or the number of relative value units for a physicians’ service based on whether the physician furnishing the service is a specialist or based on the type of specialty of the physician.

(d) Conversion factors

(1) Establishment

(A) In general
The conversion factor for each year shall be the conversion factor established under this subsection for the previous year (or, in the case of 1992, specified in subparagraph (B)) adjusted by the update (established under paragraph (3)) for the year involved (for years before 2001) and, for years beginning with 2001, multiplied by the update (established under paragraph (4)) for the year involved.

(B) Special provision for 1992
For purposes of subparagraph (A), the conversion factor specified in this subparagraph is a conversion factor (determined by the Secretary) which, if this section were to apply during 1991 using such conversion factor, would result in the same aggregate amount of payments under this part for physicians’ services as the estimated aggregate amount of the payments under this part for such services in 1991.

(C) Special rules for 1998
Except as provided in subparagraph (D), the single conversion factor for 1998 under this subsection shall be the conversion factor for primary care services for 1997, increased by the Secretary’s estimate of the weighted average of the three separate updates that would otherwise occur were it not for the enactment of chapter 1 of subtitle F of title IV of the Balanced Budget Act of 1997.

(D) Special rules for anesthesia services
The separate conversion factor for anesthesia services for a year shall be equal to 46 percent of the single conversion factor established for other physicians’ services, except as adjusted for changes in work, practice expense, or malpractice relative value units.

(E) Publication and dissemination of information
The Secretary shall—
(i) cause to have published in the Federal Register not later than November 1 of each year (beginning with 2000) the conversion factor which will apply to physicians’ services for the succeeding year, the update determined under paragraph (4) for such succeeding year, and the allowed expenditures under such paragraph for such succeeding year; and
(ii) make available to the Medicare Payment Advisory Commission and the public by March 1 of each year (beginning with 2000) an estimate of the sustainable growth rate and of the conversion factor which will apply to physicians’ services for the succeeding year and data used in making such estimate.


(3) Update for 1999 and 2000

(A) In general
Unless otherwise provided by law, subject to subparagraph (D) and the budget-neutrality factor determined by the Secretary under subsection (c)(2)(B)(ii) of this section, the update to the single conversion factor established in paragraph (1)(C) for 1999 and 2000 is equal to the product of—
(i) 1 plus the Secretary’s estimate of the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year (divided by 100), and
(ii) 1 plus the Secretary’s estimate of the update adjustment factor for the year (divided by 100), minus 1 and multiplied by 100.
(B) Update adjustment factor

For purposes of subparagraph (A)(ii), the "update adjustment factor" for a year is equal (as estimated by the Secretary) to—

(i) the difference between (I) the sum of the allowed expenditures for physicians' services (as determined under subparagraph (C)) for the period beginning April 1, 1997, and ending on March 31 of the year involved, and (II) the amount of actual expenditures for physicians' services furnished during the period beginning April 1, 1997, and ending on March 31 of the preceding year; divided by

(ii) the actual expenditures for physicians' services for the 12-month period ending on March 31 of the preceding year, increased by the sustainable growth rate under subsection (f) of this section for the fiscal year which begins during such 12-month period.

(C) Determination of allowed expenditures

For purposes of this paragraph and paragraph (4), the allowed expenditures for physicians' services for the 12-month period ending with March 31 of—

(i) 1997 is equal to the actual expenditures for physicians' services furnished during such 12-month period, as estimated by the Secretary; or

(ii) a subsequent year is equal to the allowed expenditures for physicians' services for the previous year, increased by the sustainable growth rate under subsection (f) of this section for the fiscal year which begins during such 12-month period.

(D) Restriction on variation from medicare economic index

Notwithstanding the amount of the update adjustment factor determined under subparagraph (B) for a year, the update in the conversion factor under this paragraph for the year may not be—

(i) greater than 100 times the following amount: (1.03 + (MEI percentage/100)) − 1; or

(ii) less than 100 times the following amount: (0.93 + (MEI percentage/100)) − 1, where "MEI percentage" means the Secretary's estimate of the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year involved.

(4) Update for years beginning with 2001

(A) In general

Unless otherwise provided by law, subject to the budget-neutrality factor determined by the Secretary under subsection (c)(2)(B)(ii) of this section and subject to adjustment under subparagraph (F), the update to the single conversion factor established in paragraph (1)(C) for a year beginning with 2001 is equal to the product of—

(i) 1 plus the Secretary's estimate of the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for the year (divided by 100); and

(ii) 1 plus the Secretary's estimate of the update adjustment factor under subparagraph (B) for the year.

(B) Update adjustment factor

For purposes of subparagraph (A)(ii), the "update adjustment factor" for a year is equal (as estimated by the Secretary) to the sum of the following:

(i) Prior year adjustment component

An amount determined by—

(I) computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services for the prior year (as determined under subparagraph (C)) and the amount of the actual expenditures for such services for that year;

(II) dividing that difference by the amount of the actual expenditures for such services for that year; and

(III) multiplying that quotient by 0.75.

(ii) Cumulative adjustment component

An amount determined by—

(I) computing the difference (which may be positive or negative) between the amount of the allowed expenditures for physicians' services (as determined under subparagraph (C)) from April 1, 1996, through the end of the prior year and the amount of the actual expenditures for such services during that period;

(II) dividing that difference by actual expenditures for such services for the prior year as increased by the sustainable growth rate under subsection (f) of this section for the year for which the update adjustment factor is to be determined; and

(III) multiplying that quotient by 0.33.

(C) Determination of allowed expenditures

For purposes of this paragraph:

(i) Period up to April 1, 1999

The allowed expenditures for physicians' services for a period before April 1, 1999, shall be the amount of the allowed expenditures for such period as determined under paragraph (3)(C).

(ii) Transition to calendar year allowed expenditures

Subject to subparagraph (E), the allowed expenditures for—

(I) the 9-month period beginning April 1, 1999, shall be the Secretary's estimate of the amount of the allowed expenditures that would be permitted under paragraph (3)(C) for such period; and

(II) the year of 1999, shall be the Secretary's estimate of the amount of the allowed expenditures that would be permitted under paragraph (3)(C) for such year.

(iii) Years beginning with 2000

The allowed expenditures for a year (beginning with 2000) is equal to the allowed expenditures for physicians' services for the previous year, increased by the sustainable growth rate under subsection (f) of this section for the year involved.
(D) Restriction on update adjustment factor
The update adjustment factor determined under subparagraph (B) for a year may not be less than −0.07 or greater than 0.03.

(E) Recalculation of allowed expenditures for updates beginning with 2001
For purposes of determining the update adjustment factor for a year beginning with 2001, the Secretary shall recompute the allowed expenditures for previous periods beginning on or after April 1, 1999, consistent with subsection (f)(3) of this section.

(F) Transitional adjustment designed to provide for budget neutrality
Under this subparagraph the Secretary shall provide for an adjustment to the update under subparagraph (A)—

(i) for each of 2001, 2002, 2003, and 2004, of −0.2 percent; and
(ii) for 2005 of +0.8 percent.

(5) Update for 2004 and 2005
The update to the single conversion factor established in paragraph (1)(C) for each of 2004 and 2005 shall be not less than 1.5 percent.

(6) Update for 2006
The update to the single conversion factor established in paragraph (1)(C) for 2006 shall be 0 percent.

(7) Conversion factor for 2007
(A) In general
The conversion factor that would otherwise be applicable under this subsection for 2007 shall be the amount of such conversion factor divided by the product of—

(i) 1 plus the Secretary’s estimate of the percentage increase in the MEI (as defined in section 1395u(i)(3) of this title) for 2007 (divided by 100); and
(ii) 1 plus the Secretary’s estimate of the update adjustment factor under paragraph (4)(B) for 2007.

(B) No effect on computation of conversion factor for 2008
The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2008 as if subparagraph (A) had never applied.

(8) Update for 2008
(A) In general
Subject to paragraph (7)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2010 for the period beginning on January 1, 2010, and ending on May 31, 2010, the update to the single conversion factor shall be 0 percent.

(B) No effect on computation of conversion factor for remaining portion of 2010 and subsequent years
The conversion factor under this subsection shall be computed under paragraph (1)(A) for the period beginning on June 1, 2010, and ending on December 31, 2010, and for 2011 and subsequent years as if subparagraph (A) had never applied.

(9) Update for 2009
(A) In general
Subject to paragraphs (7)(B) and (8)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2009, the update to the single conversion factor shall be 1.1 percent.

(B) No effect on computation of conversion factor for 2010 and subsequent years
The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2010 and subsequent years as if subparagraph (A) had never applied.

(10) Update for January through May of 2010
(A) In general
Subject to paragraphs (7)(B), (8)(B), and (9)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2010 for the period beginning on January 1, 2010, and ending on May 31, 2010, the update to the single conversion factor shall be 0 percent for 2010.

(B) No effect on computation of conversion factor for remaining portion of 2010 and subsequent years
The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2011 and subsequent years as if subparagraph (A) had never applied.

(11) Update for June through December of 2010
(A) In general
Subject to paragraphs (7)(B), (8)(B), (9)(B), and (10)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2010 for the period beginning on June 1, 2010, and ending on December 31, 2010, the update to the single conversion factor shall be 2.2 percent.

(B) No effect on computation of conversion factor for 2011 and subsequent years
The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2011 and subsequent years as if subparagraph (A) had never applied.

(12) Update for 2011
(A) In general
Subject to paragraphs (7)(B), (8)(B), (9)(B), (10)(B), and (11)(B), in lieu of the update to the single conversion factor established in paragraph (1)(C) that would otherwise apply for 2011, the update to the single conversion factor shall be 0 percent.

(B) No effect on computation of conversion factor for 2012 and subsequent years
The conversion factor under this subsection shall be computed under paragraph (1)(A) for 2012 and subsequent years as if subparagraph (A) had never applied.

(e) Geographic adjustment factors
(1) Establishment of geographic indices
(A) In general
Subject to subparagraphs (B), (C), (E), (G), (H), and (I), the Secretary shall establish—

(i) an index which reflects the relative costs of the mix of goods and services com-
The Secretary shall increase any such index to 1.67 if such index would otherwise be less than 1.67. For purposes of payment for services furnished in the State described in the preceding sentence on or after January 1, 2009, after calculating the work geographic index in subparagraph (A)(iii), the Secretary shall increase the work geographic index to 1.5 if such index would otherwise be less than 1.5.

**H) Practice expense geographic adjustment for 2010 and subsequent years**

 gre obtain for services furnished during 2010, the employee wage and rent portions of the practice expense geographic index described in subparagraph (A)(i) shall reflect ½ of the difference between the relative costs of employee wages and rents in each of the different fee schedule areas and the national average of such employee wages and rents.

(ii) For 2011

Subject to clause (iii), for services furnished during 2011, the employee wage and rent portions of the practice expense geographic index described in subparagraph (A)(i) shall reflect ½ of the difference between the relative costs of employee wages and rents in each of the different fee schedule areas and the national average of such employee wages and rents.

(iii) Hold harmless

The practice expense portion of the geographic adjustment factor applied in a fee schedule area for services furnished in 2010 or 2011 shall not, as a result of the application of such clause (i) or (ii), be reduced below the practice expense portion of the geographic adjustment factor under subparagraph (A)(i) as calculated prior to the application of such clause (i) or (ii), respectively, for such area for such year.

(iv) Analysis

The Secretary shall analyze methods of establishing practice expense geographic adjustments under subparagraph (A)(i) and evaluate data that fairly and reliably establishes distinctions in the costs of operating a medical practice in the different fee schedule areas. Such analysis shall include an evaluation of the following:

(I) The feasibility of using actual data or reliable survey data developed by medical organizations on the costs of operating a medical practice, including office rents and non-physician staff wages, in different fee schedule areas.

(II) The office expense portion of the practice expense geographic adjustment described in subparagraph (A)(i), including the extent to which types of office expenses are determined in local markets instead of national markets.

(III) The weights assigned to each of the categories within the practice ex-

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pense geographic adjustment described in subparagraph (A)(i).

(v) Revision for 2012 and subsequent years

As a result of the analysis described in clause (iv), the Secretary shall, not later than January 1, 2012, make appropriate adjustments to the practice expense geographic adjustment described in subparagraph (A)(i) to ensure accurate geographic adjustments across fee schedule areas, including—

(I) basing the office rents component and its weight on office expenses that vary among fee schedule areas; and

(II) considering a representative range of professional and non-professional personnel employed in a medical office based on the use of the American Community Survey data or other reliable data for wage adjustments.

Such adjustments shall be made without regard to adjustments made pursuant to clauses (i) and (ii) and shall be made in a budget neutral manner.

(1) Floor for practice expense index for services furnished in frontier States

(i) In general

Subject to clause (ii), for purposes of payment for services furnished in a frontier State (as defined in section 1395ww(d)(3)(E)(iii)(II) of this title) on or after January 1, 2011, after calculating the practice expense index in subparagraph (A)(i), the Secretary shall increase any such index to 1.00 if such index would otherwise be less than \(^{4}1.00\). The preceding sentence shall not be applied in a budget neutral manner.

(ii) Limitation

This subparagraph shall not apply to services furnished in a State that receives a non-labor related share adjustment under section 1395ww(d)(5)(H) of this title.

(2) Computation of geographic adjustment factor

For purposes of subsection (b)(1)(C) of this section, for all physicians' services for each fee schedule area the Secretary shall establish a geographic adjustment factor equal to the sum of the geographic cost-of-practice adjustment factor (specified in paragraph (3)), the geographic malpractice adjustment factor (specified in paragraph (4)), and the geographic physician work adjustment factor (specified in paragraph (5)) for the service and the area.

(3) Geographic cost-of-practice adjustment factor

For purposes of paragraph (2), the “geographic cost-of-practice adjustment factor”, for a service for a fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the practice expense component, and

(B) the geographic cost-of-practice index value for the area for the service, based on the index established under paragraph (1)(A)(i) or (1)(B) (as the case may be).

(4) Geographic malpractice adjustment factor

For purposes of paragraph (2), the “geographic malpractice adjustment factor”, for a service for a fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the malpractice component, and

(B) the geographic malpractice index value for the area, based on the index established under paragraph (1)(A)(ii).

(5) Geographic physician work adjustment factor

For purposes of paragraph (2), the “geographic physician work adjustment factor”, for a service for a fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the work component, and

(B) the geographic physician work index value for the area, based on the index established under paragraph (1)(A)(iii).

(f) Sustainable growth rate

(1) Publication

The Secretary shall cause to have published in the Federal Register not later than—

(A) November 1, 2000, the sustainable growth rate for 2000 and 2001; and

(B) November 1 of each succeeding year the sustainable growth rate for such succeeding year and each of the preceding 2 years.

(2) Specification of growth rate

The sustainable growth rate for all physicians’ services for a fiscal year (beginning with fiscal year 1998 and ending with fiscal year 2000) and a year beginning with 2000 shall be equal to the product of—

(A) 1 plus the Secretary’s estimate of the weighted average percentage increase (divided by 100) in the fees for all physicians’ services in the applicable period involved,

(B) 1 plus the Secretary’s estimate of the percentage change (divided by 100) in the average number of individuals enrolled under this part (other than Medicare+Choice plan enrollees) from the previous applicable period to the applicable period involved,

(C) 1 plus the Secretary’s estimate of the annual average percentage growth in real gross domestic product per capita (divided by 100) during the 10-year period ending with the applicable period involved, and

(D) 1 plus the Secretary’s estimate of the percentage change (divided by 100) in expenditures for all physicians’ services in the applicable period (compared with the previous applicable period) which will result from changes in law and regulations, determined without taking into account estimated changes in expenditures resulting

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\section*{Revision for 2012 and subsequent years}

As a result of the analysis described in clause (iv), the Secretary shall, not later than January 1, 2012, make appropriate adjustments to the practice expense geographic adjustment described in subparagraph (A)(i) to ensure accurate geographic adjustments across fee schedule areas, including—

(i) basing the office rents component and its weight on office expenses that vary among fee schedule areas; and

(ii) considering a representative range of professional and non-professional personnel employed in a medical office based on the use of the American Community Survey data or other reliable data for wage adjustments.

Such adjustments shall be made without regard to adjustments made pursuant to clauses (i) and (ii) and shall be made in a budget neutral manner.

(1) Floor for practice expense index for services furnished in frontier States

(i) In general

Subject to clause (ii), for purposes of payment for services furnished in a frontier State (as defined in section 1395ww(d)(3)(E)(iii)(II) of this title) on or after January 1, 2011, after calculating the practice expense index in subparagraph (A)(i), the Secretary shall increase any such index to 1.00 if such index would otherwise be less than \(^{4} 1.00\). The preceding sentence shall not be applied in a budget neutral manner.

(ii) Limitation

This subparagraph shall not apply to services furnished in a State that receives a non-labor related share adjustment under section 1395ww(d)(5)(H) of this title.

(2) Computation of geographic adjustment factor

For purposes of subsection (b)(1)(C) of this section, for all physicians' services for each fee schedule area the Secretary shall establish a geographic adjustment factor equal to the sum of the geographic cost-of-practice adjustment factor (specified in paragraph (3)), the geographic malpractice adjustment factor (specified in paragraph (4)), and the geographic physician work adjustment factor (specified in paragraph (5)) for the service and the area.

(3) Geographic cost-of-practice adjustment factor

For purposes of paragraph (2), the “geographic cost-of-practice adjustment factor”, for a service for a fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the practice expense component, and

(B) the geographic cost-of-practice index value for the area for the service, based on the index established under paragraph (1)(A)(i) or (1)(B) (as the case may be).

(4) Geographic malpractice adjustment factor

For purposes of paragraph (2), the “geographic malpractice adjustment factor”, for a service for a fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the malpractice component, and

(B) the geographic malpractice index value for the area, based on the index established under paragraph (1)(A)(ii).

(5) Geographic physician work adjustment factor

For purposes of paragraph (2), the “geographic physician work adjustment factor”, for a service for a fee schedule area, is the product of—

(A) the proportion of the total relative value for the service that reflects the relative value units for the work component, and

(B) the geographic physician work index value for the area, based on the index established under paragraph (1)(A)(iii).

(f) Sustainable growth rate

(1) Publication

The Secretary shall cause to have published in the Federal Register not later than—

(A) November 1, 2000, the sustainable growth rate for 2000 and 2001; and

(B) November 1 of each succeeding year the sustainable growth rate for such succeeding year and each of the preceding 2 years.

(2) Specification of growth rate

The sustainable growth rate for all physicians’ services for a fiscal year (beginning with fiscal year 1998 and ending with fiscal year 2000) and a year beginning with 2000 shall be equal to the product of—

(A) 1 plus the Secretary’s estimate of the weighted average percentage increase (divided by 100) in the fees for all physicians’ services in the applicable period involved,

(B) 1 plus the Secretary’s estimate of the percentage change (divided by 100) in the average number of individuals enrolled under this part (other than Medicare+Choice plan enrollees) from the previous applicable period to the applicable period involved,

(C) 1 plus the Secretary’s estimate of the annual average percentage growth in real gross domestic product per capita (divided by 100) during the 10-year period ending with the applicable period involved, and

(D) 1 plus the Secretary’s estimate of the percentage change (divided by 100) in expenditures for all physicians’ services in the applicable period (compared with the previous applicable period) which will result from changes in law and regulations, determined without taking into account estimated changes in expenditures resulting

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from the update adjustment factor determined under subsection (d)(3)(B) or (d)(4)(B) of this section, as the case may be, minus 1 and multiplied by 100.

(3) Data to be used

For purposes of determining the update adjustment factor under subsection (d)(4)(B) of this section for a year beginning with 2001, the sustainable growth rates taken into consideration in the determination under paragraph (2) shall be determined as follows:

(A) For 2001

For purposes of such calculations for 2001, the sustainable growth rates for fiscal year 2000 and the years 2000 and 2001 shall be determined on the basis of the best data available to the Secretary as of September 1, 2000.

(B) For 2002

For purposes of such calculations for 2002, the sustainable growth rates for fiscal year 2000 and for years 2000, 2001, and 2002 shall be determined on the basis of the best data available to the Secretary as of September 1, 2001.

(C) For 2003 and succeeding years

For purposes of such calculations for a year after 2002—

(i) the sustainable growth rates for that year and the preceding 2 years shall be determined on the basis of the best data available to the Secretary as of September 1 of the year preceding the year for which the calculation is made; and

(ii) the sustainable growth rate for any year before a year described in clause (i) shall be the rate as most recently determined for that year under this subsection.

Nothing in this paragraph shall be construed as affecting the sustainable growth rates established for fiscal year 1998 or fiscal year 1999.

(4) Definitions

In this subsection:

(A) Services included in physicians’ services

The term ‘‘physicians’ services’’ includes other items and services (such as clinical diagnostic laboratory tests and radiology services), specified by the Secretary, that are commonly performed or furnished by a physician or in a physician’s office, but does not include services furnished to a Medicare+Choice plan enrollee.

(B) Medicare+Choice plan enrollee

The term ‘‘Medicare+Choice plan enrollee’’ means, with respect to a fiscal year, an individual enrolled under this part who has elected to receive benefits under this subchapter for the fiscal year through a Medicare+Choice plan offered under part C of this subchapter, and also includes an individual who is receiving benefits under this part through enrollment with an eligible organization with a risk-sharing contract under section 1395mm of this title.

(C) Applicable period

The term ‘‘applicable period’’ means—

(i) a fiscal year, in the case of fiscal year 1998, fiscal year 1999, and fiscal year 2000; or

(ii) a calendar year with respect to a year beginning with 2000; as the case may be.

(g) Limitation on beneficiary liability

(1) Limitation on actual charges

(A) In general

In the case of a nonparticipating physician or nonparticipating supplier or other person (as defined in section 1395u(j)(2) of this title) who does not accept payment on an assignment-related basis for a physician’s service furnished with respect to an individual enrolled under this part, the following rules apply:

(i) Application of limiting charge

No person may bill or collect an actual charge for the service in excess of the limiting charge described in paragraph (2) for such service.

(ii) No liability for excess charges

No person is liable for payment of any amounts billed for the service in excess of such limiting charge.

(iii) Correction of excess charges

If such a physician, supplier, or other person collects an actual charge for a service in violation of clause (i), the physician, supplier, or other person shall reduce on a timely basis the actual charge billed for the service to an amount not to exceed the limiting charge for the service.

(iv) Refund of excess collections

If such a physician, supplier, or other person collects an actual charge for a service in violation of clause (i), the physician, supplier, or other person shall provide on a timely basis a refund to the individual charged in the amount by which the amount collected exceeded the limiting charge for the service. The amount of such a refund shall be reduced to the extent the individual has an outstanding balance owed by the individual to the physician.

(B) Sanctions

If a physician, supplier, or other person—

(i) knowingly and willfully bills or collects for services in violation of subparagraph (A)(i) on a repeated basis, or

(ii) fails to comply with clause (iii) or (iv) of subparagraph (A) on a timely basis, the Secretary may apply sanctions against the physician, supplier, or other person in accordance with paragraph (2) of section 1395u(j) of this title. In applying this subparagraph, paragraph (4) of such section applies in the same manner as such paragraph applies to such section and any reference in such section to a physician is deemed also to include a reference to a supplier or other person under this subparagraph.

(C) Timely basis

For purposes of this paragraph, a correction of a bill for an excess charge or refund
of an amount with respect to a violation of subparagraph (A)(i) in the case of a service is considered to be provided “on a timely basis”, if the reduction or refund is made not later than 30 days after the date the physician, supplier, or other person is notified by the carrier under this part of such violation and of the requirements of subparagraph (A).

(2) “Limiting charge” defined

(A) For 1991

For physicians’ services of a physician furnished during 1991, other than radiologist services subject to section 1395m(b) of this title, the “limiting charge” shall be the same percentage (or, if less, 25 percent) above the recognized payment amount under this part with respect to the physician (as a nonparticipating physician) as the percentage by which—

(i) the maximum allowable actual charge (as determined under section 1395u(j)(1)(C) of this title as of December 31, 1990, or, if less, the maximum actual charge otherwise permitted for the service under this part as of such date) for the service of the physician, exceeds

(ii) the recognized payment amount for the service of the physician (as a nonparticipating physician) as of such date.

In the case of evaluation and management services (as specified in section 1395u(b)(16)(B)(ii) of this title), the preceding sentence shall be applied by substituting “40 percent” for “25 percent”.

(B) For 1992

For physicians’ services furnished during 1992, other than radiologist services subject to section 1395m(b) of this title, the “limiting charge” shall be the same percentage (or, if less, 20 percent) above the recognized payment amount under this part for nonparticipating physicians as the percentage by which—

(i) the limiting charge (as determined under subparagraph (A) as of December 31, 1991) for the service, exceeds

(ii) the recognized payment amount for the service for nonparticipating physicians as of such date.

(C) After 1992

For physicians’ services furnished in a year after 1992, the “limiting charge” shall be 115 percent of the recognized payment amount under this part for nonparticipating physicians or for nonparticipating suppliers or other persons.

(D) Recognized payment amount

In this section, the term “recognized payment amount” means, for services furnished on or after January 1, 1992, the fee schedule amount determined under subsection (a) of this section (or, if payment under this part is made on a basis other than the fee schedule under this section, 95 percent of the other payment basis), and, for services furnished during 1991, the applicable percentage (as defined in section 1395u(b)(4)(A)(iv) of this title) of the prevailing charge (or fee schedule amount) for nonparticipating physicians for that year.

(3) Limitation on charges for medicare beneficiaries eligible for medicaid benefits

(A) In general

Payment for physicians’ services furnished on or after April 1, 1990, to an individual who is enrolled under this part and eligible for any medical assistance (including as a qualified medicare beneficiary, as defined in section 1396d(p)(1) of this title) with respect to such services under a State plan approved under subchapter XIX of this chapter may only be made on an assignment-related basis and the provisions of section 1396u(n)(3)(A) of this title apply to further limit permissible charges under this section.

(B) Penalty

A person may not bill for physicians’ services subject to subparagraph (A) other than on an assignment-related basis. No person is liable for payment of any amounts billed for such a service in violation of the previous sentence. If a person knowingly and willfully bills for physicians’ services in violation of the first sentence, the Secretary may apply sanctions against the person in accordance with section 1395u(j)(2) of this title.

(4) Physician submission of claims

(A) In general

For services furnished on or after September 1, 1990, within 1 year after the date of providing a service for which payment is made under this part on a reasonable charge or fee schedule basis, a physician, supplier, or other person (or an employer or facility in the cases described in section 1395u(b)(6)(A) of this title) shall complete and submit a claim for such service on a standard claim form specified by the Secretary to the carrier on behalf of a beneficiary, and (ii) may not impose any charge relating to completing and submitting such a form.

(B) Penalty

(i) With respect to an assigned claim wherever a physician, provider, supplier or other person (or an employer or facility in the cases described in section 1395u(b)(6)(A) of this title) fails to submit such a claim as required in subparagraph (A), the Secretary shall reduce by 10 percent the amount that would otherwise be paid for such claim under this part.

(ii) If a physician, supplier, or other person (or an employer or facility in the cases described in section 1395u(b)(6)(A) of this title) fails to submit a claim required to be submitted under subparagraph (A) or imposes a charge in violation of such subparagraph, the Secretary shall apply the sanction with respect to such a violation in the same manner as a sanction may be imposed under section 1395u(p)(3) of this title for a violation of section 1395u(p)(1) of this title.

(5) Electronic billing; direct deposit

The Secretary shall encourage and develop a system providing for expedited payment for
claims submitted electronically. The Secretary shall also encourage and provide incentives allowing for direct deposit as payments for services furnished by participating physicians. The Secretary shall provide physicians with such technical information as necessary to enable such physicians to submit claims electronically. The Secretary shall submit a plan to Congress on this paragraph by May 1, 1990.

(6) Monitoring of charges

(A) In general

The Secretary shall monitor—

(i) the actual charges of nonparticipating physicians for physicians’ services furnished on or after January 1, 1991, to individuals enrolled under this part, and

(ii) changes (by specialty, type of service, and geographic area) in (I) the proportion of expenditures for physicians’ services provided under this part by participating physicians, (II) the proportion of expenditures for such services for which payment is made under this part on an assignment-related basis, and (III) the amounts charged above the recognized payment amounts under this part.

(B) Report

The Secretary shall, by not later than April 15 of each year (beginning in 1992), report to the Congress information on the extent to which actual charges exceed limiting charges, the number and types of services involved, and the average amount of excess charges and information regarding the changes described in subparagraph (A)(ii).

(C) Plan

If the Secretary finds that there has been a significant decrease in the proportions described in subclauses (I) and (II) of subparagraph (A)(ii) or an increase in the amounts described in subclause (III) of that subparagraph, the Secretary shall develop a plan to address such a problem and transmit to Congress recommendations regarding the plan. The Medicare Payment Advisory Commission shall review the Secretary’s plan and recommendations and transmit to Congress its comments regarding such plan and recommendations.

(7) Monitoring of utilization and access

(A) In general

The Secretary shall monitor—

(i) changes in the utilization of and access to services furnished under this part within geographic, population, and service related categories,

(ii) possible sources of inappropriate utilization of services furnished under this part which contribute to the overall level of expenditures under this part, and

(iii) factors underlying these changes and their interrelationships.

(B) Report

The Secretary shall by not later than April 15, 1990, submit to Congress a report to the Congress on the changes described in subparagraph (A)(i) and shall include in the report an examination of the factors (including factors relating to different services and specific categories and groups of services and demographic variations in utilization) which may contribute to such changes.

(C) Recommendations

The Secretary shall include in each annual report under subparagraph (B) recommendations—

(i) addressing any identified patterns of inappropriate utilization,

(ii) on utilization review,

(iii) on physician education or patient education,

(iv) addressing any problems of beneficiary access to care made evident by the monitoring process, and

(v) on such other matters as the Secretary deems appropriate.

The Medicare Payment Advisory Commission shall comment on the Secretary’s recommendations and in developing its comments, the Commission shall convene and consult a panel of physician experts to evaluate the implications of medical utilization patterns for the quality of and access to patient care.

(h) Sending information to physicians

Before the beginning of each year (beginning with 1992), the Secretary shall send to each physician or nonparticipating supplier or other person furnishing physicians’ services (as defined in section 1395u(h) of this title (relating to the participating physician program) for a year.

(i) Miscellaneous provisions

(1) Restriction on administrative and judicial review

There shall be no administrative or judicial review under section 1395ff of this title or otherwise of—

(A) the determination of the adjusted historical payment basis (as defined in subsection (c)(2)(D)(i) of this section),

(B) the determination of relative values and relative value units under subsection (c) of this section, including adjustments under subsections (c)(2)(F), (c)(2)(H), and (c)(2)(I) of this section and section 13515(b) of the Omnibus Budget Reconciliation Act of 1990,

(C) the determination of conversion factors under subsection (d) of this section, including without limitation a prospective re-determination of the sustainable growth rates for any or all previous fiscal years,

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(D) the establishment of geographic adjustment factors under subsection (e) of this section, and
(E) the establishment of the system for the coding of physicians’ services under this section.

(2) Assistants-at-surgery

(A) In general
Subject to subparagraph (B), in the case of a surgical service furnished by a physician, if payment is made separately under this part for the services of a physician serving as an assistant-at-surgery, the fee schedule amount shall not exceed 16 percent of the fee schedule amount otherwise determined under this section for the global surgical service involved.

(B) Denial of payment in certain cases
If the Secretary determines, based on the most recent data available, that for a surgical procedure (or class of surgical procedures) the national average percentage of such procedure performed under this part which involve the use of a physician as an assistant at surgery is less than 5 percent, no payment may be made under this part for services of an assistant at surgery involved in the procedure.

(3) No comparability adjustment
For physicians’ services for which payment under this part is determined under this section—
(A) a carrier may not make any adjustment in the payment amount under section 1395u(b)(3)(B) of this title on the basis that the payment amount is higher than the charge applicable, for comparable services and under comparable circumstances, to the policyholders and subscribers of the carrier,
(B) no payment adjustment may be made under section 1395u(b)(6) of this title, and
(C) section 1395u(b)(9) of this title shall not apply.

(j) Definitions
In this section:

(1) Category
For services furnished before January 1, 1998, the term “category” means, with respect to physicians’ services, surgical services, and all physicians’ services other than surgical services (as defined by the Secretary and including anesthesia services), primary care services (as defined in section 1395u(i)(4) of this title), and all other physicians’ services. The Secretary shall define surgical services and publish such definition in the Federal Register no later than May 1, 1999, after consultation with organizations representing physicians.

(2) Fee schedule area
The term “fee schedule area” means a locality used under section 1395u(b) of this title for purposes of computing payment amounts for physicians’ services.

(3) Physicians’ services
The term “physicians’ services” includes items and services described in paragraphs (1), (2)(A), (2)(D), (2)(G), (2)(P) (with respect to services described in subparagraphs (A) and (C) of section 1395x(aa)(2) of this title), (2)(B) (with respect to services described in subparagraphs (B), (C), and (D) of section 1395x(pp)(1) of this title), (2)(S), (2)(W), (2)(AA), (2)(DD), (2)(EE), (2)(FF) (including administration of the health risk assessment), (3), (4), (13), (14) (with respect to services described in section 1395x(nn)(2) of this title), and (15) of section 1395x(s) of this title (other than clinical diagnostic laboratory tests and, except for purposes of subsections (a)(3), (g), and (h) of this section6 such other items and services as the Secretary may specify).

(4) Practice expenses
The term “practice expenses” includes all expenses for furnishing physicians’ services, excluding malpractice expenses, physician compensation, and other physician fringe benefits.

(k) Quality reporting system

(1) In general
The Secretary shall implement a system for the reporting by eligible professionals of data on quality measures specified under paragraph (2). Such data shall be submitted in a form and manner specified by the Secretary (by program instruction or otherwise), which may include submission of such data on claims under this part.

(2) Use of consensus-based quality measures

(A) For 2007
(i) In general
For purposes of applying this subsection for the reporting of data on quality measures for covered professional services furnished during the period beginning July 1, 2007, and ending December 31, 2007, the quality measures specified under this paragraph are the measures identified as 2007 physician quality measures under the Physician Voluntary Reporting Program as published on the public website of the Centers for Medicare & Medicaid Services as of December 20, 2006, except as may be changed by the Secretary based on the results of a consensus-based process in January of 2007, if such change is published on such website by not later than April 1, 2007.

(ii) Subsequent refinements in application permitted
The Secretary may, from time to time (but not later than July 1, 2007), publish on such website (without notice or opportunity for public comment) modifications or refinements (such as code additions, corrections, or revisions) for the application of quality measures previously published under clause (i), but may not, under this clause, change the quality measures under the reporting system.

(iii) Implementation
Notwithstanding any other provision of law, the Secretary may implement by pro-

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6So in original. Probably should be followed by a comma.
gram instruction or otherwise this subsection for 2007.

(B) For 2008 and 2009

(i) In general

For purposes of reporting data on quality measures for covered professional services furnished during 2008 and 2009, the quality measures specified under this paragraph for covered professional services shall be measures that have been adopted or endorsed by a consensus organization (such as the National Quality Forum or AQA), that include measures that have been submitted by a physician specialty, and that the Secretary identifies as having used a consensus-based process for developing such measures. Such measures shall include structural measures, such as the use of electronic health records and electronic prescribing technology.

(ii) Proposed set of measures

Not later than August 15 of each of 2007 and 2008, the Secretary shall publish in the Federal Register a proposed set of quality measures that the Secretary determines are described in clause (i) and would be appropriate for eligible professionals to use to submit data to the Secretary in 2008 or 2009, as applicable. The Secretary shall provide for a period of public comment on such set of measures.

(iii) Final set of measures

Not later than November 15 of each of 2007 and 2008, the Secretary shall publish in the Federal Register a final set of quality measures that the Secretary determines are described in clause (i) and would be appropriate for eligible professionals to use to submit data to the Secretary in 2008 or 2009, as applicable.

(C) For 2010 and subsequent years

(i) In general

Subject to clause (i), for purposes of reporting data on quality measures for covered professional services furnished during 2010 and each subsequent year, subject to subsection (m)(3)(C), the quality measures (including electronic prescribing quality measures) specified under this paragraph shall be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary 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, such as the AQA alliance.

(D) Opportunity to provide input on measures for 2009 and subsequent years

For each quality measure (including an electronic prescribing quality measure) adopted by the Secretary under subparagraph (B) (with respect to 2009) or subparagraph (C), the Secretary shall ensure that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish.

(3) Covered professional services and eligible professionals defined

For purposes of this subsection:

(A) Covered professional services

The term “covered professional services” means services for which payment is made under, or is based on, the fee schedule established under this section and which are furnished by an eligible professional.

(B) Eligible professional

The term “eligible professional” means any of the following:

(i) A physician.

(ii) A practitioner described in section 1395u(b)(18)(C) of this title.

(iii) A physical or occupational therapist or a qualified speech-language pathologist.

(iv) Beginning with 2009, a qualified audiologist (as defined in section 1395x(l)(3)(B) of this title).

(4) Use of registry-based reporting

As part of the publication of proposed and final quality measures for 2008 under clauses (ii) and (iii) of paragraph (2)(B), the Secretary shall address a mechanism whereby an eligible professional may provide data on quality measures through an appropriate medical registry (such as the Society of Thoracic Surgeons National Database) or through a Maintenance of Certification program operated by a specialty body of the American Board of Medical Specialties that meets the criteria for such a registry, as identified by the Secretary.

(5) Identification units

For purposes of applying this subsection, the Secretary may identify eligible professionals through billing units, which may include the use of the Provider Identification Number, the unique physician identification number (described in section 1395l(q)(1) of this title), the taxpayer identification number, or the National Provider Identifier. For purposes of applying this subsection for 2007, the Secretary shall use the taxpayer identification number as the billing unit.

(6) Education and outreach

The Secretary shall provide for education and outreach to eligible professionals on the operation of this subsection.

(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 development and implementation of the reporting system under paragraph (1), including
(i) Establishment
The Secretary shall establish under this subsection a Physician Assistance and Quality Initiative Fund (in this subsection referred to as the “Fund”) which shall be available to the Secretary for physician payment and quality improvement initiatives, which may include application of an adjustment to the update of the conversion factor under subsection (d).

(2) Funding

(A) Amount available
   (i) In general
   Subject to clause (ii), there shall be available to the Fund the following amounts:
   (I) For expenditures during 2008, an amount equal to $150,500,000.
   (II) For expenditures during 2009, an amount equal to $24,500,000.

   (ii) Limitations on expenditures
   (I) 2008
   The amount available for expenditures during 2008 shall be reduced as provided by subparagraph (A) of section 225(c)(1) and section 524 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008 (division G of the Consolidated Appropriations Act, 2008).

   (II) 2009
   The amount available for expenditures during 2009 shall be reduced as provided by subparagraph (B) of such section 225(c)(1).

(B) Timely obligation of all available funds for services
The Secretary shall provide for expenditures from the Fund in a manner designed to provide (to the maximum extent feasible) for the obligation of the entire amount available for expenditures, after application of subparagraph (A)(ii), during—
   (i) 2008 for payment with respect to physicians’ services furnished during 2008; and
   (ii) 2009 for payment with respect to physicians’ services furnished during 2009.

(C) Payment from Trust Fund
The amount specified in subparagraph (A) shall be available to the Fund, as expenditures are made from the Fund, from the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title.

(D) Funding limitation
Amounts in the Fund shall be available in advance of appropriations in accordance with subparagraph (B) but only if the total amount obligated from the Fund does not exceed the amount available to the Fund under subparagraph (A). 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.

(E) Construction
In the case that expenditures from the Fund are applied to, or otherwise affect, a conversion factor under subsection (d) for a year, the conversion factor under such subsection shall be computed for a subsequent year as if such application or effect had never occurred.

(m) Incentive payments for quality reporting

(1) Incentive payments

(A) In general
For 2007 through 2014, with respect to covered professional services furnished during a reporting period by an eligible professional, if—
   (i) there are any quality measures that have been established under the physician reporting system that are applicable to any such services furnished by such professional for such reporting period; and
   (ii) the eligible professional satisfactorily submits (as determined under this subsection) to the Secretary data on such quality measures in accordance with such reporting system for such reporting period.

   In addition to the amount otherwise paid under this part, there shall also be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1395u(b)(6) of this title) or, in the case of a group practice under paragraph (3)(C), to the group practice, from the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title an amount equal to the applicable quality percent of the Secretary’s estimate (based on claims submitted not later than 2 months after the end of the reporting period) of the allowed charges under this part for all such covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (3)(C), by the group practice) during the reporting period.

(B) Applicable quality percent
For purposes of subparagraph (A), the term “applicable quality percent” means—
   (i) for 2007 and 2008, 1.5 percent;
   (ii) for 2009 and 2010, 2.0 percent;
   (iii) for 2011, 1.0 percent; and
   (iv) for 2012, 2013, and 2014, 0.5 percent.

(2) Incentive payments for electronic prescribing

(A) In general
Subject to subparagraph (D), for 2009 through 2013, with respect to covered profes-
sional services furnished during a reporting period by an eligible professional, if the eligible professional is a successful electronic prescriber for such reporting period, in addition to the amount otherwise paid under this part, there also shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1395u(b)(6) of this title) or, in the case of a group practice under paragraph (3)(C), to the group practice, from the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title an amount equal to the applicable electronic prescribing percent of the Secretary’s estimate (based on claims submitted not later than 2 months after the end of the reporting period) of the allowed charges under this part for all such covered professional services furnished by the eligible professional (or, in the case of a group practice under paragraph (3)(C), by the group practice) during the reporting period.

(B) Limitation with respect to electronic prescribing quality measures

The provisions of this paragraph and subsection (a)(5) shall not apply to an eligible professional (or, in the case of a group practice under paragraph (3)(C), to the group practice) if, for the reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year)—

the allowed charges under this part for all covered professional services furnished by the eligible professional (or group, as applicable) for the codes to which the electronic prescribing quality measure applies (as identified by the Secretary and published on the Internet website of the Centers for Medicare & Medicaid Services as of January 1, 2008, and as subsequently modified by the Secretary) are less than 10 percent of the total of the allowed charges under this part for all such covered professional services furnished by the eligible professional (or the group, as applicable); or

(ii) if determined appropriate by the Secretary, the eligible professional does not submit (including both electronically and nonelectronically) a sufficient number (as determined by the Secretary) of prescriptions under part D.

If the Secretary makes the determination to apply clause (ii) for a period, then clause (i) shall not apply for such period.

(C) Applicable electronic prescribing percent

For purposes of subparagraph (A), the term “applicable electronic prescribing percent” means—

(i) for 2009 and 2010, 2.0 percent;

(ii) for 2011 and 2012, 1.0 percent; and

(iii) for 2013, 0.5 percent.

(D) Limitation with respect to EHR incentive payments

The provisions of this paragraph shall not apply to an eligible professional (or, in the case of a group practice under paragraph (3)(C), to the group practice) if, for the EHR reporting period the eligible professional (or group practice) receives an incentive payment under subsection (a)(1)(A) with respect to a certified EHR technology (as defined in subsection (a)(4)) that has the capability of electronic prescribing.

(3) Satisfactory reporting and successful electronic prescriber described

(A) In general

For purposes of paragraph (1), an eligible professional shall be treated as satisfactorily submitting data on quality measures for covered professional services for a reporting period (or, for purposes of subsection (a)(8), for the quality reporting period for the year) if quality measures have been reported as follows:

(i) Three or fewer quality measures applicable

If there are no more than 3 quality measures that are provided under the physician reporting system and that are applicable to such services of such professional furnished during the period, each such quality measure has been reported under such system in at least 80 percent of the cases in which such measure is reportable under the system.

(ii) Four or more quality measures applicable

If there are 4 or more quality measures that are provided under the physician reporting system and that are applicable to such services of such professional furnished during the period, at least 3 such quality measures have been reported under such system in at least 80 percent of the cases in which the respective measure is reportable under the system.

For years after 2008, quality measures for purposes of this subparagraph shall not include electronic prescribing quality measures.

(B) Successful electronic prescriber

(i) In general

For purposes of paragraph (2) and subsection (a)(5), an eligible professional shall be treated as a successful electronic prescriber for a reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year) if the eligible professional meets the requirement described in clause (ii), or, if the Secretary determines appropriate, the requirement described in clause (iii). If the Secretary makes the determination under the preceding sentence to apply the requirement described in clause (ii) for a period, then the requirement described in clause (ii) shall not apply for such period.

(ii) Requirement for submitting data on electronic prescribing quality measures

The requirement described in this clause is that, with respect to covered professional services furnished by an eligible professional during a reporting period (or, for purposes of subsection (a)(5), for the re-
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porting period for a year), if there are any electronic prescribing quality measures that have been established under the physician reporting system and are applicable to any such services furnished by such professional for the period, such professional reported each such measure under such system in at least 50 percent of the cases in which such measure is reportable by such professional under such system.

(iii) Requirement for electronically prescribing under part D

The requirement described in this clause is that the eligible professional electronically submitted a sufficient number (as determined by the Secretary) of prescriptions under part D during the reporting period (or, for purposes of subsection (a)(5), for the reporting period for a year).

(iv) Use of part D data

Notwithstanding sections 1395w–116(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 clause (iii), paragraph (2)(B)(ii), and paragraph (5)(G).

(v) Standards for electronic prescribing

To the extent practicable, in determining whether eligible professionals meet the requirements under clauses (ii) and (iii) for purposes of clause (i), the Secretary shall ensure that eligible professionals utilize electronic prescribing systems in compliance with standards established for such systems pursuant to the Part D Electronic Prescribing Program under section 1395w–104(e) of this title.

(C) Satisfactory reporting measures for group practices

(i) In general

By January 1, 2010, the Secretary shall establish and have in place a process under which eligible professionals in a group practice (as defined by the Secretary) shall be treated as satisfactorily submitting data on quality measures under subparagraph (A) and as meeting the requirement described in subparagraph (B)(ii) for covered professional services for a reporting period (or, for purposes of subsection (a)(5), for a reporting period for a year), or, for purposes of subsection (a)(8), for a quality reporting period for the year if, in lieu of reporting measures under subsection (k)(2)(C), the group practice reports measures determined appropriate by the Secretary, such as measures that target high-cost chronic conditions and preventive care, in a form and manner, and at a time, specified by the Secretary.

(ii) Statistical sampling model

The process under clause (i) shall provide for the use of a statistical sampling model to submit data on measures, such as the model used under the Physician Group Practice demonstration project under section 1395cc–1 of this title.

(iii) No double payments

Payments to a group practice under this subsection by reason of the process under clause (i) shall be in lieu of the payments that would otherwise be made under this subsection to eligible professionals in the group practice for satisfactorily submitting data on quality measures.

(D) Authority to revise satisfactorily reporting data

For years after 2009, the Secretary, in consultation with stakeholders and experts, may revise the criteria under this subsection for satisfactorily submitting data on quality measures under subparagraph (A) and the criteria for submitting data on electronic prescribing quality measures under subparagraph (B)(ii).

(4) Form of payment

The payment under this subsection shall be in the form of a single consolidated payment.

(5) Application

(A) Physician reporting system rules

Paragraphs (6), (8), and (9) of subsection (k) shall apply for purposes of this subsection in the same manner as they apply for purposes of such subsection.

(B) Coordination with other bonus payments

The provisions of this subsection shall not be taken into account in applying subsections (m) and (u) of section 1395f of this title and any payment under such subsections shall not be taken into account in computing allowable charges under this subsection.

(C) Implementation

Notwithstanding any other provision of law, for 2007, 2008, and 2009, the Secretary may implement by program instruction or otherwise this subsection.

(D) Validation

(i) In general

Subject to the succeeding provisions of this subparagraph, for purposes of determining whether a measure is applicable to the covered professional services of an eligible professional under this subsection for 2007 and 2008, the Secretary shall presume that if an eligible professional submits data for a measure, such measure is applicable to such professional.

(ii) Method

The Secretary may establish procedures to validate (by sampling or other means as the Secretary determines to be appropriate) whether measures applicable to covered professional services of an eligible professional have been reported.

(iii) Denial of payment authority

If the Secretary determines that an eligible professional (or, in the case of a group practice under paragraph (3)(C), the group practice) has not reported measures applicable to covered professional services of such professional, the Secretary shall
not pay the incentive payment under this subsection. If such payments for such period have already been made, the Secretary shall recoup such payments from the eligible professional (or the group practice).

(E) Limitations on review
Except as provided in subparagraph (I), there shall be no administrative or judicial review under section 1395ff of this title, section 1396oo of this title, or otherwise of—
(i) the determination of measures applicable to services furnished by eligible professionals under this subsection;
(ii) the determination of satisfactory reporting under this subsection;
(iii) the determination of a successful electronic prescriber under paragraph (3), the limitation under paragraph (2)(B), and the exception under subsection (a)(5)(B); and
(iv) the determination of any incentive payment under this subsection and the payment adjustment under paragraphs (5)(A) and (6)(A) of subsection (a).

(F) Extension
For 2008 and subsequent years, the Secretary shall establish alternative criteria for satisfactorily reporting under this subsection and alternative reporting periods under paragraph (6)(C) for reporting groups of measures under subsection (k)(2)(B) and for reporting using the method specified in subsection (k)(4).

(G) 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 following:
(i) The eligible professionals (or, in the case of reporting under paragraph (3)(C), the group practices) who satisfactorily submitted data on quality measures under this subsection.
(ii) The eligible professionals (or, in the case of reporting under paragraph (3)(C), the group practices) who are successful electronic prescribers.

(H) Feedback
The Secretary shall provide timely feedback to eligible professionals on the performance of the eligible professional with respect to satisfactorily submitting data on quality measures under this subsection.

(I) Informal appeals process
The Secretary shall, by not later than January 1, 2011, establish and have in place an informal process for eligible professionals to seek a review of the determination that an eligible professional did not satisfactorily submit data on quality measures under this subsection.

(6) Definitions
For purposes of this subsection:

(A) Eligible professional; covered professional services
The terms "eligible professional" and "covered professional services" have the meanings given such terms in subsection (k)(3).

(B) Physician reporting system
The term "physician reporting system" means the system established under subsection (k).

(C) Reporting period
(i) In general
Subject to clauses (ii) and (iii), the term "reporting period" means—
(I) for 2007, the period beginning on July 1, 2007, and ending on December 31, 2007; and
(II) for 2008 and subsequent years, the entire year.

(ii) Authority to revise reporting period
For years after 2009, the Secretary may revise the reporting period under clause (i) if the Secretary determines such revision is appropriate, produces valid results on measures reported, and is consistent with the goals of maximizing scientific validity and reducing administrative burden. If the Secretary revises such period pursuant to the preceding sentence, the term "reporting period" shall mean such revised period.

(iii) Reference
Any reference in this subsection to a reporting period with respect to the application of subsection (a)(5)(A)(i) or (a)(8)(A) shall be deemed a reference to the reporting period under subsection (a)(5)(D)(ii) or the quality reporting period under subsection (a)(8)(D)(ii), respectively.

(7) Integration of physician quality reporting and EHR reporting
Not later than January 1, 2012, the Secretary shall develop a plan to integrate reporting on quality measures under this subsection with reporting requirements under subsection (a) relating to the meaningful use of electronic health records. Such integration shall consist of the following:

(A) The selection of measures, the reporting of which would both demonstrate—
(i) meaningful use of an electronic health record for purposes of subsection (o); and
(ii) quality of care furnished to an individual.

(B) Such other activities as specified by the Secretary.

(7) Additional incentive payment
(A) In general
For 2011 through 2014, if an eligible professional meets the requirements described in subparagraph (B), the applicable quality percent for such year, as described in clauses (iii) and (iv) of paragraph (1)(B), shall be increased by 0.5 percentage points.

(B) Requirements described
In order to qualify for the additional incentive payment described in subparagraph

\footnotesize{\textsuperscript{7}So in original. \textsuperscript{8}So in original. Probably should be "(a)(8)(C)(iii).". \textsuperscript{9}So in original. Two pars. (7) have been enacted.}
(A), an eligible professional shall meet the following requirements:

(i) The eligible professional shall—
   (I) satisfactorily submit data on quality measures for purposes of paragraph (I) for a year; and
   (II) have such data submitted on their behalf through a Maintenance of Certification Program (as defined in subparagraph (C)(i)) that meets—
   (aa) the criteria for a registry (as described in subsection (k)(4)); or
   (bb) an alternative form and manner determined appropriate by the Secretary.

(ii) The eligible professional, more frequently than is required to qualify for or maintain board certification status—
   (I) participates in such a Maintenance of Certification program for a year; and
   (II) successfully completes a qualified Maintenance of Certification Program practice assessment (as defined in subparagraph (C)(ii)) for such year.

(iii) A Maintenance of Certification program submits to the Secretary, on behalf of the eligible professional, information—
   (I) in a form and manner specified by the Secretary, that the eligible professional has successfully met the requirements of clause (ii) (which may be in the form of a structural measure);
   (II) if requested by the Secretary, on the survey of patient experience with care (as described in subparagraph (C)(ii)); and
   (III) as the Secretary may require, on the methods, measures, and data used under the Maintenance of Certification Program and the qualified Maintenance of Certification Program practice assessment.

(C) Definitions

For purposes of this paragraph:

(i) The term ‘Maintenance of Certification Program’ means a continuous assessment program, such as qualified American Board of Medical Specialties Maintenance of Certification program or an equivalent program (as determined by the Secretary), that advances quality and the lifelong learning and self-assessment of board certified specialty physicians by focusing on the competencies of patient care, medical knowledge, practice-based learning, interpersonal and communication skills and professionalism. Such a program shall include the following:
   (I) The program requires the physician to maintain a valid, unrestricted medical license in the United States.
   (II) The program requires a physician to participate in educational and self-assessment programs that require an assessment of what was learned.
   (III) The program requires a physician to demonstrate, through a formalized, secure examination, that the physician has the fundamental diagnostic skills, medical knowledge, and clinical judgment to provide quality care in their respective specialty.

(iv) The program requires successful completion of a qualified Maintenance of Certification Program practice assessment as described in clause (i).

(ii) The term ‘qualified Maintenance of Certification Program practice assessment’ means an assessment of a physician’s practice that—
   (I) includes an initial assessment of an eligible professional’s practice that is designed to demonstrate the physician’s use of evidence-based medicine;
   (II) includes a survey of patient experience with care; and
   (III) requires a physician to implement a quality improvement intervention to address a practice weakness identified in the initial assessment under subclause (I) and then to remeasure to assess performance improvement after such intervention.

(n) Physician Feedback Program

(1) Establishment

(A) In general

(i) Establishment

The Secretary shall establish a Physician Feedback Program (in this subsection referred to as the ‘Program’).

(ii) Reports on resources

The Secretary shall use claims data under this subchapter (and may use other data) to provide confidential reports to physicians (and, as determined appropriate by the Secretary, to groups of physicians) that measure the resources involved in furnishing care to individuals under this subchapter.

(iii) Inclusion of certain information

If determined appropriate by the Secretary, the Secretary may include information on the quality of care furnished to individuals under this subchapter (and may use other data) to provide confidential reports to physicians (and, as determined appropriate by the Secretary, to groups of physicians) in such reports.

(B) Resource use

The resources described in subparagraph (A)(ii) may be measured—
   (i) on an episode basis; or
   (ii) on a per capita basis; or
   (iii) on both an episode and a per capita basis.

(2) Implementation

The Secretary shall implement the Program by not later than January 1, 2009.

(3) Data for reports

To the extent practicable, reports under the Program shall be based on the most recent data available.

(4) Authority to focus initial application

The Secretary may focus the initial application of the Program as appropriate, such as focusing the Program on—
(A) physician specialties that account for a certain percentage of all spending for physicians' services under this subchapter;

(B) physicians who treat conditions that have a high cost or a high volume, or both, under this subchapter;

(C) physicians who use a high amount of resources compared to other physicians;

(D) physicians practicing in certain geographic areas; or

(E) physicians who treat a minimum number of individuals under this subchapter.

(5) Authority to exclude certain information if insufficient information

The Secretary may exclude certain information regarding a service from a report under the Program with respect to a physician (or group of physicians) if the Secretary determines that there is insufficient information relating to that service to provide a valid report on that service.

(6) Adjustment of data

To the extent practicable, the Secretary shall make appropriate adjustments to the data used in preparing reports under the Program, such as adjustments to take into account variations in health status and other patient characteristics. For adjustments for reports on utilization under paragraph (9), see subparagraph (D) of such paragraph.

(7) Education and outreach

The Secretary shall provide for education and outreach activities to physicians on the operation of, and methodologies employed under, the Program.

(8) Disclosure exemption

Reports under the Program shall be exempt from disclosure under section 552 of title 5.

(9) Reports on utilization

(A) Development of episode grouper

(i) In general

The Secretary shall develop an episode grouper that combines separate but clinically related items and services into an episode of care for an individual, as appropriate.

(ii) Timeline for development

The episode grouper described in subparagraph (A) shall be developed by not later than January 1, 2012.

(iii) Public availability

The Secretary shall make the details of the episode grouper described in subparagraph (A) available to the public.

(iv) Endorsement

The Secretary shall seek endorsement of the episode grouper described in subparagraph (A) by the entity with a contract under section 1395aaa(a) of this title.

(B) Reports on utilization

Effective beginning with 2012, the Secretary shall provide reports to physicians that compare, as determined appropriate by the Secretary, patterns of resource use of the individual physician to such patterns of other physicians.

(C) Analysis of data

The Secretary shall, for purposes of preparing reports under this paragraph, establish methodologies as appropriate, such as to—

(i) attribute episodes of care, in whole or in part, to physicians;

(ii) identify appropriate physicians for purposes of comparison under subparagraph (B); and

(iii) aggregate episodes of care attributed to a physician under clause (i) into a composite measure per individual.

(D) Data adjustment

In preparing reports under this paragraph, the Secretary shall make appropriate adjustments, including adjustments—

(i) to account for differences in socioeconomic and demographic characteristics, ethnicity, and health status of individuals (such as to recognize that less healthy individuals may require more intensive interventions); and

(ii) to eliminate the effect of geographic adjustments in payment rates (as described in subsection (e)).

(E) Public availability of methodology

The Secretary shall make available to the public—

(i) the methodologies established under subparagraph (C);

(ii) information regarding any adjustments made to data under subparagraph (D); and

(iii) aggregate reports with respect to physicians.

(F) Definition of physician

In this paragraph:

(i) In general

The term “physician” has the meaning given that term in section 1395x(r)(1) of this title.

(ii) Treatment of groups

Such term includes, as the Secretary determines appropriate, a group of physicians.

(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 the establishment of the methodology under subparagraph (C), including the determination of an episode of care under such methodology.

(10) Coordination with other value-based purchasing reforms

The Secretary shall coordinate the Program with the value-based payment modifier established under subsection (p) and, as the Secretary determines appropriate, other similar provisions of this subchapter.

10So in original. Probably means cl. (i) of this subpar.
(o) Incentives for adoption and meaningful use of certified EHR technology

(1) Incentive payments

(A) In general

(i) In general

Subject to the succeeding subparagraphs of this paragraph, with respect to covered professional services furnished by an eligible professional during a payment year (as defined in subparagraph (E)), if the eligible professional is a meaningful EHR user (as determined under paragraph (2)) for the EHR reporting period with respect to such year, in addition to the amount otherwise paid under this part, there also shall be paid to the eligible professional (or to an employer or facility in the cases described in clause (A) of section 1395u(b)(6) of this title), from the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title an amount determined under paragraph (2) for the professional services furnished by an eligible professional during such year.

(ii) No incentive payments with respect to years after 2016

No incentive payments may be made under this subsection with respect to a year after 2016.

(B) Limitations on amounts of incentive payments

(i) In general

In no case shall the amount of the incentive payment provided under this paragraph for an eligible professional for a payment year exceed the applicable amount specified under this subparagraph with respect to such eligible professional and such year.

(ii) Amount

Subject to clauses (iii) through (v), the applicable amount specified in this subparagraph for an eligible professional is as follows:

(I) For the first payment year for such professional, $15,000 (or, if the first payment year for such eligible professional is 2011 or 2012, $18,000).

(II) For the second payment year for such professional, $12,000.

(III) For the third payment year for such professional, $8,000.

(IV) For the fourth payment year for such professional, $4,000.

(V) For the fifth payment year for such professional, $2,000.

(VI) For any succeeding payment year for such professional, $0.

(iii) Phase down for eligible professionals first adopting EHR after 2013

If the first payment year for an eligible professional is after 2013, then the amount specified in this subparagraph for a payment year for such professional is the same as the amount specified in clause (ii) for such payment year for an eligible professional whose first payment year is 2013.

(iv) Increase for certain eligible professionals

In the case of an eligible professional who predominantly furnishes services under this part in an area that is designated by the Secretary (under section 254e(a)(1)(A) of this title) as a professional shortage area, the amount that would otherwise apply for a payment year for such professional under subclauses (I) through (V) of clause (ii) shall be increased by 10 percent. In implementing the preceding sentence, the Secretary may, as determined appropriate, apply provisions of subsections (m) and (u) of section 1395l of this title in a similar manner as such provisions apply under such subsection.

(v) No incentive payment if first adopting after 2014

If the first payment year for an eligible professional is after 2014 then the applicable amount specified in this subparagraph for such professional for such year and any subsequent year shall be $0.

(C) Non-application to hospital-based eligible professionals

(i) In general

No incentive payment may be made under this paragraph in the case of a hospital-based eligible professional.

(ii) Hospital-based eligible professional

For purposes of clause (i), the term “hospital-based eligible professional” means, with respect to covered professional services furnished by an eligible professional during the EHR reporting period for a payment year, an eligible professional, such as a pathologist, anesthesiologist, or emergency physician, who furnishes substantially all of such services in a hospital inpatient or emergency room setting and through the use of the facilities and equipment, including qualified electronic health records, of the hospital. The determination of whether an eligible professional is a hospital-based eligible professional shall be made on the basis of the site of service (as defined by the Secretary) and without regard to any employment or billing arrangement between the eligible professional and any other provider.

(D) Payment

(i) Form of payment

The payment under this paragraph may be in the form of a single consolidated payment or in the form of such periodic installments as the Secretary may specify.

(ii) Coordination of application of limitation for professionals in different practices

In the case of an eligible professional furnishing covered professional services in
more than one practice (as specified by the Secretary), the Secretary shall establish rules to coordinate the incentive payments, including the application of the limitation on amounts of such incentive payments under this paragraph, among such practices.

(iii) Coordination with Medicaid

The Secretary shall seek, to the maximum extent practicable, to avoid duplicative requirements from Federal and State governments to demonstrate meaningful use of certified EHR technology under this subchapter and subchapter XIX. The Secretary may also adjust the reporting periods under such subchapter and such subsections in order to carry out this clause.

(E) Payment year defined

(i) In general

For purposes of this subsection, the term “payment year” means a year beginning with 2011.

(ii) First, second, etc. payment year

The term “first payment year” means, with respect to covered professional services furnished by an eligible professional, the first year for which an incentive payment is made for such services under this subsection. The terms “second payment year”, “third payment year”, “fourth payment year”, and “fifth payment year” mean, with respect to covered professional services furnished by such eligible professional, each successive year immediately following the first payment year for such professional.

(2) Meaningful EHR user

(A) In general

For purposes of paragraph (1), an eligible professional shall be treated as a meaningful EHR user for an EHR reporting period for a payment year (or, for purposes of subsection (a)(7), for an EHR reporting period under such subsection for a year) if each of the following requirements is met:

(i) Meaningful use of certified EHR technology

The eligible professional demonstrates to the satisfaction of the Secretary, in accordance with subparagraph (C)(i), that during such period the professional is using certified EHR technology in a meaningful manner, which shall include the use of electronic prescribing as determined to be appropriate by the Secretary.

(ii) Information exchange

The eligible professional 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 professional 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 may provide for the use of alternative means for meeting the requirements of clauses (i), (ii), and (iii) in the case of an eligible professional furnishing covered professional services in a group practice (as defined by the Secretary). 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 endorsed by the entity with a contract with the Secretary under section 1395aaa(a) of this title.

(ii) Limitation

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 otherwise required, including reporting under subsection (k)(2)(C).

(C) Demonstration of meaningful use of certified EHR technology and information exchange

(i) In general

A professional 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 a patient encounter was documented using certified EHR technology);

(III) a survey response;

(IV) reporting under subparagraph (A)(iii); and
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(3) Application

(A) Physician reporting system rules

Paragraphs (5), (6), and (8) of subsection (k) shall apply for purposes of this subsection in the same manner as they apply for purposes of such subsection.

(B) Coordination with other payments

The provisions of this subsection shall not be taken into account in applying the provisions of subsection (m) of this section and of section 1395(m) of this title and any payment under such provisions shall not be taken into account in computing allowable charges under this subsection.

(C) 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—

(i) the methodology and standards for determining payment amounts under this subsection and payment adjustments under subsection (a)(7)(A), including the coordination under clauses (ii) and (iii) of paragraph (1)(D);

(ii) the methodology and standards for determining a meaningful EHR user under paragraph (2), including selection of measures under paragraph (2)(B), specification of the means of demonstrating meaningful EHR use under paragraph (2)(C), and the hardship exception under subsection (a)(7)(B);

(iii) the methodology and standards for determining a hospital-based eligible professional under paragraph (1)(C); and

(iv) the specification of reporting periods under paragraph (5) and the selection of the form of payment under paragraph (1)(D)(i).

(D) 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, business addresses, and business phone numbers of the eligible professionals who are meaningful EHR users and, as determined appropriate by the Secretary, of group practices receiving incentive payments under paragraph (1).

(4) Certified EHR technology defined

For purposes of this section, the term “certified EHR technology” means a qualified electronic health record (as defined in section 300jj(13) of this title) that is certified pursuant to section 300jj–11(c)(5) of this title as meeting standards adopted under section 300jj–14 of this title that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

(5) Definitions

For purposes of this subsection:

(A) Covered professional services

The term “covered professional services” has the meaning given such term in subsection (k)(3).

(B) EHR reporting period

The term “EHR reporting period” means, with respect to a payment year, any period (or periods) as specified by the Secretary.

(C) Eligible professional

The term “eligible professional” means a physician, as defined in section 1395x(r) of this title.

(p) Establishment of value-based payment modifier

(1) In general

The Secretary shall establish a payment modifier that provides for differential payment to a physician or a group of physicians under the fee schedule established under subsection (b) based upon the quality of care furnished compared to cost (as determined under paragraphs (2) and (3), respectively) during a performance period. Such payment modifier shall be separate from the geographic adjustment factors established under subsection (e).

(2) Quality

(A) In general

For purposes of paragraph (1), quality of care shall be evaluated, to the extent practicable, based on a composite of measures of the quality of care furnished (as established by the Secretary under subparagraph (B)).

(B) Measures

(i) The Secretary shall establish appropriate measures of the quality of care furnished by a physician or group of physicians to individuals enrolled under this part, such as measures that reflect health outcomes. Such measures shall be risk adjusted as determined appropriate by the Secretary.

(ii) The Secretary shall seek endorsement of the measures established under this subparagraph by the entity with a contract under section 1899aa(a) of this title.

(3) Costs

For purposes of paragraph (1), costs shall be evaluated, to the extent practicable, based on a composite of appropriate measures of costs established by the Secretary (such as the composite measure under the methodology established under subsection (n)(9)(C)(iii)) that eliminate the effect of geographic adjustments in payment rates (as described in subsection (e)), and take into account risk factors (such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals (such as to recognize that less healthy individuals may require more intensive inter-
ventions)\(^1\) and other factors determined appropriate by the Secretary.

(4) **Implementation**

(A) **Publication of measures, dates of implementation, performance period**

Not later than January 1, 2012, the Secretary shall publish the following:

(i) The measures of quality of care and costs established under paragraphs (2) and (3), respectively.

(ii) The dates for implementation of the payment modifier (as determined under subparagraph (B)).

(iii) The initial performance period (as specified under subparagraph (B)(ii)).

(B) **Deadlines for implementation**

(i) **Initial implementation**

Subject to the preceding provisions of this subparagraph, the Secretary shall begin implementing the payment modifier established under this subsection through the rulemaking process during 2013 for the physician fee schedule established under subsection (b).

(ii) **Initial performance period**

(I) **In general**

The Secretary shall specify an initial performance period for application of the payment modifier established under this subsection with respect to 2015.

(II) **Provision of information during initial performance period**

During the initial performance period, the Secretary shall, to the extent practicable, provide information to physicians and groups of physicians about the quality of care furnished by the physician or group of physicians to individuals enrolled under this part compared to cost (as determined under paragraphs (2) and (3), respectively) with respect to the performance period.

(iii) **Application**

The Secretary shall apply the payment modifier established under this subsection for items and services furnished—

(I) beginning on January 1, 2015, with respect to specific physicians and groups of physicians the Secretary determines appropriate; and

(II) beginning not later than January 1, 2017, with respect to all physicians and groups of physicians.

(C) **Budget neutrality**

The payment modifier established under this subsection shall be implemented in a budget neutral manner.

(5) **Systems-based care**

The Secretary shall, as appropriate, apply the payment modifier established under this subsection in a manner that promotes systems-based care.

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\(^1\) So in original. Probably should be followed by a second closing parenthesis.
Section 212 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999, referred to in subsec. (c)(2)(H)(i), (D)(ii)(I), is section 1000(a)(6) (title II and title IV of Pub. L. 106-113, which is set out as a note under this section.


Chapter 1 of title IV of the Act is chapter 1 (§§ 4501–4513) of subtitle F of title IV of Pub. L. 105–33, which amended this section and sections 1395a, 1395k, 1395s, 1395x, 1395y, 1395cc, and 1395yy of this title and enacted provisions set out as notes under this section and sections 1395a, 1395k, 1395x, 1395y, and 1395ww of this title. For complete classification of this Act to the Code, see Table II.

Part C of this subchapter, referred to in subsec. (f)(4)(B), is classified to section 1395w-21 et seq. of this title.

Section 225(c)(1) and section 524 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008, referred to in subsec. (j)(2)(A)(ii)(I), (II), are sections 225(c)(1) of title II and 524 of title V of Pub. L. 110-161, Dec. 26, 2007, 121 Stat. 2494, which was formerly set out as a note under this section, was transferred to subsec. (m) of this section and amended by Pub. L. 110-275.

Compensation

The text of section 101(c) of Pub. L. 109-422, 22, title I, Dec. 29, 2006, 120 Stat. 2977, as amended by Pub. L. 110-173, title I, §101(b)(2), Dec. 29, 2007, 121 Stat. 2494, which was formerly set out as a note under this section, was transferred to subsec. (m) of this section and amended by Pub. L. 110-275.

Amendments


Subsec. (b)(4)(B). Pub. L. 111-152, §1107(a)(A), substituted “paragraph (A)” for “this paragraph”.

Pub. L. 111-148, §3135(b)(1), added subpar. (B). For 2010 and 2011, dual-energy x-ray absorptiometry services (as defined in paragraph (6))” before the period.

Subsec. (b)(4)(C). Pub. L. 111-152, §1107(b)(1), amended subpar. (C) generally. Prior to amendment, text read as follows: “Consistent with the methodology for computing the number of practice expense relative value units under subsection (c)(2)(C)(ii) with respect to advanced diagnostic imaging services (as defined in section 1395m(e)(1)(B) of this title) furnished on or after January 1, 2008, the Secretary shall adjust such number of units so it reflects—

‘‘(i) in the case of services furnished on or after January 1, 2010, and before January 1, 2013, a 65 percent (rather than 50 percent) presumed rate of utilization of imaging equipment;”

‘‘(ii) in the case of services furnished on or after January 1, 2013, and before January 1, 2014, a 70 percent (rather than 50 percent) presumed rate of utilization of imaging equipment; and

‘‘(iii) in the case of services furnished on or after January 1, 2014, a 75 percent (rather than 50 percent) presumed rate of utilization of imaging equipment.”


Pub. L. 111–148, §3102(b)(1), substituted “(G), and (H)” for “(and) (G)” in introductory provisions.


Subsec. (k)(4). Pub. L. 111–148, §3102(a)(1), inserted “or through a Maintenance of Certification program operated by a specialty body of the American Board of Medical Specialties that meets the criteria for such a registry” after “Database”.


Subsec. (m)(5)(C). Pub. L. 111–148, §3002(a)(2)(B), inserted “or, for purposes of subsection (a)(8), for a quality reporting period for the year” after “(a)(5), for a reporting period for a year”.


Subsec. (m)(5)(H), (I). Pub. L. 111–148, §3002(e), (f)(2), added subpars. (H) and (I).


Subsec. (m)(6)(C)(iii). Pub. L. 111–148, §3002(a)(4)(B), inserted “(a)(5)” after “(a)(5)” and substituted “under subsection (a)(5)(D)(iii) or the quality reporting period under subsection (a)(5)(D)(iii), respectively” for “under subparagraph (D)(iii) of such subsection”.

Subsec. (m)(7). Pub. L. 111–148, §10327(a), added par. (7) relating to additional incentive payment.


Subsec. (n)(1)(A). Pub. L. 111–148, §3003(a)(1)(A), designated existing provisions as cl. (i), inserted heading, substituted “the ‘Program’” for “the Program” under which the Secretary shall use claims data under this subchapter (and may use other data) to provide confidential reports to physicians (and, as determined appropriate by the Secretary, to groups of physicians) that measure the resources involved in furnishing care to individuals under this subchapter. If determined appropriate by the Secretary, the Secretary may include information on the quality of care furnished to individuals under this subchapter by the physician (or group of physicians) in such reports.” and added cls. (ii) and (iii).


Subsec. (e)(1)(G). Pub. L. 110–275, § 134(b), inserted at end "‘For purposes of payment for services furnished in the State described in the preceding sentence on or after January 1, 2009, after calculating the work geographic index in subparagraph (A)(iii), the Secretary shall increase the work geographic index to 1.5 if such index would otherwise be less than 1.5’.”


Pub. L. 110–252, § 7002(c)(1)(A), substituted "‘$4,670,000,000’ for ‘$4,960,000,000’.”

Pub. L. 110–275, § 131(a)(3)(C)(i)(I), struck out subcl. (IV) which read as follows: "‘For expenditures during 2014, an amount equal to $250,000,000.’’”


Pub. L. 110–252, § 7002(c)(2), added subcl. (IV). Subsec. (j)(2)(B). Pub. L. 110–275, § 131(a)(3)(C)(ii), inserted "‘and’ at end of cl. (i), substituted period for semicolon at end of cl. (ii), and struck out cls. (iii) and (iv) which read as follows: ‘(iii) 2013 for payment with respect to physicians’ services furnished during 2013; and (iv) 2014 for payment with respect to physicians’ services furnished during 2014.’”


Subsec. (m)(1). Pub. L. 110–275, § 131(b)(3)(B), added par. (1) and struck out former par. (1) which provided for an additional payment for certain covered professional services furnished by an eligible professional. Subsec. (m)(2). Pub. L. 110–275, § 132(a)(1), added par. (2). Former par. (2) redesignated (3). Subsec. (m)(3). Pub. L. 110–275, § 132(a)(2)(A), inserted "‘and successful electronic prescriber’ after ‘reporting in’ in heading. Pub. L. 110–275, § 131(b)(3)(D)(ii), (ii), designated existing provisions as subpars. (A) and inserted heading, redesignated former subpars. (A) and (B) as cls. (I) and (II), respectively, of subpar. (A), and realigned margins. Pub. L. 110–275, § 131(b)(3)(C), redesignated par. (2) as (3) and struck out former par. (3) which provided for payment limitation.


Subsec. (m)(3)(C). (D). Pub. L. 110–275, § 131(b)(3)(D)(iv), added subpars. (C) and (D). Subsec. (m)(5)(A). Pub. L. 110–275, § 131(b)(5)(A)(i), substituted "‘subsection (k)’ for ‘section 1848(k) of the Social Security Act, as added by subsection (b),’ and ‘such subsection’ for ‘such section’.”


Subsec. (m)(5)(D)(i). Pub. L. 110–275, § 131(b)(3)(E)(ii), which directed amendment of cl. (i) by inserting "for 2007 and 2008” after “under this subsection” and then substituting "this subsection" for "paragraph (2)”, was executed by substituting "under this subsection for 2007 and 2008” for “under paragraph (2)” to reflect the probable intent of Congress.

Subsec. (m)(5)(D)(ii). Pub. L. 110–275, § 131(b)(3)(E)(iii), substituted “may establish procedures to” for “shall”

Subsec. (m)(5)(D)(iii). Pub. L. 110–275, § 131(b)(3)(E)(iv), inserted "‘in the case of a group practice under paragraph (3), the group practice after ‘an eligible professional’, substituted ‘incentive payment under this subsection’ for ‘bonus incentive payment’, and inserted at end ‘If such payments for such period have already been made, the Secretary shall recoup such payments from the eligible professional (or the group practice).’”
Subsec. (m)(5)(E). Pub. L. 110–275, §131(b)(3)(E)(iii), substituted “1395f of this title, section 1395oo of this title, or otherwise” for “1869 or 1878 of the Social Security Act, as otherwise”.

Pub. L. 110–275, §131(b)(3)(E)(iii)(I)–(III), struck out cl. (i) designation and heading before “There shall be”, redesignated subcls. (I) to (IV) as cl. (i) to (iv), respectively, and struck out former cl. (ii). Prior to amendment, text of cl. (ii) read as follows: “A determination under this subsection shall not be treated as a determination for purposes of section 1869 of the Social Security Act.”


Subsec. (k)(2)(B). Pub. L. 110–173, §101(b)(1), in heading and cl. (i), inserted “and after 2007” and, in clses. (ii) and (iii), substituted “of each of 2007 and 2008” for “2007” and inserted “or 2009, as applicable” after “2008”.

Subsec. (k)(2)(A). Pub. L. 110–173, §101(a)(2)(A)(i), added subpar. (A) and struck out former subpar. (A), which read as follows: “There shall be available to the Fund for expenditures an amount equal to $1,200,000,000, as reduced by section 524 and section 225(c)(1)(A) of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008 (division G of the Consolidated Appropriations Act, 2008)” after “$1,350,000,000” and, in second sentence, “as reduced by section 225(c)(1)(B) of such Act,” after “$325,000,000.”

Pub. L. 110–90, §6(1), inserted at end: “In addition, there shall be available to the Fund for expenditures during 2009 an amount equal to $325,000,000 and for expenditures during or after 2013 an amount equal to $60,000,000.”

Subsec. (l)(2)(B). Pub. L. 110–173, §101(a)(2)(A)(ii), substituted “entire amount available for expenditures, after application of subparagraph (A)(i), during—” and clses. (i) to (iii) for “entire amount specified in the first sentence of subparagraph (A) for payment with respect to physicians’ services furnished during 2008 and for the obligation of the entire first amount specified in the second sentence of such subparagraph for payment with respect to physicians’ services furnished during 2009 and of the entire second amount so specified for payment with respect to physicians’ services furnished on or after January 1, 2013” after “furnished during 2008.”


Subsec. (c)(2)(B)(ii)(II). Pub. L. 109–171, §5102(a)(1), substituted “subparagraphs (A) and (B)” for “subparagraphs (A) and (C)”.


Subsec. (e)(1)(A). Pub. L. 108–173, §602(1), as amended by Pub. L. 110–275, §134(c), substituted “subparagraphs (B), (C), (E), and (G)” for “subparagraphs (B), (C), and (E)”. Pub. L. 108–173, §412(1), substituted “subparagraphs (B) and (C)”.


Subsec. (i)(2)(C), Pub. L. 106–173, § 603(b)(1), substituted “annual average” for “projected” and “during the 18-year period ending with the applicable period involved”.

Subsec. (i)(1)(B), Pub. L. 106–173, § 303(g)(2), substituted “subsections (c)(2)(F), (c)(2)(H), and (c)(2)(I) of this section” for “subsection (c)(2)(F) of this section”.

Subsec. (i)(1)(C), Pub. L. 108–7 amended subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: “The Secretary shall cause to have published in the Federal Register, during the last 15 days of October of—


Subsec. (d)(1)(E), Pub. L. 106–113, § 1000(a)(6) [title II, § 211(a)(1)(A)], amended heading and text of subpar. (B) generally. Prior to amendment, text read as follows: “The Secretary shall cause to have published in the Federal Register, during the last 15 days of October of—


Subsec. (d)(3)(C), Pub. L. 106–113, § 1000(a)(6) [title II, § 211(a)(1)(A)(iii)], inserted “and (paragraph (4))” after “for purposes of this paragraph” in introductory provisions.


Subsec. (f)(1), Pub. L. 106–113, § 1000(a)(6) [title II, § 211(b)(1)], amended heading and text of par. (1) generally. Prior to amendment, text read as follows: “The Secretary shall cause to have published in the Federal Register, during the sustainable growth rate for each fiscal year beginning with fiscal year 1998. Such publication shall occur by not later than August 1 before each fiscal year beginning with fiscal year 1998 will be published not later than November 1, 1997.”


Subsec. (f)(2)(A), Pub. L. 106–113, § 1000(a)(6) [title II, § 211(b)(2)(B)], substituted “applicable period” for “fiscal year”.

Subsec. (f)(2)(B), (C), Pub. L. 106–113, § 1000(a)(6) [title II, § 211(b)(2)(C)], substituted “applicable period” for “fiscal year” in two places.


Subsec. (f)(3), Pub. L. 106–113, § 1000(a)(6) [title II, § 211(b)(5)], added par. (3). Former par. (3) redesignated (4).

Subsec. (f)(3)(C), Pub. L. 106–113, § 1000(a)(6) [title II, § 211(b)(3)], added subpar. (C).

Subsec. (f)(4), Pub. L. 106–113, § 1000(a)(6) [title II, § 211(b)(4)], redesignated par. (3) as (4).

Subsec. (f)(3), Pub. L. 106–113, § 1000(a)(6) [title III, § 321(k)(5)], substituted “section 1395x(o)(2) of this title” for “section 1395x(o)(2) of this title”, “(B),” for “(B),” and “, and (15)” for “and (15)”.

1997—Subsec. (b)(1), Pub. L. 105–33, § 4644(d), substituted “Before November 1 of the preceding year, for each year beginning with 1998” for “Before January 1 of each year beginning with 1992” in introductory provisions.


Subsec. (c)(2)(C)(ii), Pub. L. 105–33, § 4505(b)(1)(A), which directed an amendment striking the comma at the end of cl. (ii) and inserting a period and the following: “For 1999, such number of units shall be determined based 75 percent on such product and based 25 percent on the relative practice expense resources involved in furnishing the service. For 2000, such number of units shall be determined based 50 percent on such product and based 50 percent on such relative practice expense resources. For a subsequent year, such number of units shall be determined based entirely on such relative practice expense resources.”, was executed by making the insertion at end of cl. (ii) to reflect the probable intent of Congress, because cl. (ii) ended with a period rather than a comma.


Subsec. (c)(2)(C)(ii), Pub. L. 105–33, § 4505(c)(1)(A), inserted “for the service for years before 2000” before “equal” in introductory provisions, substituted comma for period at end of subcl. (II), and inserted concluding provisions.

Subsec. (c)(2)(G), Pub. L. 105–33, § 4505(e), added subpar. (G).


Subsec. (c)(3)(C)(ii), Pub. L. 105–33, § 4505(c)(1)(B), substituted “For years before 1999, the malpractice” for “The malpractice” in introductory provisions.

Subsec. (d)(1)(A), Pub. L. 105–33, § 4501(b)(1), (2), struck out “(or factors)” after “conversion factor” in two places and struck out “or updates” after “update”.

Subsec. (d)(1)(C), Pub. L. 105–33, § 4504(a)(1), substituted “Except as provided in subparagraph (D), the single conversion factor” for “The single conversion factor”.

Pub. L. 105–33, § 4501(a)(2), added subpar. (C). Former subpar. (C) redesignated (D).


Pub. L. 105–33, § 4501(b)(1), (3), struck out “(or updates)” after “update in two places and struck out “(or factors)” after “conversion factor” in cl. (i).

Pub. L. 105–33, § 4504(a)(1), redesignated subpar. (C) as (D).


Subsec. (d)(2), Pub. L. 105–33, § 4502(b), struck out heading and text of par. (2) which related to recommendation of update.

Subsec. (d)(2)(F), Pub. L. 105–33, § 4022(b)(1)(B)(1), struck out heading and text of subpar. (F). Text read as follows: “The Physician Payment Review Commission shall review the report submitted under subparagraph (A) in a year and shall submit to the Congress, by not later than May 15 of the year, a report including its recommendation respecting the update (or updates) in the conversion factor (or factors) for the following year.”

Subsec. (d)(3), Pub. L. 105–33, § 4502(a)(1), amended heading and text generally. Prior to amendment, text related to updates of conversion factor based on index and made provision for adjusting updates in case.

Subsec. (f), Pub. L. 105–33, § 4503(b), amended subsec. heading and heading and text of par. (1) generally.
Prior to amendment, par. (1) related to process for establishing medicare volume performance standard rates of increase. 

Subsec. (b)(1)(B). Pub. L. 105–33, §4022(b)(2)(B)(i), struck out heading and text of subpar. (B). Text read as follows: “The Secretary shall establish procedures for providing, on a quarterly basis to the Congress, the Congressional Research Service, the Committees on Ways and Means and Energy and Commerce of the House of Representatives, and the Committee on Finance of the Senate, information on compliance with performance standard rates of increase for fiscal years beginning in 1991.”

Subsec. (b)(2). Pub. L. 105–33, §4505(a), added par. (2) and struck out heading and text of former par. (5) which related to specification of performance standard rates of increase for physician services for fiscal years beginning in 1991.

Subsec. (c)(3). Pub. L. 105–33, §4505(a), added par. (3) and struck out heading and text of former par. (5) which defined “physicians’ services” and “HMO enrollee.”

Subsec. (g)(3)(A). Pub. L. 105–33, §4714(b)(2), inserted before period at end “and the average amount of excess charges and limiting charges, the number and types of services involved, and the average amount of excess charges and information” after “report to the Congress”.

Subsec. (g)(3)(B). Pub. L. 103–432, §123(d), inserted “information on the extent to which actual charges exceed limiting charges, the number and types of services involved, and the average amount of excess charges and information” after “report to the Congress”.

Subsec. (j)(3). Pub. L. 103–432, §123(a)(1), amended text read as follows: “In the case of physicians’ services (including services which the Secretary excludes pursuant to subsection (j)(3) of this section, furnished with respect to an individual enrolled under this part on or after January 1, 1991) an actual charge in excess of the limiting charge described in paragraph (2) and for which payment is not made on an assignment-related basis under this part, the Secretary may apply sanctions against such physician, supplier, or other person in accordance with section 1396u(j)(2) of this title. In applying this subsection the Secretary shall take into account whether such a service is deemed also to include a reference to a supplier or other person under this subparagraph.”

Subsec. (g)(3)(B). Pub. L. 103–432, §123(a)(2), inserted after first sentence “No person is liable for payment of any amounts billed for such a service in violation of the previous sentence.” and in last sentence substituted “first sentence” for “previous sentence”.

Subsec. (g)(6)(B). Pub. L. 103–432, §123(d), inserted “information on the extent to which actual charges exceed limiting charges, the number and types of services involved, and the average amount of excess charges and information” after “report to the Congress”.

Subsec. (g)(3). Pub. L. 103–432, §123(a)(1), amended text read as follows: “If payment is made under this part for a visit to a physician or consultation with a physician, supplier, or other person for which payment is made under this section to a physician is deemed also to include a reference to a supplier or other person under this subparagraph.”

Subsec. (a)(3). Pub. L. 103–432, §13514(a)(1), heading inserted “and suppliers” after “physician” and in text inserted “or a nonparticipating supplier or other person” after “physician.”

Subsec. (a)(4). Pub. L. 103–432, §13514(c)(1), added par. (4). Text read as follows: “In the case of physicians’ services furnished by a physician before the end of the physician’s first full calendar year of furnishing services for which payment may be made under this part, and during each of the 3 succeeding years, the fee schedule amount to be applied shall be 85 percent, 85 percent, 90 percent, and 95 percent, respectively, of the fee schedule amount applicable to physicians who are not subject to this paragraph. The preceding sentence shall not apply to primary care services or services furnished in a rural area (as defined in section 1395ww(w)(2) of this title) that is designated as a health manpower shortage area.”
physician and, as part of or in conjunction with the visit or consultation there is an electrocardiogram performed or ordered to be performed, no payment may be made under this part with respect to the interpretation of the electrocardiogram and no physician may bill an individual enrolled under this part separately for such an interpretation. If a physician knowingly and willfully fails to enroll one or more individuals in violation of the previous sentence, the Secretary may apply sanctions against the physician or entity in accordance with section 1395u(j)(2) of this title.

Subsec. (c)(2)(A)(i). Pub. L. 103–66, §13513(c)(2), inserted before period at end “and section 13515(b) of the Omnibus Budget Reconciliation Act of 1993”.

Subsec. (c)(2)(C). Pub. L. 103–66, §13513(c)(2), inserted at end “Such relative values are subject to adjustment under subparagraph (F)(i).”


Subsec. (f)(2)(B). Pub. L. 103–66, §13512(a), added cls. (i) to (v) and struck out former cl. (i) which read as follows: “for each succeeding year is 2 percentage points.”

Subsec. (g)(1). Pub. L. 103–66, §13517(a)(2)(C), (D), inserted “or physician, or other person” after “such physician” and inserted at end “In applying this subparagraph, any reference in such section to a physician is deemed also to include a reference to a supplier or other person under this subparagraph.”

Pub. L. 103–66, §13517(a)(2)(B), which directed insertion of “including services which the Secretary excludes pursuant to subsection (j)(3) of this section,” after “physician’s services (” was executed by making the insertion after “physicians’ services (” to reflect the probable intent of Congress.

Pub. L. 103–66, §13517(a)(4), inserted “or nonparticipating supplier or other person” which are enrolled under this part who are HMO enrollees for “proportion of HMO enrollees in last sentence.


Pub. L. 103–66, §13518(a)(3), inserted “except for purposes of subsections (a)(3), (g), and (h) of this section” after “clauses (ii) and (iii)”.


Subsec. (e)(1)(A). Pub. L. 101–508, § 4118(c)(1), substituted “subparagraphs (B) and (C)” for “subparagraph (B)” in introductory provisions.


Subsec. (f)(2)(A). Pub. L. 101–508, § 4118(b)(1), (f)(1)(N)(i), in introductory provisions, substituted “the performance standard rate of increase, for all physicians’ services and for each category of physicians’ services,” for “each performance standard rate of increase” and “product” for “sum”.

Subsec. (f)(2)(A)(i). Pub. L. 101–508, § 4118(f)(1)(N)(i), as amended by Pub. L. 101–432, § 128(g)(7), substituted “all physicians’ services or for the category of physicians’ services, respectively,” for “physicians’ services” as defined in subsection (f)(5)(A) of this section”.

Pub. L. 101–508, § 4118(f)(1)(M), substituted “portions of calendar years” for “calendar years”.

Subsec. (f)(2)(A)(ii). Pub. L. 101–508, § 4118(b)(2), (3), substituted “1 plus the Secretary’s” for “the Secretary’s” and inserted “(divided by 100)” after “decrease”.


Pub. L. 101–508, § 4118(b)(2), (5), substituted “1 plus the Secretary’s” for “the Secretary’s” and inserted “(divided by 100)” after “percentage growth”.

Subsec. (f)(2)(A)(iv). Pub. L. 101–508, § 4118(b)(2)(v), (f)(1)(N)(iv), substituted “all physicians’ services or of the category of physicians’ services, respectively,” for “physicians’ services” as defined in subsection (f)(5)(A) of this section” and inserted “including changes in law and regulations affecting the percentage increase described in clause (i)” after “law or regulations”.

Pub. L. 101–508, § 4118(b)(2), (4), substituted “1 plus the Secretary’s” for “the Secretary’s” and “decrease” for “decrease of”.


Pub. L. 101–508, § 4116, inserted at end “In the case of evaluation and management services (as specified in section 1395m(b)(16)(B)(ii) of this title), the preceding sentence shall be applied by substituting ‘40 percent’ for ‘25 percent’.


Subsec. (1)(A). Pub. L. 101–508, § 4118(f)(1)(R), substituted “adjusted historical payment basis (as defined in section (a)(2)(D)(ii))” for “historical payment basis (as defined in subsection (a)”)”.


Subsec. (2). Pub. L. 101–508, § 4118(f)(1)(S), which directed the amendment of par. (1) by substituting “(as defined by the Secretary) and all other physicians’ services” for “, and such other” and all that follows through the period was executed by making the substitution for “, and such other category or categories of physicians’ services as the Secretary, from time to time, defines in regulation.” to reflect the probable intent of Congress.

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. 102–773, set out as a note under section 1965w–21 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT


Pub. L. 111–152, title I, § 1106, Mar. 30, 2010, 124 Stat. 1050, provided that the amendment made by section 1106 is effective as if included in the enactment of the Patient Protection and Affordable Care Act (Pub. L. 111–148).


Amendment by section 4103(c)(2) 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


EFFECTIVE DATE OF 2007 AMENDMENT

Pub. L. 110–173, title I, § 101(a)(2)(B), Dec. 29, 2007, 121 Stat. 2949, provided that: “(i) IN GENERAL.—Subject to clause (ii), the amendments made by subparagraph (A) [amending this section] shall take effect on the date of the enactment of this Act [Dec. 29, 2007].

“(ii) SPECIAL RULE FOR COORDINATION WITH CONSOLIDATED APPROPRIATIONS ACT, 2008.—If the date of the enactment of the Consolidated Appropriations Act, 2008 [Dec. 26, 2007], occurs on or after the date described in clause (i), the amendments made by subparagraph (A) shall be deemed to be made on the day after the effective date of sections 225(c)(1) [121 Stat. 2106] and 524 [amending this section] of the Department of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2008 [division G of the Consolidated Appropriations Act, 2008].”

EFFECTIVE DATE OF 2006 AMENDMENT

Amendment by section 512(c) of Pub. L. 109–171 applicable to services furnished on or after Jan. 1, 2007, see section 512(f) of Pub. L. 109–171, set out as a note under section 1395f of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

paragraph (1) [amending this section] shall apply to computations of the sustainable growth rate for years beginning with 2003.''

Amendment by Pub. L. 106–554 applicable with respect to services furnished on or after Jan. 1, 2002, see section 1(a)(6) [title I, § 104(c)] of Pub. L. 106–554, set out as a note under section 1395m of this title.

**Effective Date of 2000 Amendment**

Amendment by Pub. L. 106–554 applicable with respect to bone mass measurements performed on or after Jan. 1, 2002, see section 1(a)(6) [title I, § 104(c)] of Pub. L. 106–554, set out as a note under section 1395m of this title.

**Effective Date of 1999 Amendment**

Amendment by section 4022(b)(2)(B), (C) of Pub. L. 105–33 effective Nov. 1, 1997, the date of termination of the Prospective Payment Assessment Commission and the Prospective 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 1395p–6 of this title.

Amendment by section 4102(d) 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 1395m of this title.

Amendment by section 4103(d) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4103(e) of Pub. L. 105–33, set out as a note under section 1395m of this title.

Amendment by section 4104(d) 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 1395m of this title.

Amendment by section 4105(a)(2) of Pub. L. 105–33 applicable to services furnished on or after July 1, 1998, see section 4105(d)(1) of Pub. L. 105–33, set out as a note under section 1395m of this title.

Amendment by section 4106(b) of Pub. L. 105–33 applicable to items and services furnished on or after July 1, 1998, see section 4106(d)(1) of Pub. L. 105–33, set out as a note under section 1395m of this title.

Amendment by section 4107(a)(2) of Pub. L. 101–508, as amended by Pub. L. 103–322, title I, §126(d)(2), Oct. 31, 1994, 108 Stat. 4415, provided that: "Section 1848(b)(2) of the Social Security Act [subsec. (i)(2) of this section], as added by the amendment made by paragraph (1), shall apply to services furnished in 1991 in the same manner as it applies to services furnished after 1991. In applying the previous sentence, the prevailing charge shall be substituted for the fee schedule amount. In applying section 1848(g)(2)(D) of the Social Security Act for services of an assistant-at-surgery furnished during 1991, the recognized payment amount shall not exceed the maximum amount specified under section 1848(b)(2)(A) of such Act (as applied under this paragraph in such year)."


Amendment by section 4108(b) of Pub. L. 101–508 provided that: "The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after Jan. 1, 1994, but inapplicable to services of nonparticipating supplier or other person furnished before Jan. 1, 1995, see section 125(f)(1) of Pub. L. 103–432, set out as a note under section 1395f of this title.

Amendment by section 126(c)(5) of Pub. L. 103–432 provided that: 'The amendment made by subsection (d) [amending this section] shall apply to reports for years beginning with 1995.'

Amendment by section 126(b)(6), (g)(2)(B), (5)–(7), (10)(A) of Pub. L. 103–432 effective as if included in the enactment of Pub. L. 101–508, see section 126(f) of Pub. L. 103–432, set out as a note under section 1395m of this title.

**Effective Date of 1993 Amendment**

Amendment by section 1351(b) of Pub. L. 103–66 provided that: 'The amendments made by this section [amending this section] shall apply to services furnished on or after Jan. 1, 1994, except that amendment made by subsection (a)(2) shall not apply—'

'(1) to volume performance standard rates of increase established under section 1848(f) of the Social Security Act [subsec. (f) of this section] for fiscal years before fiscal year 1994, effective Nov. 30, 1993; and

'(2) to adjustment in updates in the conversion factor for physicians' services under section 1848(d)(3)(B) of such Act for physician services to be furnished in calendar years before 1996.'

Section 13514(d) of Pub. L. 103–66 provided that: 'The amendments made by this section [amending this section] shall apply to services furnished on or after Jan. 1, 1994.'

Amendment by section 13515(a)(1) of Pub. L. 103–66 applicable to services furnished on or after Jan. 1, 1994, see section 13515(d) of Pub. L. 103–66, set out as a note under section 1395u of this title.

Section 13517(c) of Pub. L. 103–66 provided that: 'The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after Jan. 1, 1994.'

Amendment by section 13518(c) of Pub. L. 103–66 provided that: 'The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after Jan. 1, 1995.'

**Effective Date of 1990 Amendment**

Amendment by section 4102(b), (g)(2) of Pub. L. 101–508 applicable to services furnished on or after Jan. 1, 1991, see section 4102(c)(1) of Pub. L. 101–508, set out as a note under section 1395m of this title.

Amendment by section 4104(b)(2) of Pub. L. 101–508 applicable to services furnished on or after Jan. 1, 1991, see section 4104(d) of Pub. L. 101–508, set out as a note under section 1395m of this title.

Amendment by section 4106(b)(1) of Pub. L. 101–508 applicable to services furnished after 1991, see section 4106(d)(2) of Pub. L. 101–508, set out as a note under section 1389u of this title.

Section 4107(a)(2) of Pub. L. 101–508, as amended by Pub. L. 103–322, title I, §126(d)(2), Oct. 31, 1994, 108 Stat. 4415, provided that: "Section 1848(b)(2) of the Social Security Act [subsec. (i)(2) of this section], as added by the amendment made by paragraph (1), shall apply to services furnished in 1991 in the same manner as it applies to services furnished after 1991. In applying the previous sentence, the prevailing charge shall be substituted for the fee schedule amount. In applying section 1848(g)(2)(D) of the Social Security Act for services of an assistant-at-surgery furnished during 1991, the recognized payment amount shall not exceed the maximum amount specified under section 1848(b)(2)(A) of such Act (as applied under this paragraph in such year)."

Section 4107(c) of Pub. L. 101–508, as amended by Pub. L. 103–432, title I, §126(d)(1), Oct. 31, 1994, 108 Stat. 4415, provided that: 'The amendment made by subsection (a)(1) [amending this section] shall apply with respect to services furnished on or after Jan. 1, 1994.'

Section 4108(b) of Pub. L. 101–508 provided that: 'The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after Jan. 1, 1994, but inapplicable to services of nonparticipating supplier or other person furnished before Jan. 1, 1995, see section 125(f)(1) of Pub. L. 103–432, set out as a note under section 1395f of this title.'
tion] shall apply to services furnished on or after January 1, 1992. In applying section 1848(d)(1)(B) of the Social Security Act [subsec. (d)(1)(B) of this section] (in computing the initial budget-neutral conversion factor for 1991), the Secretary shall compute such factor assuming that section 1848(b)(3) of such Act (as added by the amendment made by subsection (a)) had applied to physicians' services furnished during 1991. 

TRANSFER OF FUNCTIONS

Physician Payment Review Commission (PPRC) was terminated and its assets and staff transferred to the Medicare Payment Advisory Commission (MedPAC) by section 4022(c)(2), (3) of Pub. L. 105–33, 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 PPRC, and that, for that purpose, any reference in law to PPRC was to be deemed, after the appointment of MedPAC, to refer to MedPAC.

TERMINATION OF REPORTING REQUIREMENTS

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 8 on page 94 identifies a reporting provision which, as subsequently amended, is contained in subsec. (g)(6)(B) of this section and in which item 9 on page 94 identifies a reporting provision which is contained in subsec. (g)(7)(B) of this section), see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance.

IMPLEMENTATION OF 2010 AMENDMENT

Pub. L. 111–157, §(c), Apr. 15, 2010, 124 Stat. 1118, provided that: "Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the amendments made by this section [amending this section and section 1395b–6 of this title] and set out as a note under section 1113 of Title 31, Money and Finance.

ADJUSTMENT FOR MEDICARE MENTAL HEALTH SERVICES

Pub. L. 110–275, title I, § 138, July 15, 2008, 122 Stat. 2525, provided that: "Nothing in the amendments made by this subsection or section 132 [amending this section] shall affect the operation of the provisions of section 1395w–4(m) of the Social Security Act [42 U.S.C. 1395w–4(m)], as redesignated and amended by such subsection and section, with respect to 2007 or 2008."
this section, was transferred to subsec. (m) of this section.

TREATMENT OF OTHER SERVICES CURRENTLY IN THE NONPHYSICIAN WORK POOL

Pub. L. 108–173, title III, § 303(a)(2), Dec. 8, 2003, 117 Stat. 2236, provided that: “The Secretary [of Health and Human Services] shall make adjustments to the nonphysician work pool methodology (as such term is used in the final rule promulgated by the Secretary in the Federal Register on December 31, 2002 (67 Fed. Reg. 25168), for the determination of practice expense relative value units under the physician fee schedule under section 1848(c)(2)(C)(ii) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)(C)(ii)), so that the practice expense relative value units for services determined under such methodology, as a result of the amendments made by paragraph (1) [amending this section].”

PAYMENT FOR MULTIPLE CHEMOTHERAPY AGENTS FURNISHED ON A SINGLE DAY THROUGH THE PUSH TECHNIQUE

Pub. L. 108–173, title III, § 303(a)(3), Dec. 8, 2003, 117 Stat. 2236, provided that: “(A) REVIEW OF POLICY.—The Secretary [of Health and Human Services] shall review the policy, as in effect on October 1, 2003, with respect to payment under section 1395w–4 of the Social Security Act (42 U.S.C. 1395w–4) for the administration of more than 1 drug or biological to an individual on a single day through the push technique.

(B) MODIFICATION OF POLICY.—After conducting the review under subparagraph (A), the Secretary shall modify such payment policy as the Secretary determines to be appropriate.

(C) EXEMPTION FROM BUDGET NEUTRALITY UNDER PHYSICIAN PER SCHEDULE.—If the Secretary modifies such payment policy pursuant to subparagraph (B), any increased expenditures under title XVIII of the Social Security Act (this part) resulting from such modification shall be treated as additional expenditures attributable to subparagraph (H) of section 1848(c)(2) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)), as added by paragraph (1)(B), for purposes of applying the exemption to budget neutrality under subparagraph (B)(iv) of such section, as added by paragraph (1)(A).

TRANITIONAL ADJUSTMENT

Pub. L. 108–173, title III, § 303(a)(4), Dec. 8, 2003, 117 Stat. 2237, provided that: “(A) IN GENERAL.—In order to provide for a transition during 2004 and 2005 to the payment system established under the amendments made by this section [enacting sections 1395w–3a and 1395w–3b of this title, amending this section and sections 1395u, 1395s, 1395x, 1395y, and 1396i–8 of this title, and repealing provisions set out as a note under section 1395u of this title] and to different geographic areas and to different physician practice sizes; and

(B) APPLICABLE PERCENTAGE.—The applicable percentage specified in this subparagraph for services furnished—

(1) during 2004, is 32 percent; and

(2) during 2005, is 3 percent.

MEDFAC REVIEW AND REPORTS; SECRETARIAL RESPONSE

Pub. L. 108–173, title III, § 303(a)(5), Dec. 8, 2003, 117 Stat. 2237, provided that: “(A) REVIEW.—The Medicare Payment Advisory Commission shall review the payment changes made under this section [enacting sections 1395w–3a and 1395w–3b of this title, amending this section and sections 1395u, 1395s, 1395x, 1395y, and 1396i–8 of this title, enacting provisions set out as notes under this section and sections 1395u, 1395w–3a, and 1395w–3b of this title, and repealing provisions set out as a note under section 1395u of this title] insofar as they affect payment under part B of title XVIII of the Social Security Act [this part]—

(i) for items and services furnished by oncologists; and

(ii) for drug administration services furnished by other specialists.

(B) OTHER MATTERS STUDIED.—In conducting the review under subparagraph (A), the Commission shall also review such changes as they affect—

(i) the quality of care furnished to individuals enrolled under part B and the satisfaction of such individuals with that care;

(ii) the adequacy of reimbursement as applied in, and the availability in, different geographic areas and to different physician practice sizes; and

(iii) the impact on physician practices.

(C) REPORTS.—The Commission shall submit to the Secretary [of Health and Human Services] and Congress—

(i) not later than January 1, 2006, a report on the review conducted under subparagraph (A)(i); and

(ii) not later than January 1, 2007, a report on the review conducted under subparagraph (A)(ii).

Each such report may include such recommendations regarding further adjustments in such payments as the Commission deems appropriate.

(D) SECRETARIAL RESPONSE.—As part of the rulemaking with respect to payment for physicians services under section 1395w–4 of the Social Security Act (42 U.S.C. 1395w–4) for 2007, the Secretary may make appropriate adjustments to payment for items and services described in subparagraph (A)(i), taking into account the report submitted under such subparagraph (C)(i).

MULTIPLE CHEMOTHERAPY AGENTS, OTHER SERVICES CURRENTLY ON THE NON-PHYSICIAN WORK POOL, AND TRANSITIONAL ADJUSTMENT

Pub. L. 108–173, title III, § 303(g)(3), Dec. 8, 2003, 117 Stat. 2253, provided that: “There shall be no administrative or judicial review under section 1869 (probably means section 1869 of the Social Security Act, which is classified to section 1395ff of this title) or section 1878 (probably means section 1878 of the Social Security Act, which is classified to section 1395oo of this title), or otherwise, of determinations of payment amounts, methods, or adjustments under section 413 of subsection (a) of section 1395w–4 (for 2006 and before January 1, 2007, a report to the Secretary on the implementation of the transitional adjustments to payment for items and services described in subparagraph (A)(i)), taking into account the report submitted under such subparagraph (C)(i).

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.

GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAYMENTS FOR PHYSICIANS’ SERVICES

“(1) STUDY.—The Comptroller General of the United States shall conduct a study of differences in payment amounts under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for physicians’ services in different geographic areas. Such study shall include—

(A) an assessment of the validity of the geographic adjustment factors used for each component of the fee schedule;

(B) an evaluation of the measures used for such adjustment, including the frequency of revisions;

(C) an evaluation of the methods used to determine professional liability insurance costs used in computing the malpractice component, including a review of increases in professional liability insurance premiums and variation in such increases by State and physician specialty and methods used to update the geographic cost of practice index and relative weights for the malpractice component; and

(D) an evaluation of the effect of the adjustment to the physician work geographic index under section 1848(e)(1)(E) of the Social Security Act [subsection (e)(1)(E) of this section], as added by section 412, on physician location and retention in areas affected by such adjustment, taking into account—

(1) differences in recruitment costs and retention rates for physicians, including specialists, between large urban areas and other areas; and

(2) the mobility of physicians, including specialists, over the last decade.

(2) REPORT.—Not later than 1 year 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 paragraph (1). The report shall include recommendations regarding the use of more current geographic cost of practice indices as well as the use of data directly representative of physicians’ costs (rather than proxy measures of such costs).

AMENDMENTS NOT TREATED AS CHANGE IN LAW AND REGULATION IN SUSTAINABLE GROWTH RATE DETERMINATION


COLLABORATIVE DEMONSTRATION-BASED REVIEW OF PHYSICIAN PRACTICE EXPENSE GEOGRAPHIC ADJUSTMENT DATA


“(a) IN GENERAL.—Not later than January 1, 2005, the Secretary [of Health and Human Services] shall, in collaboration with State and other appropriate organizations representing physicians, and other appropriate persons, review and consider alternative data sources than those currently used in establishing the geographic index for the practice expense component under the medicare physician fee schedule under section 1848(e)(1)(A)(i) of the Social Security Act (42 U.S.C. 1395w–4(e)(1)(A)(i)).

“(1) STUDY.—The Secretary shall select two physician payment localities in which to carry out subsection (a). One locality shall include rural areas and at least one locality shall be a statewide locality that includes both urban and rural areas.

“(1) REPORT AND RECOMMENDATIONS.—

“(1) REPORT.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the review and consideration conducted under subsection (a). Such report shall include information on the alternative developed data sources considered by the Secretary under subsection (a), including the accuracy and validity of the data as measures of the elements of the geographic index for practice expenses under the medicare physician fee schedule as well as the feasibility of using such alternative data nationwide in lieu of current proxy data used in such index, and the estimated impacts of using such alternative data.

“(2) RECOMMENDATIONS.—The report submitted under paragraph (1) shall contain recommendations on which data sources reviewed and considered under subsection (a) are appropriate for use in calculating the geographic index for practice expenses under the medicare physician fee schedule.”

MEDPAC REPORT ON PAYMENT FOR PHYSICIANS’ SERVICES


“(1) PRACTICE EXPENSE COMPONENT.—Not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Medicare Payment Advisory Commission shall submit to Congress a report on the effect of refinements to the practice expense component of payments for physicians’ services, after the transition to a full resource-based payment system in 2002, under section 1848 of the Social Security Act (42 U.S.C. 1395w–4). Such report shall examine the following matters by physician specialty:

“(1) The effect of such refinements on payment for physicians’ services.

“(2) The interaction of the practice expense component with other components of and adjustments to payment for physicians’ services under such section.

“(3) The appropriateness of the amount of compensation by reason of such refinements.

“(4) The effect of such refinements on access to care by medicare beneficiaries to physicians’ services.

“(5) The effect of such refinements on physician participation under the medicare program.

“(b) VOLUME OF PHYSICIANS’ SERVICES.—Not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Medicare Payment Advisory Commission shall submit to Congress a report on the extent to which increases in the volume of physicians’ services under part B [this part] of the medicare program are a result of care that improves the health and well-being of medicare beneficiaries. The study shall include the following:

“(1) An analysis of recent and historic growth in the components that the Secretary [of Health and Human Services] includes under the sustainable growth rate (under section 1848(f) of the Social Security Act [42 U.S.C. 1395w–4(f)]).

“(2) An examination of the relative growth of volume in physicians’ services between medicare beneficiaries and other populations.

“(3) An analysis of the degree to which new technology, including coverage determinations of the Centers for Medicare & Medicaid Services, has affected the volume of physicians’ services.

“(4) An examination of the impact on volume of demographic changes.

“(5) An examination of shifts in the site of service or services that influence the number and intensity of services furnished in physicians’ offices and the extent to which changes in reimbursement rates to other providers have affected these changes.

“(6) An evaluation of the extent to which the Centers for Medicare & Medicaid Services takes into account the impact of law and regulations on the sustainable growth rate.”

MIDPAC STUDY OF PAYMENT FOR CARDIO-THORACIC SURGEONS

“(a) STUDY.—The Medicare Payment Advisory Commission (in this section referred to as the ‘Commission’) shall conduct a study on the practice expense relative values established by the Secretary of Health and Human Services under the medicare physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for physicians in the specialties of thoracic and cardiac surgery to determine whether such values adequately take into account the attendant costs that such physicians incur in providing clinical staff for patient care in hospitals.

“(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.”

REPORT ON PHYSICIAN COMPENSATION

Pub. L. 108–173, title IX, §953(a)(2), Dec. 22, 2003, 117 Stat. 2573, provided that: ‘‘Not later than 12 months after the date of the enactment of this Act [Dec. 8, 2003], the Comptroller General shall submit to Congress a report on the practice expense relative values established by the Secretary of Health and Human Services under the medicare physician fee schedule under section XVIII of the Social Security Act [this subchapter], and how those aspects interact and the effect on appropriate compensation for physician services. Such report shall review alternatives for the physician fee schedule under section 1848 of such title (42 U.S.C. 1395w–4).’’

TREATMENT OF CERTAIN PHYSICIAN PATHOLOGY SERVICES UNDER MEDICARE

Pub. L. 106–554, §111(a)(6) [title V, §502], Dec. 21, 2000, 114 Stat. 2861, provided that: ‘‘Not later than 12 months after the date of the enactment of this Act [December 21, 2000], the Secretary shall submit to the Congress a report on the practice expense relative values established by the Secretary of Health and Human Services for procedures relating to laboratory services, and not as an outpatient hospital service for which payment is made to the hospital under section 1833(t) of such Act (42 U.S.C. 1395w–4(c)), and as an outpatient hospital service for which payment is made to the hospital under section 1833(t) of such Act (42 U.S.C. 1395w–4(c)) for purposes of determining relative values under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for purposes of determining relative values under section 1848 of the Social Security Act (42 U.S.C. 1395w–4), as amended by section 114 of the Balanced Budget Act of 1997 (42 U.S.C. 1395w–4(e)).’’

USE OF DATA COLLECTED BY ORGANIZATIONS AND ENTITIES IN DETERMINING PRACTICE EXPENSE RELATIVE VALUES

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §212], Nov. 29, 1999, 113 Stat. 1536, 1501A–350, provided that: ‘‘(a) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study of the effects of the previous provisions of this section on hospitals and laboratories and access of fee-for-service medicare beneficiaries to the technical component of physician pathology services.

‘‘(b) REPORT.—Not later than April 1, 2002, the Comptroller General shall submit to Congress a report on such study. The report shall include recommendations about whether such provisions should be extended after the end of the period specified in subsection (c) for either or both inpatient and outpatient hospital services, and whether the provisions should be extended to other hospitals.’’

ONE-TIME PUBLICATION OF INFORMATION ON TRANSITION

Pub. L. 106–113, div. B, §1000(a)(6) [title II, §211(a)(2)(C)], Nov. 29, 1999, 113 Stat. 1536, 1501A–347, provided that: ‘‘The Secretary of Health and Human Services shall cause to have published in the Federal Register, not later than 90 days after the date of the enactment of this section [Nov. 29, 1999], the Secretary’s determination, based upon the best available data, of—

‘‘(i) the allowed expenditures under subclauses (I) and (II) of subsection (d)(4)(C)(i) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4), as added by subsection (a)(1)(B), for the 9-month period beginning on April 1, 1999, and for 1999;

‘‘(ii) the estimated actual expenditures described in subsection (d) of such section for 1999; and

‘‘(iii) the sustainable growth rate under subsection (f) of such section for 2000.’’
which the data otherwise used are inadequate because such data are not based upon a large enough sample size to be statistically reliable.’’

**Consultation With Organizations in Establishing Payment Amounts for Services Provided by Physicians**

Section 4106(a)(3) of Pub. L. 105–33 provided that: “In establishing payment amounts under section 1848 of the Social Security Act [this section] for physicians’ services consisting of diabetes outpatient self-management training services, the Secretary of Health and Human Services shall consult with appropriate organizations, including such organizations representing individuals or medicare beneficiaries with diabetes.”

**Development of Resource-Based Practice Expense Relative Value Units**


**Application of Certain Budget Neutrality Provisions**

Section 4056(f)(2) of Pub. L. 105–33 provided that: “In implementing the amendment made by paragraph (1A)(ii) [amending this section], the provisions of clauses (ii)(I) and (iii) of section 1848(c)(2)(B) of the Social Security Act (42 U.S.C. 13506–4(c)(2)(B)) shall apply in the same manner as they apply to adjustments under clause (ii)(I) of such section.”

**Development of Resource-Based Methodology for Practice Expenses**

Section 121(a) of Pub. L. 103–432 provided that: “(1) IN GENERAL.—The Secretary of Health and Human Services shall develop a methodology for implementing in 1996 a resource-based system for determining practice expense relative value units relating to physicians’ service. The methodology utilized shall recognize the staff, equipment, and supplies used in the provision of various medical and surgical services in various settings.

“(2) REPORT.—The Secretary shall transmit a report by June 30, 1996, on the methodology developed under paragraph (1) to the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate. The report shall include a presentation of data utilized in developing the methodology and an explanation of the methodology.”

**Application of Subsection (c)(2)(B)(ii)(I), (ii)**

Section 121(b)(3) of Pub. L. 103–432 provided that: “In implementing the amendment made by paragraph (1)(C) [amending this section], the provisions of clauses (ii)(II) and (iii) of section 1848(c)(2)(B) of the Social Security Act [subsec. (c)(2)(B)(ii)(I), (ii) of this section] shall apply in the same manner as they apply to adjustments under clause (ii)(I) of such section.”

**Report on Review Process**

Section 122(c) of Pub. L. 103–432 provided that not later than 1 year after Oct. 31, 1994, Secretary of Health and Human Services was to study and report to Congress on data necessary to review and revise indices established under subsec. (e)(1)(A) of this section, any limitations on availability of data necessary to review and revise such indices at least every three years, ways of addressing such limitations, with particular attention to the development of alternative data sources for input components for which current index values are based on data collected less frequently than every three years, and costs of developing more accurate and timely data.

**Relative Value for Pediatric Services**

Section 124(a) of Pub. L. 103–432 provided that: “The Secretary of Health and Human Services shall fully develop, by not later than July 1, 1995, relative values for the full range of pediatric physicians’ services which are consistent with the relative values developed for other physicians’ services under section 1848(c) of the Social Security Act [subsec. (c) of this section]. In developing such values, the Secretary shall conduct such refinements as may be necessary to produce appropriate estimates for such relative values.”

**Budget Neutrality Adjustment**

For provisions requiring reduction of relative values established under subsec. (c) of this section and amounts determined under subsec. (a)(2)(B)(ii)(I) of this section for 1994 (to be applied for that year and subsequent years) in order to assure that the amendments to this section and section 13515 of this title by section 13515(a) of Pub. L. 103–66 will not result in expenditures under this part that exceed the amount of such expenditures that would have been made if such amendments had not been made, see section 13515(b) of Pub. L. 103–66, set out as a note under section 1395u of this title.

Section 13515(b) of Pub. L. 103–66 provided that: “Notwithstanding any other provision of law, the Secretary of Health and Human Services shall implement the amendment made by subsection (a) [amending this section] in a manner to assure that such amendment will result in expenditures under part B of title XVIII of the Social Security Act [this part] in 1995 for services described in such amendment that shall be equal to the amount of expenditures for such services that would have been made if such amendment had not been made.”

**Ancillary Policies; Adjustment for Independent Laboratories Furnishing Physician Pathology Services**

Section 410(c) of Pub. L. 101–508 provided that: “The Secretary of Health and Human Services, in establishing ancillary policies under section 1848(c)(3) of the Social Security Act [subsec. (c)(3) of this section], shall consider an appropriate adjustment to reflect the technical component of furnishing physician pathology services through a laboratory that is independent of a hospital and separate from an attending or consulting physician’s office.”

**Computation of Conversion Factor for 1992**


Section 410(c) of Pub. L. 101–508, as amended by Pub. L. 103–432, title I, § 126(g)(3), Oct. 31, 1994, 108 Stat. 4416, provided that: “In computing the conversion factor under section 1848(d)(1)(B) of the Social Security Act [subsec. (d)(1)(B) of this section] for 1992, the Secretary of Health and Human Services shall determine the estimated aggregate amount of payments under part B [this part] for physicians’ services in 1991 assuming that the amendments made by this section [amending this section, section 1395u of this title, and provisions set out as a note under section 1395u of this title] (not—withstanding subsection (d) [set out as an Effective
Date of 1990 Amendment note under section 1395u of this title,) applied to all services furnished during such year.”

**Publication of Performance Standard Rates**

Section 4106(d) of Pub. L. 101–508, as amended by Pub. L. 103–432, title I, §126(b)(2)(C), Oct. 31, 1994. Stat. 4416, provided that: “Not later than 45 days after the date of enactment of this Act (Nov. 5, 1990), the Secretary of Health and Human Services, based on the most recent data available, shall estimate and publish in the ‘Federal Register’ the performance standard rates of increase specified in section 1848(h)(2)(C) of the Social Security Act [subsection (f)(2)(C) of this section] for fiscal year 1991.”

**Study of Regional Variations in Impact of Medicare Physician Payment Reform**

Section 4115 of Pub. L. 101–508 provided that:

“(a) Study.—The Secretary of Health and Human Services shall conduct a study of—

“(1) factors that may explain geographic variations in Medicare reasonable charges for physicians’ services that are not attributable to variations in physician practice costs (including the supply of physicians in an area and area variations in the mix of services furnished);

“(2) the extent to which the geographic practice cost indices applied under the fee schedule established under section 1848 of the Social Security Act [this section] accurately reflect variations in practice costs and malpractice costs (and alternative sources of information upon which to base such indices);

“(3) the impact of the transition to a national, resource-based fee schedule for physicians’ services under Medicare on access to physicians’ services in areas that experience a disproportionately large reduction in payments for physicians’ services under the fee schedule by reason of such variations; and

“(4) appropriate adjustments or modifications in the transition to, or manner of determining payments under, the fee schedule established under section 1848 of the Social Security Act, to compensate for such variations and ensure continued access to physicians’ services for Medicare beneficiaries in such areas.

“(b) Report.—By not later than July 1, 1992, the Secretary shall submit to Congress a report on the study conducted under subsection (a).”

**Statewide Fee Schedule Areas for Physicians’ Services**


“(1) the adjusted historical payment basis (as defined in section 1848(a)(2)(D) of such Act (42 U.S.C. 1395w–4(a)(2)(D))), and

“(2) the fee schedule amount (as referred to in section 1848(a) (42 U.S.C. 1395w–4(a)) of such Act), for physicians’ services (as defined in section 1848(h)(3) of such Act (42 U.S.C. 1395w–4(j)(3))) furnished on or after January 1, 1992.”

**Studies**

Pub. L. 101–139, title VI, §6102(d), Dec. 19, 1989. 103 Stat. 2315, as amended by Pub. L. 103–432, title I, §126(b)(1), Oct. 31, 1994. Stat. 4416; Pub. L. 105–362, title VI, §601(b)(5), Nov. 10, 1998. 112 Stat. 3286, provided for various studies and reports as follows: (1) directed Comptroller General to conduct study of alternative payment methodology for malpractice component for physicians’ services, and to submit report to Congress by not later than Apr. 1, 1991; (2) directed Secretary of Health and Human Services to conduct study of how payments under this section may affect payments to eligible organizations with risk-sharing contracts under section 1395mm of this title, and to submit report to Congress by not later than Apr. 1, 1990; (3) directed Secretary to conduct study of volume performance standard rates of increase for services furnished by geography, specialty, and type of service, and to submit report with appropriate recommendations to Congress by not later than July 1, 1990; (4) directed Physician Payment Review Commission to conduct study of payment for practice and malpractice expenses, including appropriate methods for allocating malpractice expenses to particular procedures which could be incorporated into the determination of relative values for such procedures using a consensus panel and other appropriate methodologies, and to submit report and recommendations to Congress by not later than July 1, 1991; (5) directed Physician Payment Review Commission to conduct study of feasibility and desirability of using Metropolitan Statistical Areas or other payment areas for purposes of payment for physicians’ services under this part, and to submit report to Congress by not later than July 1, 1991; and (6) directed Comptroller General to conduct study of effect of anti-trust laws on ability of physicians to act in groups to educate and discipline peers of such physicians in order to reduce and eliminate ineffective practice patterns and inappropriate utilization, and to submit report to Congress by no later than July 1, 1991.

**Distribution of Model Fee Schedule**

Section 6102(e)(1) of Pub. L. 101–239, as amended by Pub. L. 101–508, title IV, §4118(f)(2)(E), Nov. 5, 1990. 104 Stat. 1388–70, provided that: “By September 1, 1990, the Secretary of Health and Human Services shall develop a Model Fee Schedule, using the methodology set forth in section 1848 of the Social Security Act [this section]. The Model Fee Schedule shall include as many services as the Secretary of Health and Human Services concludes can be assigned valid relative values. The Secretary of Health and Human Services shall submit the Model Fee Schedule to the appropriate committees of Congress and make it generally available to the public.”

§ 1395w–5. Public reporting of performance information

(a) In general

(1) Development

Not later than January 1, 2011, the Secretary shall develop a Physician Compare Internet website with information on physicians enrolled in the Medicare program under section 1866(j) of the Social Security Act (42 U.S.C. 1395cc(j)) and other eligible professionals who participate in the Physician Quality Reporting Initiative under section 1848 of such Act (42 U.S.C. 1395w–5). (2) Plan

Not later than January 1, 2013, and with respect to reporting periods that begin no earlier than January 1, 2012, the Secretary shall...
also implement a plan for making publicly available through Physician Compare, consistent with subsection (c), information on physician performance that provides comparable information for the public on quality and patient experience measures with respect to physicians enrolled in the Medicare program under such section 1866(j). To the extent scientifically sound measures that are developed consistent with the requirements of this section are available, such information, to the extent practicable, shall include—

(A) measures collected under the Physician Quality Reporting Initiative;

(B) an assessment of patient health outcomes and the functional status of patients;

(C) an assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use;

(D) an assessment of efficiency;

(E) an assessment of patient experience and patient, caregiver, and family engagement;

(F) an assessment of the safety, effectiveness, and timeliness of care; and

(G) other information as determined appropriate by the Secretary.

(b) Other required considerations

In developing and implementing the plan described in subsection (a)(2), the Secretary shall, to the extent practicable, include—

(1) processes to assure that data made public, either by the Centers for Medicare & Medicaid Services or by other entities, is statistically valid and reliable, including risk adjustment mechanisms used by the Secretary;

(2) processes by which a physician or other eligible professional whose performance on measures is being publicly reported has a review of the Secretary, to review his or her individual results before they are made public;

(3) processes by the Secretary to assure that the implementation of the plan and the data made available on Physician Compare provide a robust and accurate portrayal of a physician’s performance;

(4) data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent practicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance;

(5) processes to ensure appropriate attribution of care when multiple physicians and other providers are involved in the care of a patient;

(6) processes to ensure timely statistical performance feedback is provided to physicians concerning the data reported under any program subject to public reporting under this section; and

(7) implementation of computer and data systems of the Centers for Medicare & Medicaid Services that support valid, reliable, and accurate public reporting activities authorized under this section.

(c) Ensuring patient privacy

The Secretary shall ensure that information on physician performance and patient experience is not disclosed under this section in a manner that violates sections 552 or 552a of title 5 with regard to the privacy of individually identifiable health information.

(d) Feedback from multi-stakeholder groups

The Secretary shall take into consideration input provided by multi-stakeholder groups, consistent with sections 1890(b)(7) and 1890A of the Social Security Act [42 U.S.C. 1395aaa(b)(7), 1395aaa–1], as added by section 3014 of this Act, in selecting quality measures for use under this section.

(e) Consideration of transition to value-based purchasing

In developing the plan under this section 1866(j), the Secretary shall, as the Secretary determines appropriate, consider the plan to transition to a value-based purchasing program for physicians and other practitioners developed under section 131 of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275).

(f) Report to Congress

Not later than January 1, 2015, the Secretary shall submit to Congress a report on the Physician Compare Internet website developed under subsection (a)(1). Such report shall include information on the efforts of and plans made by the Secretary to collect and publish data on physician quality and efficiency and on patient experience of care in support of value-based purchasing and consumer choice, together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

(g) Expansion

At any time before the date on which the report is submitted under subsection (f), the Secretary may expand (including expansion to other providers of services and suppliers under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.]) the information made available on such website.

(h) Financial incentives to encourage consumers to choose high quality providers

The Secretary may establish a demonstration program, not later than January 1, 2019, to provide financial incentives to Medicare beneficiaries who are furnished services by high quality physicians, as determined by the Secretary based on factors in subparagraphs (A) through (G) of subsection (a)(2). In no case may Medicare beneficiaries be required to pay increased premiums or cost sharing or be subject to a reduction in benefits under title XVIII of the Social Security Act as a result of such demonstration program. The Secretary shall ensure that any such demonstration program does not disadvantage those beneficiaries without reasonable access to high performing physicians or create financial inequities under such title.

(i) Definitions

In this section:

(1) Eligible professional

The term “eligible professional” has the meaning given that term for purposes of the

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1 So in original. Probably should be “section”.

2 So in original. The word “this” probably should not appear.
Physician Quality Reporting Initiative under section 1848 of the Social Security Act (42 U.S.C. 1395w–4).

(2) Physician
The term “physician” has the meaning given that term in section 1861(r) of such Act (42 U.S.C. 1395x(r)).

(3) Physician Compare
The term “Physician Compare” means the Internet website developed under subsection (a)(1).

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


REFERENCES IN TEXT
Section 3014 of this Act, referred to in subsec. (d), is section 3014 of Pub. L. 111–148 which enacted section 1395aaa–1 of this title and amended section 1395aaa of this title.

Section 131 of the Medicare Improvements for Patients and Providers Act of 2008, referred to in subsec. (e), is section 131 of Pub. L. 110–275, 122 Stat. 2520, which amended section 1395w–21 of this title, enacted provisions set out as notes under section 1395w–4 of this title, and redesignated provisions formerly set out as a note under section 1395w–4 of this title as section 1395w–4(m).

The Social Security Act, referred to in subsecs. (g) and (h), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XVIII of the Act is classified generally to subchapter XVIII (§1395 et seq.) of chapter 7 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 Patient Protection and Affordable Care Act, and not as part of the Social Security Act which comprises this chapter.

PART C—MEDICARE+Choice PROGRAM

PRIOR PROVISIONS
A prior part C of this subchapter, consisting of section 1395x et seq., was redesignated part B of this subchapter.

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. 111–148, set out as a note under section 1395w–21 of this title.

§ 1395w–21. Eligibility, election, and enrollment
(a) Choice of medicare benefits through Medicare+Choice plans
(1) In general
Subject to the provisions of this section, each Medicare+Choice eligible individual (as defined in paragraph (3)) is entitled to elect to receive benefits (other than qualified prescription drug benefits) under this subchapter—
(A) through the original medicare fee-for-service program under parts A and B of this subchapter, or
(B) through enrollment in a Medicare+Choice plan under this part,

and may elect qualified prescription drug coverage in accordance with section 1395w–101 of this title.

(2) Types of Medicare+Choice plans that may be available
A Medicare+Choice plan may be any of the following types of plans of health insurance:

(A) Coordinated care plans (including regional plans)
(i) In general
Coordinated care plans which provide health care services, including but not limited to health maintenance organization plans (with or without point of service options), plans offered by provider-sponsored organizations (as defined in section 1395w–25(d) of this title), and regional or local preferred provider organization plans (including MA regional plans).

(ii) Specialized MA plans for special needs individuals
Specialized MA plans for special needs individuals (as defined in section 1395w–28(b)(6) of this title) may be any type of coordinated care plan.

(B) Combination of MSA plan and contributions to Medicare+Choice MSA
An MSA plan, as defined in section 1395w–28(b)(3) of this title, and a contribution into a Medicare+Choice medical savings account (MSA).

(C) Private fee-for-service plans
A Medicare+Choice private fee-for-service plan, as defined in section 1395w–28(b)(2) of this title.

(3) Medicare+Choice eligible individual
(A) In general
In this subchapter, subject to subparagraph (B), the term “Medicare+Choice eligible individual” means an individual who is entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter.

(B) Special rule for end-stage renal disease
Such term shall not include an individual medically determined to have end-stage renal disease, except that—
(i) an individual who develops end-stage renal disease while enrolled in a Medicare+Choice plan may continue to be enrolled in that plan; and
(ii) in the case of such an individual who is enrolled in a Medicare+Choice plan under clause (i) (or subsequently under this clause), if the enrollment is discontinued under circumstances described in subsection (e)(4)(A) of this section, then the individual will be treated as a “Medicare+Choice eligible individual” for purposes of electing to continue enrollment in another Medicare+Choice plan.

(b) Special rules
(1) Residence requirement
(A) In general
Except as the Secretary may otherwise provide and except as provided in subpara-
(2) Special rule for certain individuals covered beneficiary (as defined in section 1396d(p)(1) of
this title), a qualified disabled and working individual (described in section 1396d(s) of this
title), an individual described in section 1396a(a)(10)(E)(iii) of this title, or otherwise
titled to medicare cost-sharing under a State plan under subchapter XIX of this chapter
is not eligible to enroll in an MSA plan.

(4) Coverage under MSA plans

(A) In general

Under rules established by the Secretary, an individual is not eligible to enroll (or continue enrollment) in an MSA plan for a
year unless the individual provides assurances satisfactory to the Secretary that the individual will reside in the United States
for at least 183 days during the year.

(B) Evaluation

The Secretary shall regularly evaluate the impact of permitting enrollment in MSA plans under this part on selection (including adverse selection), use of preventive care, access to care, and the financial status of the Trust Funds under this subchapter.

(C) Reports

The Secretary shall submit to Congress periodic reports on the numbers of individuals enrolled in such plans and on the evaluation being conducted under subparagraph (B).

(e) Process for exercising choice

(1) In general

The Secretary shall establish a process through which elections described in subsection (a) of this section are made and changed, including the form and manner in which such elections are made and changed. Such elections shall be made or changed only during coverage election periods specified under subsection (e) of this section and shall become effective as provided in subsection (f) of this section.

(2) Coordination through Medicare+Choice organizations

(A) Enrollment

Such process shall permit an individual who wishes to elect a Medicare+Choice plan offered by a Medicare+Choice organization to make such election through the filing of an appropriate election form with the organization.

(B) Disenrollment

Such process shall permit an individual who has elected a Medicare+Choice plan offered by a Medicare+Choice organization and who wishes to terminate such election to terminate such election through the filing of an appropriate election form with the organization.

(3) Default

(A) Initial election

(i) In general

Subject to clause (ii), an individual who fails to make an election during an initial election period under subsection (e)(1) of
this section is deemed to have chosen the
original medicare fee-for-service program option.

(ii) Seamless continuation of coverage
The Secretary may establish procedures under which an individual who is enrolled in a health plan (other than Medicare+Choice plan) offered by a Medicare+Choice organization at the time of the initial election period and who fails to elect to receive coverage other than through the organization is deemed to have elected the Medicare+Choice plan offered by the organization (or, if the organization offers more than one such plan, such plan or plans as the Secretary identifies under such procedures).

(B) Continuing periods
An individual who has made (or is deemed to have made) an election under this section is considered to have continued to make such election until such time as—

(i) the individual changes the election under this section, or
(ii) the Medicare+Choice plan with respect to which such election is in effect is discontinued or, subject to subsection (b)(1)(B) of this section, no longer serves the area in which the individual resides.

(d) Providing information to promote informed choice

(1) In general
The Secretary shall provide for activities under this subsection to broadly disseminate information to medicare beneficiaries (and prospective medicare beneficiaries) on the coverage options provided under this section in order to promote an active, informed selection among such options.

(2) Provision of notice

(A) Open season notification
At least 15 days before the beginning of each annual, coordinated election period (as defined in subsection (e)(3)(B) of this section), the Secretary shall mail to each Medicare+Choice eligible individual residing in an area the following:

(i) General information
The general information described in paragraph (3).

(ii) List of plans and comparison of plan options
A list identifying the Medicare+Choice plans that are (or will be) available to residents of the area and information described in paragraph (4) concerning such plans. Such information shall be presented in a comparative form.

(iii) Additional information
Any other information that the Secretary determines will assist the individual in making the election under this section.

The mailing of such information shall be coordinated, to the extent practicable, with the mailing of any annual notice under section 1395b–2 of this title.

(B) Notification to newly eligible Medicare+Choice eligible individuals
To the extent practicable, the Secretary shall, not later than 30 days before the beginning of the initial Medicare+Choice enrollment period for an individual described in subsection (e)(1) of this section, mail to the individual the information described in subparagraph (A).

(C) Form
The information disseminated under this paragraph shall be written and formatted using language that is easily understandable by medicare beneficiaries.

(D) Periodic updating
The information described in subparagraph (A) shall be updated on at least an annual basis to reflect changes in the availability of Medicare+Choice plans and the benefits and Medicare+Choice monthly basic and supplemental beneficiary premiums for such plans.

(3) General information
General information under this paragraph, with respect to coverage under this part during a year, shall include the following:

(A) Benefits under original medicare fee-for-service program option
A general description of the benefits covered under the original medicare fee-for-service program under parts A and B of this subchapter, including—

(i) covered items and services,
(ii) beneficiary cost sharing, such as deductibles, coinsurance, and copayment amounts, and
(iii) any beneficiary liability for balance billing.

(B) Election procedures
Information and instructions on how to exercise election options under this section.

(C) Rights
A general description of the benefits, enrollment rights, and other requirements applicable to medicare supplemental policies under section 1395ss of this title and provisions relating to medicare select policies described in section 1395ss(t) of this title.

(D) Information on medigap and medicare select
A general description of the benefits, enrollment rights, and other requirements applicable to medicare select policies under section 1395ss of this title and provisions relating to medicare select policies described in section 1395ss(t) of this title.

(E) Potential for contract termination
The fact that a Medicare+Choice organization may terminate its contract, refuse to renew its contract, or reduce the service area included in its contract, under this part, and the effect of such a termination, nonrenewal, or service area reduction may have on individuals enrolled with the Medicare+Choice plan under this part.
(F) Catastrophic coverage and single deductible
In the case of an MA regional plan, a description of the catastrophic coverage and single deductible applicable under the plan.

(4) Information comparing plan options
Information under this paragraph, with respect to a Medicare+Choice plan for a year, shall include the following:

(A) Benefits
The benefits covered under the plan, including the following:
   (i) Covered items and services beyond those provided under the original Medicare fee-for-service program.
   (ii) Any beneficiary cost sharing, including information on the single deductible (if applicable) under section 1395w–27a(b)(1) of this title.
   (iii) Any maximum limitations on out-of-pocket expenses.
   (iv) In the case of an MSA plan, differences in cost sharing, premiums, and balance billing under such a plan compared to under other Medicare+Choice plans.
   (v) In the case of a Medicare+Choice private fee-for-service plan, differences in cost sharing, premiums, and balance billing under such a plan compared to under other Medicare+Choice plans.
   (vi) The extent to which an enrollee may obtain benefits through out-of-network health care providers.
   (vii) The extent to which an enrollee may select among in-network providers and the types of providers participating in the plan’s network.
   (viii) The organization’s coverage of emergency and urgently needed care.

(B) Premiums
   (i) In general
   The monthly amount of the premium charged to an individual.
   (ii) Reductions
   The reduction in part B premiums, if any.

(C) Service area
The service area of the plan.

(D) Quality and performance
To the extent available, plan quality and performance indicators for the benefits under the plan (and how they compare to such indicators under the original Medicare fee-for-service program under parts A and B of this subchapter in the area involved), including—
   (i) disenrollment rates for Medicare enrollees electing to receive benefits through the plan for the previous 2 years (excluding disenrollment due to death or moving outside the plan’s service area),
   (ii) information on Medicare enrollee satisfaction,
   (iii) information on health outcomes, and
   (iv) the recent record regarding compliance of the plan with requirements of this part (as determined by the Secretary).

(E) Supplemental benefits
Supplemental health care benefits, including any reductions in cost-sharing under section 1395w–22(a)(3) of this title and the terms and conditions (including premiums) for such benefits.

(5) Maintaining a toll-free number and Internet site
The Secretary shall maintain a toll-free number for inquiries regarding Medicare+Choice options and the operation of this part in all areas in which Medicare+Choice plans are offered and an Internet site through which individuals may electronically obtain information on such options and Medicare+Choice plans.

(6) Use of non-Federal entities
The Secretary may enter into contracts with non-Federal entities to carry out activities under this subsection.

(7) Provision of information
A Medicare+Choice organization shall provide the Secretary with such information on the organization and each Medicare+Choice plan it offers as may be required for the preparation of the information referred to in paragraph (2)(A).

(e) Coverage election periods

(1) Initial choice upon eligibility to make election if Medicare+Choice plans available to individual
If, at the time an individual first becomes entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter, there is one or more Medicare+Choice plans offered in the area in which the individual resides, the individual shall make the election under this section during a period specified by the Secretary such that if the individual elects a Medicare+Choice plan during the period, coverage under the plan becomes effective as of the first date on which the individual may receive such coverage. If any portion of an individual’s initial enrollment period under part B of this subchapter occurs after the end of the annual, coordinated election period described in paragraph (3)(B)(iii), the initial enrollment period under this part shall further extend through the end of the individual’s initial enrollment period under part B of this subchapter.

(2) Open enrollment and disenrollment opportunities
Subject to paragraph (5)—

(A) Continuous open enrollment and disenrollment through 2005
At any time during the period beginning January 1, 1998, and ending on December 31, 2005, a Medicare+Choice eligible individual may change the election under subsection (a)(1) of this section.
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(B) Continuous open enrollment and disenrollment for first 6 months during 2006

(i) In general

Subject to clause (ii), subparagraph (C)(ii), and subparagraph (D), at any time during the first 6 months of 2006, or, if the individual first becomes a Medicare+Choice eligible individual during 2006, during the first 6 months during 2006 in which the individual is a Medicare+Choice eligible individual, a Medicare+Choice eligible individual may change the election under subsection (a)(1) of this section.

(ii) Limitation of one change

An individual may exercise the right under clause (i) only once. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under the first sentence of paragraph (4).

(C) Annual 45-day period for disenrollment from MA plans to elect to receive benefits under the original Medicare fee-for-service program

Subject to subparagraph (D), at any time during the first 45 days of a year (beginning with 2011), an individual who is enrolled in a Medicare Advantage plan may change the election under subsection (a)(1), but only with respect to coverage under the original medicare fee-for-service program under parts A and B, and may elect qualified prescription drug coverage in accordance with section 1395w–101 of this title.

(D) Continuous open enrollment for institutionalized individuals

At any time after 2005 in the case of a Medicare+Choice eligible individual who is institutionalized (as defined by the Secretary), the individual may elect under subsection (a)(1) of this section—

(i) to enroll in a Medicare+Choice plan; or

(ii) to change the Medicare+Choice plan in which the individual is enrolled.

(E) Limited continuous open enrollment of original fee-for-service enrollees in medicare advantage non-prescription drug plans

(i) In general

On any date during the period beginning on January 1, 2007, and ending on July 31, 2007, on which a Medicare Advantage eligible individual is an unenrolled fee-for-service individual (as defined in clause (ii)), the individual may elect under subsection (a)(1) to enroll in a Medicare Advantage plan that is not an MA–PD plan.

(ii) Unenrolled fee-for-service individual defined

In this subparagraph, the term “unenrolled fee-for-service individual” means, with respect to a date, a Medicare Advantage eligible individual who—

(I) is receiving benefits under this subchapter through enrollment in the original medicare fee-for-service program under parts A and B; and (II) is not enrolled in an MA plan on such date; and (III) as of such date is not otherwise eligible to elect to enroll in an MA plan.

(iii) Limitation of one change during the applicable period

An individual may exercise the right under clause (i) only once during the period described in such clause.

(iv) No effect on coverage under a prescription drug plan

Nothing in this subparagraph shall be construed as permitting an individual exercising the right under clause (i)—

(I) who is enrolled in a prescription drug plan under part D, to disenroll from such plan or to enroll in a different prescription drug plan; or (II) who is not enrolled in a prescription drug plan, to enroll in such a plan.

(3) Annual, coordinated election period

(A) In general

Subject to paragraph (5), each individual who is eligible to make an election under this section may change such election during an annual, coordinated election period.

(B) Annual, coordinated election period

For purposes of this section, the term “annual, coordinated election period” means—

(i) with respect to a year before 2002, the month of November before such year; (ii) with respect to 2002, 2003, 2004, and 2005, the period beginning on November 15 and ending on December 31 of the year before such year; (iii) with respect to 2006, the period beginning on November 15, 2005, and ending on May 15, 2006; (iv) with respect to 2007, 2008, 2009, and 2010, the period beginning on November 15 and ending on December 31 of the year before such year; and (v) with respect to 2012 and succeeding years, the period beginning on October 15 and ending on December 7 of the year before such year.

(C) Medicare+Choice health information fairs

During the fall season of each year (beginning with 1999) and during the period described in subparagraph (B)(iii), in conjunction with the annual coordinated election period defined in subparagraph (B), the Secretary shall provide for a nationally coordinated educational and publicity campaign to inform Medicare+Choice eligible individuals about Medicare+Choice plans and the election process provided under this section.

(D) Special information campaigns

During November 1998 the Secretary shall provide for an educational and publicity campaign to inform Medicare+Choice eligi-
ble individuals about the availability of Medicare+Choice plans, and eligible organizations with risk-sharing contracts under section 1395mm of this title, offered in different areas and the election process provided under this section. During the period described in subparagraph (B)(iii), the Secretary shall provide for an educational and publicity campaign to inform MA eligible individuals about the availability of MA plans (including MA–PD plans) offered in different areas and the election process provided under this section.

(4) Special election periods

Effective as of January 1, 2006, an individual may discontinue an election of a Medicare+Choice plan offered by a Medicare+Choice organization other than during an annual, coordinated election period and make a new election under this section if—

(A) (i) the certification of the organization or plan under this part has been terminated, or the organization or plan has notified the individual of an impending termination of such certification; or

(ii) the organization has terminated or otherwise discontinued providing the plan in the area in which the individual resides, or has notified the individual of an impending termination or discontinuation of such plan;

(B) the individual is no longer eligible to elect the plan because of a change in the individual’s place of residence or other change in circumstances (specified by the Secretary, but not including termination of the individual’s enrollment on the basis described in clause (i) or (ii) of subsection (g)(3)(B) of this section);

(C) the individual demonstrates (in accordance with guidelines established by the Secretary) that—

(i) the organization offering the plan substantially violated a material provision of the organization’s contract under this part in relation to the individual (including the failure to provide an enrollee on a timely basis medically necessary care for which benefits are available under the plan or the failure to provide such covered care in accordance with applicable quality standards); or

(ii) the organization (or an agent or other entity acting on the organization’s behalf) materially misrepresented the plan’s provisions in marketing the plan to the individual; or

(D) the individual meets such other exceptional conditions as the Secretary may provide.

Effective as of January 1, 2006, an individual who, upon first becoming eligible for benefits under part A of this subchapter at age 65, enrolls in a Medicare+Choice plan under this part, the individual may discontinue the election of such plan, and elect coverage under the original fee-for-service plan, at any time during the 12-month period beginning on the effective date of such enrollment.

(5) Special rules for MSA plans

Notwithstanding the preceding provisions of this subsection, an individual—

(A) may elect an MSA plan only during—

(i) an initial open enrollment period described in paragraph (1), or

(ii) an annual, coordinated election period described in paragraph (5)(B); and

(B) subject to subparagraph (A), may not discontinue an election of an MSA plan except during the periods described in clause (ii) or (iii) of subparagraph (A) and under the first sentence of paragraph (4); and

(C) who elects an MSA plan during an annual, coordinated election period, and who never previously had elected such a plan, may revoke such election, in a manner determined by the Secretary, by not later than December 15 following the date of the election.

(6) Open enrollment periods

Subject to paragraph (5), a Medicare+Choice organization—

(A) shall accept elections or changes to elections during the initial enrollment periods described in paragraph (1), the month of November 1998 and during the annual, coordinated election period under paragraph (3) for each subsequent year, and during special election periods described in the first sentence of paragraph (4); and

(B) may accept other changes to elections at such other times as the organization provides.

(f) Effectiveness of elections and changes of elections

(1) During initial coverage election period

An election of coverage made during the initial coverage election period under subsection (e)(1) of this section shall take effect upon the date the individual becomes entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter, except as the Secretary may provide (consistent with section 1395q of this title) in order to prevent retroactive coverage.

(2) During continuous open enrollment periods

An election or change of coverage made under subsection (e)(2) of this section shall take effect with the first day of the first calendar month following the date on which the election or change is made.

(3) Annual, coordinated election period

An election or change of coverage made during an annual, coordinated election period (as defined in subsection (e)(3)(B) of this section, other than the period described in clause (iii) of such subsection) in a year shall take effect as of the first day of the following year.

(4) Other periods

An election or change of coverage made during any other period under subsection (e)(4) of this section shall take effect in such manner as the Secretary provides in a manner consistent (to the extent practicable) with protecting continuity of health benefit coverage.
(g) Guaranteed issue and renewal
   (1) In general

   Except as provided in this subsection, a Medicare+Choice organization shall provide that at any time during which elections are accepted under this section with respect to a Medicare+Choice plan offered by the organization, the organization will accept without restrictions individuals who are eligible to make such election.

(2) Priority

   If the Secretary determines that a Medicare+Choice organization, in relation to a Medicare+Choice plan it offers, has a capacity limit and the number of Medicare+Choice eligible individuals who elect the plan under this section exceeds the capacity limit, the organization may limit the election of individuals of the plan under this section but only if priority in election is provided—

   (A) first to such individuals as have elected the plan at the time of the determination, and
   (B) then to other such individuals in such a manner that does not discriminate, on a basis described in section 1395w–22(b) of this title, among the individuals (who seek to elect the plan).

The preceding sentence shall not apply if it would result in the enrollment of enrollees substantially nonrepresentative, as determined in accordance with regulations of the Secretary, of the Medicare population in the service area of the plan.

(3) Limitation on termination of election

   (A) In general

   Subject to subparagraph (B), a Medicare+Choice organization may not for any reason terminate the election of any individual under this section for a Medicare+Choice plan it offers.

   (B) Basis for termination of election

   A Medicare+Choice organization may terminate an individual’s election under this section with respect to a Medicare+Choice plan it offers if—

   (i) any Medicare+Choice monthly basic and supplemental beneficiary premiums required with respect to such plan are not paid on a timely basis (consistent with standards under section 1395w–26 of this title that provide for a grace period for late payment of such premiums),
   (ii) the individual has engaged in disruptive behavior (as specified in such standards), or
   (iii) the plan is terminated with respect to all individuals under this part in the area in which the individual resides.

   (C) Consequence of termination

   (i) Terminations for cause

   Any individual whose election is terminated under clause (i) or (ii) of subparagraph (B) is deemed to have elected the original medicare fee-for-service program option described in subsection (a)(1)(A) of this section.

   (ii) Termination based on plan termination or service area reduction

   Any individual whose election is terminated under subparagraph (B)(iii) shall have a special election period under subsection (e)(4)(A) of this section in which to change coverage to coverage under another Medicare+Choice plan. Such an individual who fails to make an election during such period is deemed to have chosen to change coverage to the original medicare fee-for-service program option described in subsection (a)(1)(A) of this section.

(D) Organization obligation with respect to election forms

Pursuant to a contract under section 1395w–27 of this title, each Medicare+Choice organization receiving an election form under subsection (c)(2) of this section shall transmit to the Secretary (at such time and in such manner as the Secretary may specify) a copy of such form or such other information respecting the election as the Secretary may specify.

(h) Approval of marketing material and application forms

(1) Submission

No marketing material or application form may be distributed by a Medicare+Choice organization to (or for the use of) Medicare+Choice eligible individuals unless—

   (A) at least 45 days (or 10 days in the case described in paragraph (5)) before the date of distribution the organization has submitted the material or form to the Secretary for review, and
   (B) the Secretary has not disapproved the distribution of such material or form.

(2) Review

The standards established under section 1395w–26 of this title shall include guidelines for the review of any material or form submitted and under such guidelines the Secretary shall disapprove (or later require the correction of) such material or form if the material or form is materially inaccurate or misleading or otherwise makes a material misrepresentation.

(3) Deemed approval (1-stop shopping)

In the case of material or form that is submitted under paragraph (1)(A) to the Secretary or a regional office of the Department of Health and Human Services and the Secretary or the office has not disapproved the distribution of marketing material or form under paragraph (1)(B) with respect to a Medicare+Choice plan in an area, the Secretary is deemed not to have disapproved such distribution in all other areas covered by the plan and organization except with regard to that portion of such material or form that is specific only to an area involved.

(4) Prohibition of certain marketing practices

Each Medicare+Choice organization shall conform to fair marketing standards, in relation to Medicare+Choice plans offered under
this part, included in the standards established under section 1395w–26 of this title. Such standards—

(A) shall not permit a Medicare+Choice organization to provide for, subject to subsection (j)(2)(C), cash, gifts, prizes, or other monetary rebates as an inducement for enrollment or otherwise;

(B) may include a prohibition against a Medicare+Choice organization (or agent of such an organization) completing any portion of any election form used to carry out elections under this section on behalf of any individual;

(C) shall not permit a Medicare Advantage organization (or the agents, brokers, and other third parties representing such organization) to conduct the prohibited activities described in subsection (j)(1); and

(D) shall only permit a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization) to conduct the activities described in subsection (j)(2) in accordance with the limitations established under such subsection.

(5) Special treatment of marketing material following model marketing language

In the case of marketing material of an organization that uses, without modification, proposed model language specified by the Secretary, the period specified in paragraph (1)(A) shall be reduced from 45 days to 10 days.

(6) Required inclusion of plan type in plan name

For plan years beginning on or after January 1, 2010, a Medicare Advantage organization must ensure that the name of each Medicare Advantage plan offered by the Medicare Advantage organization includes the plan type of the plan (using standard terminology developed by the Secretary).

(7) Strengthening the ability of States to act in collaboration with the Secretary to address fraudulent or inappropriate marketing practices

(A) Appointment of agents and brokers

Each Medicare Advantage organization shall—

(i) only use agents and brokers who have been licensed under State law to sell Medicare Advantage plans offered by the Medicare Advantage organization;

(ii) in the case where a State has a State appointment law, abide by such law; and

(iii) report to the applicable State the termination of any such agent or broker, including the reasons for such termination (as required under applicable State law).

(B) Compliance with State information requests

Each Medicare Advantage organization shall comply in a timely manner with any request by a State for information regarding the performance of a licensed agent, broker, or other third party representing the Medicare Advantage organization as part of an investigation by the State into the conduct of the agent, broker, or other third party.

(i) Effect of election of Medicare+Choice plan option

(1) Payments to organizations

Subject to sections 1395w–22(a)(5), 1395w–23(a)(4), 1395w–23(d)(1), 1395ww(d)(11), 1395ww(h)(3)(D), and 1395w–23(m) of this title, payments under a contract with a Medicare+Choice organization under section 1395w–23(a) of this title with respect to an individual electing a Medicare+Choice plan offered by the organization shall be paid to the Secretary under this subchapter for items and services furnished to the individual.

(2) Only organization entitled to payment

Subject to sections 1395w–22(a)(5), 1395w–23(a)(4), 1395w–23(d)(1), 1395ww(d)(11), 1395ww(h)(3)(D) of this title, only the Medicare+Choice organization shall be entitled to receive payments from the Secretary under this subchapter for services furnished to the individual.

(j) Prohibited activities described and limitations on the conduct of certain other activities

(1) Prohibited activities described

The following prohibited activities are described in this paragraph:

(A) Unsolicited means of direct contact

Any unsolicited means of direct contact of prospective enrollees, including soliciting door-to-door or any outbound telemarketing without the prospective enrollee initiating contact.

(B) Cross-selling

The sale of other non-health related products (such as annuities and life insurance) during any sales or marketing activity or presentation conducted with respect to a Medicare Advantage plan.

(C) Meals

The provision of meals of any sort, regardless of value, to prospective enrollees at promotional and sales activities.

(D) Sales and marketing in health care settings and at educational events

Sales and marketing activities for the enrollment of individuals in Medicare Advantage plans that are conducted—

(i) in health care settings in areas where health care is delivered to individuals (such as physician offices and pharmacies), except in the case where such activities are conducted in common areas in health care settings; and

(ii) at educational events.

(2) Limitations

The Secretary shall establish limitations with respect to at least the following:

(A) Scope of marketing appointments

The scope of any appointment with respect to the marketing of a Medicare Advantage plan. Such limitation shall require advance
agreement with a prospective enrollee on the scope of the marketing appointment and documentation of such agreement by the Medicare Advantage organization. In the case where the marketing appointment is in person, such documentation shall be in writing.

(B) Co-branding

The use of the name or logo of a co-branded network provider on Medicare Advantage plan membership and marketing materials.

(C) Limitation of gifts to nominal dollar value

The offering of gifts and other promotional items other than those that are of nominal value (as determined by the Secretary) to prospective enrollees at promotional activities.

(D) Compensation

The use of compensation other than as provided under guidelines established by the Secretary. Such guidelines shall ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs.

(E) Required training, annual retraining, and testing of agents, brokers, and other third parties

The use by a Medicare Advantage organization of any individual as an agent, broker, or other third party representing the organization that has not completed an initial training and testing program and does not complete an annual retraining and testing program.


2010—Subsec. (b)(1)(C). Pub. L. 111–148, § 3201(e)(2)(A)(i), which directed that subpar. (C) be struck out, was repealed by Pub. L. 111–152, § 1102(a). See Effective Date of 2010 Amendment note below.

References in Text

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

Subsec. (e)(2)(C) of this section, referred to in subsec. (e)(2)(B)(i), was amended generally by section 3204(a)(1) of Pub. L. 111–148 and, as so amended, no longer contains a cl. (iii).

Subsec. (b)(4)(C). Pub. L. 108–173, § 233(b)(3), struck out at end "not later than March 1, 2002, on whether the time limit under subparagraph (A)(ii) should be extended or removed and whether to change the numerical limitation under subparagraph (A)(ii)."


Subsec. (d)(4)(B)(i). Pub. L. 108–173, § 222(h)(3)(B)(ii), substituted "monthly amount of the premium charged to an individual" for "Medicare+Choice monthly basic beneficiary premium and Medicare+Choice monthly beneficiary premium, if any, for the plan or, in the case of an MSA plan, the Medicare+Choice monthly MSA premium."

Subsec. (d)(4)(E). Pub. L. 108–173, § 222(h)(3)(B)(iv), reenacted heading without change and amended text generally. Prior to amendment, text read as follows: "Whether the organization offering the plan includes mandatory supplemental benefits in its base benefit package or offers optional supplemental benefits and the terms and conditions (including premiums) for such coverage."

Subsec. (e)(1). Pub. L. 108–173, § 102(a)(4), inserted at end "and, with respect to 2003, 2004, and 2005, the period beginning on November 15 and ending on December 31 of the year before such year" for "means, with respect to a calendar year (beginning with 2000), the month of November before such year."


Subsec. (e)(6)(A). Pub. L. 108–178, § 532(c)(1)(B), substituted "during the annual, coordinated election period under paragraph (3) for each subsequent year" for "each subsequent year (as provided in paragraph (3))", for "2005—Subsec. (a)(3)(B), Pub. L. 106–554, § 1(a)(6) [title VI, § 620(a)], substituted "except that—" and cl. (i) and (ii) for "except that an individual who develops end-stage renal disease while enrolled in a Medicare+Choice plan may continue to be enrolled in that plan.


Subsec. (f)(2). Pub. L. 106–554, § 1(a)(6) [title VI, § 619(a)], struck out "except that if such election or change is made after the 10th day of any calendar month, then the election or change shall not take effect until the first day of the second calendar month following the date on which the election or change is made before period at end.

Subsec. (h)(1)(A). Pub. L. 106–554, § 1(a)(6) [title VI, § 613(a)(1)], inserted "(or 10 days in the case described in paragraph (5))" after "45 days."


1999—Subsec. (b)(1)(A). Pub. L. 106–113, § 1000(a)(6) [title VI, § 501(c)(1)], added "and except as provided in subparagraph (C) after "may otherwise provide".


Subsec. (e)(2)(B)(i). Pub. L. 106–113, § 1000(a)(6) [title VI, § 501(b)(1)], inserted "and subparagraph (D) after "clause (II)."

Subsec. (e)(2)(C)(i). Pub. L. 106–113, § 1000(a)(6) [title VI, § 501(b)(2)], inserted "and subparagraph (D) after "clause (II)."


Subsec. (e)(3)(C). Pub. L. 106–113, § 1000(a)(6) [title VI, § 519(a)], substituted "During the fall season for "In the month of November".

Subsec. (e)(4)(A). Pub. L. 106–113, § 1000(a)(6) [title VI, § 501(a)(1)], added subpar. (A) and struck out former subpar. (A) which read as follows: "The Secretary shall submit such a report, by period under this part shall further extend through the end of the individual's initial enrollment period under part B of this subchapter.".


Subsec. (f)(3). Pub. L. 108–173, § 222(i)(3)(E), inserted "other than the period described in clause (ii) of such subsection" after "subsection (e)(3)(B) of this section".


**Effective Date of 2010 Amendment**

Pub. L. 111–148, title I, §1102(a), Mar. 23, 2010, 124 Stat. 1040, provided that: sections 3201 (amending this section and sections 1395w–23, 1395w–24, 1395w–27a, 1395w–29, and 1395see of this title and enacting provisions set out as notes under this section and section 1395w–24 of this title) and 3203 (amending section 1395w–23 of this title) of Pub. L. 111–148, and the amendments made by such sections, were repealed, effective as if included in the enactment of Pub. L. 111–148.


**Effective Date of 2008 Amendment**


Pub. L. 110–275, title I, §106(b)(3), July 15, 2008, 122 Stat. 2500, provided that: “The amendments made by this subsection [amending this section and section 1395w–104 of this title] shall take effect on a date specified by the Secretary (but in no case later than November 15, 2008).”


**Effective Date of 2003 Amendment**


**Effective Date of 2002 Amendment**


**Effective Date of 2000 Amendment**

Amendment by section 1(a)(6) [title VI, §606(a)(2)(C)] of Pub. L. 106–554 applicable to years beginning with 2003, see section 1(a)(6) [title VI, §606(b)] of Pub. L. 106–554, set out as a note under section 1395r of this title.

Pub. L. 106–554, §1(a)(6) [title VI, §619(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–560, provided that: “The amendments made by subsection (a) [amending this section] shall apply to marketing material submitted on or after January 1, 2001.”

Pub. L. 106–554, §1(a)(6) [title VI, §619(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–563, provided that: “The amendment made by this section [amending this section] shall apply to elections and changes of coverage made on or after June 1, 2001.”

Pub. L. 106–554, §1(a)(6) [title VI, §620(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–564, provided that: “(1) In GENERAL.—The amendment made by subsection (a) [amending this section] shall apply to terminations and discontinuances occurring on or after the date of the enactment of this Act [Dec. 21, 2000].

(2) APPLICABILITY TO PRIOR PLAN TERMINATIONS.—Clause (ii) of section 1851(a)(3)(B) of the Social Security Act [subsection (a)(3)(B)(ii) of this section] (as inserted by subsection (a)) shall also apply to individuals whose enrollment in a Medicare+Choice plan was terminated or discontinued after December 31, 1998, and before the date of the enactment of this Act. In applying this paragraph, such an individual shall be treated, for purposes of part C of title XVIII of the Social Security Act [this part], as having discontinued enrollment in such a plan as of the date of the enactment of this Act.”

**Effective Date of 1999 Amendment**


Pub. L. 106–113, div. B, §1000(a)(6) [title V, §501(d)], Nov. 29, 1999, 113 Stat. 1538, 1501A–379, provided that: “(1) The amendments made by subsection (a) [amending this section and section 1395s of this title] apply to notices of impending terminations or discontinuances made on or after the date of the enactment of this Act [Nov. 29, 1999].

(2) The amendments made by subsection (c) [amending this section] apply to elections and changes of coverage made on or after the date of the enactment of this Act [Nov. 29, 1999] with respect to eliminations of Medicare+Choice payment areas from a service area that occur before, on, or after the date of the enactment of this Act.”


**Regulations**

Pub. L. 108–173, title II, §223(b), Dec. 8, 2003, 117 Stat. 2207, provided that: “The Secretary of Health and Human Services shall revise the regulations previously promulgated to carry out part C of title XVIII of the Social Security Act [this part] to carry out the provisions of this Act [see Tables for classification].”

**Construction**

Pub. L. 108–173, title II, §221(b)(2), Dec. 8, 2003, 117 Stat. 2181, provided that: “Nothing in part C of title XVIII of the Social Security Act [this part] shall be construed as preventing an MSA plan or MA private fee-for-service plan from having a service area that covers one or more MA regions or the entire nation.”

**No Cuts in Guaranteed Benefits.**

Title note set out under section 18001 of this title shall result in the reduction or elimination of any benefits guaranteed by law to participants in Medicare Advantage plans.’’

IMPLEMENTATION OF MEDICARE ADVANTAGE PROGRAM


‘‘(a) IN GENERAL.—There is hereby established the Medicare Advantage program. The Medicare Advantage program shall consist of the program under part C of title XVIII of the Social Security Act [this part] (as amended by this Act [see Tables for classification]).

‘‘(b) REFERENCES.—Subject to subsection (c), any reference to the program under part C of title XVIII of the Social Security Act [this part] (as amended by this Act) shall be deemed a reference to the Medicare Advantage program and, with respect to such part, any reference to ‘Medicare+Choice’ is deemed a reference to ‘Medicare Advantage’ and ‘MA’.

‘‘(c) TRANSITION.—In order to provide for an orderly transition and avoid beneficiary and provider confusion, the Secretary [of Health and Human Services] shall provide for an appropriate transition in the use of the terms ‘Medicare+Choice’ and ‘Medicare Advantage’ (or ‘MA’) in reference to the program under part C of title XVIII of the Social Security Act [this part]. Such transition shall be fully completed for all materials for plan years beginning not later than January 1, 2006. Before the completion of such transition, any reference to ‘Medicare Advantage’ or ‘MA’ shall be deemed to include a reference to ‘Medicare+Choice’.’’

REPORT ON IMPACT OF INCREASED FINANCIAL ASSISTANCE TO MEDICARE ADVANTAGE PLANS

Pub. L. 108–173, title II, § 211(g), Dec. 8, 2003, 117 Stat. 2178, directed the Secretary of Health and Human Services to submit to Congress, not later than July 1, 2006, a report that described the impact of additional financing provided under Pub. L. 108–173 and other Acts on the availability of Medicare Advantage plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

MEDPAC STUDY AND REPORT ON CLARIFICATION OF AUTHORITY REGARDING DISAPPROVAL OF UNREASONABLE BENEFICIARY COST-SHARING

Pub. L. 108–173, title II, § 211(h), Dec. 8, 2003, 117 Stat. 2178, directed the Medicare Payment Advisory Commission, in consultation with beneficiaries, consumer groups, employers, and organizations offering plans under this part, to conduct a study to determine the extent to which the cost-sharing structures under such plans affect access to covered services or select enrollees based on the health status of eligible individuals described in subsection (a), and to submit a report to Congress on such study not later than Dec. 31, 2004.

MORATORIUM ON NEW LOCAL PREFERRED PROVIDER ORGANIZATION PLANS

Pub. L. 108–173, title II, § 221(a)(2), Dec. 8, 2003, 117 Stat. 2186, directed the Secretary of Health and Human Services not to permit the offering of a local preferred provider organization plan under this part during 2006 or 2007 in a service area unless such plan was offered under this part (including under a demonstration project under this part) in such area as of Dec. 31, 2003.

SPECIALIZED MA PLANS


‘‘(1) AUTHORITY TO DESIGNATE OTHER PLANS AS SPECIALIZED MA PLANS.—During the period beginning on January 1, 2008, and ending on December 31, 2009, the Secretary of Health and Human Services shall not exercise the authority provided under section 231(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [Pub. L. 108–173] (42 U.S.C. 1395w–21 note) to designate other plans as specialized MA plans for special needs individuals under part C of title XVIII of the Social Security Act [this part]. The preceding sentence shall not apply to plans designated as specialized MA plans for special needs individuals under such authority prior to January 1, 2008.

‘‘(2) ENROLLMENT IN NEW PLANS.—During the period beginning on January 1, 2008, and ending on December 31, 2009, the Secretary of Health and Human Services shall not permit enrollment of any individual residing in an area in a specialized Medicare Advantage plan for special needs individuals under part C of title XVIII of the Social Security Act to take effect unless that specialized Medicare Advantage plan meet the standards prescribed by the Social Security Act [subsec. (a)(2)(A)(ii) of this section] (as added by subsection (a)) and section 1859(b)(6) of such Act [section 1395w–28(b)(6) of this title] (as added by subsection (b)), the Secretary [of Health and Human Services] may provide (notwithstanding section 1395w(b)(6)(A) of such Act) for the offering of specialized MA plans for special needs individuals by MA plans that disproportionately serve special needs individuals.

Pub. L. 108–173, title II, § 211(e), Dec. 8, 2003, 117 Stat. 2236, provided that: ‘‘Not later than December 31, 2007, the Secretary [of Health and Human Services] shall submit to Congress a report that assesses the impact of specialized MA plans for special needs individuals on the cost and quality of services provided to enrollees. Such report shall include an assessment of the costs and savings to the Medicare program as a result of amendments made by subsections (a), (b), and (c) [amending this section and section 1395w–28 of this title].’’

MEDPAC STUDY ON CONSUMER COALITIONS

Pub. L. 106–554, §1(a)(6) [title I, §124], Dec. 21, 2000, 114 Stat. 2763, 2763A–478, directed the Medicare Payment Advisory Commission to conduct a study examining the use of consumer coalitions in the marketing of Medicare+Choice plans under the medicare program unless included in this subchapter and to submit a report on the study to Congress no later than 1 year after Dec. 21, 2000.

REPORT ON ACCOUNTING FOR VA AND DOD EXPENDITURES FOR MEDICARE BENEFICIARIES


REPORT ON MEDICARE MSA (MEDICAL SAVINGS ACCOUNT) PLANS

Pub. L. 106–113, div. B, §1000(a)(6) [title V, §552(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–395, directed the Medicare Payment Assessment Commission to Congress, no later than 1 year after Nov. 29, 1999, a report on specific legislative changes that should be
made to make MSA plans a viable option under the Medicare+Choice program.

GAO AUDIT AND REPORTS ON PROVISION OF MEDICARE+CHOICE HEALTH INFORMATION TO BENEFICIARIES


“(1) IN GENERAL.—Beginning in 2000, the Comptroller General shall conduct an annual audit of the expenditures by the Secretary of Health and Human Services during the preceding year in providing information regarding the Medicare+Choice program under part C of title XVIII of the Social Security Act (42 U.S.C. 1395w–21 et seq.) to eligible Medicare beneficiaries.

“(3) REPORTS.—Not later than March 31 of 2001, 2004, 2007, and 2010, the Comptroller General shall submit a report to Congress on the results of the audit of the expenditures of the preceding 3 years conducted pursuant to subsection (a) [enacting provisions set out as a note under section 1395w of this title], together with an evaluation of the effectiveness of the means used by the Secretary of Health and Human Services in providing information regarding the Medicare+Choice program under part C of title XVIII of the Social Security Act (42 U.S.C. 1395w–21 et seq.) to eligible Medicare beneficiaries.”

ENROLLMENT TRANSITION RULE

Section 4002(c) of Pub. L. 105–33 provided that: “An individual who is enrolled on December 31, 1998, with an eligible organization under section 1876 of the Social Security Act (42 U.S.C. 1395mm) shall be considered to have disenrolled effective on that date.’’

SECURETIAL SUBMISSION OF LEGISLATIVE PROPOSAL


REPORT ON INTEGRATION AND TRANSITION

Pub. L. 105–33, title IV, §4014(c), Aug. 5, 1997, 111 Stat. 337, directed the Secretary of Health and Human Services to submit to Congress, no later than Jan. 1, 1999, a plan which provided for the integration of health plans offered by social health maintenance organizations and similar plans as an option under the Medicare+Choice program under this part, for a transition for such organizations operating under demonstration project authority, and for appropriate payment levels for plans offered by such organizations.

MEDICARE ENROLLMENT DEMONSTRATION PROJECT

Section 4018 of Pub. L. 105–33 provided that:

“(a) DEMONSTRATION PROJECT.—

“(1) ESTABLISHMENT.—The Secretary shall implement a demonstration project (in this section referred to as the ‘project’) for the purpose of evaluating the use of a third-party contractor to conduct the Medicare+Choice plan enrollment and disenrollment functions, as described in part C of title XVIII of the Social Security Act (this part) (as added by section 4001 of this Act), as provided in paragraph (6) for MA regional plans, for a transition for such organizations operating under demonstration project authority, and for appropriate payment levels for plans offered by such organizations.

“(2) CONSULTATION.—Before implementing the project under this section, the Secretary shall consult with affected parties on—

“(A) the design of the project;

“(B) the selection criteria for the third-party contractor; and

“(C) the establishment of performance standards, as described in paragraph (3).

“(3) PERFORMANCE STANDARDS.—

“(A) IN GENERAL.—The Secretary shall establish performance standards for the accuracy and timeliness of the Medicare+Choice plan enrollment and disenrollment functions performed by the third-party contractor.

“(B) NONCOMPLIANCE.—In the event that the third-party contractor is not in substantial compliance with the performance standards established under subparagraph (A), such enrollment and disenrollment functions shall be performed by the Medicare+Choice plan until the Secretary appoints a new third-party contractor.

“(b) REPORT TO CONGRESS.—The Secretary shall periodically report to Congress on the progress of the project conducted pursuant to this section.

“(c) WAIVER AUTHORITY.—The Secretary shall waive compliance with the requirements of part C of title XVIII of the Social Security Act (this part) (as amended by section 4001 of this Act) to such extent and for such period as the Secretary determines is necessary to conduct the project.

“(d) DURATION.—A demonstration project under this section shall be conducted for a 3-year period.

“(e) SEPARATE FROM OTHER DEMONSTRATION PROJECTS.—A project implemented by the Secretary under this section shall not be conducted in conjunction with any other demonstration project.”

§ 1395w–22. Benefits and beneficiary protections
(a) Basic benefits

(1) Requirement

(A) In general

Except as provided in section 1395w–22(b)(3) of this title for MSA plans and except as provided in paragraph (6) for MA regional plans, each Medicare+Choice plan shall provide to members enrolled under this part, through providers and other persons that meet the applicable requirements of this subchapter and part A of subchapter XI of this chapter, benefits under the original medicare fee-for-service program option (and, for plan years before 2006, additional benefits required under section 1395w–22(f)(1)(A) of this title).

(B) Benefits under the original medicare fee-for-service program option defined

(i) In general

For purposes of this part, the term “benefits under the original medicare fee-for-service program option” means those items and services (other than hospice care) for which benefits are available under parts A and B to individuals entitled to benefits under part A and enrolled under part B, with cost-sharing for those services as required under parts A and B or, subject to clause (iii), an actuarily equivalent level of cost-sharing as determined in this part.

(ii) Special rule for regional plans

In the case of an MA regional plan

(1) determining an actuarially equivalent level of cost-sharing with respect to benefits under the original medicare fee-for-service program option, there shall only be taken into account, with respect to the application of section 1395w–27a(b)(2) of this title, such expenses only with respect to subparagraph (A) of such section.
(iii) Limitation on variation of cost sharing for certain benefits
Subject to clause (v), cost-sharing for services described in clause (iv) shall not exceed the cost-sharing required for those services under parts A and B.

(iv) Services described
The following services are described in this clause:

(I) Chemotherapy administration services.
(II) Renal dialysis services (as defined in section 1395rr(b)(14)(B) of this title).
(III) Skilled nursing care.
(IV) Such other services that the Secretary determines appropriate (including services that the Secretary determines require a high level of predictability and transparency for beneficiaries).

(v) Exception
In the case of services described in clause (iv) for which there is no cost-sharing required under parts A and B, cost-sharing may be required for those services in accordance with clause (i).

(2) Satisfaction of requirement

(A) In general
A Medicare+Choice plan (other than an MSA plan) offered by a Medicare+Choice organization satisfies paragraph (1)(A), with respect to benefits for items and services furnished other than through a provider or other person that has a contract with the organization offering the plan, if the plan provides payment in an amount so that—

(i) the sum of such payment amount and any cost sharing provided for under the plan, is equal to at least

(ii) the total dollar amount of payment for such items and services as would otherwise be authorized under parts A and B of this subchapter (including any balance billing permitted under such parts).

(B) Reference to related provisions
For provision relating to—

(i) limitations on balance billing against Medicare+Choice organizations for non-contract providers, see subsection (k) of this section and section 1395cc(a)(1)(O) of this title, and

(ii) limiting actuarial value of enrollee liability for covered benefits, see section 1395w–24(e) of this title.

(C) Election of uniform coverage determination
In the case of a Medicare+Choice organization that offers a Medicare+Choice plan in an area in which more than one local coverage determination is applied with respect to different parts of the area, the organization may elect to have the local coverage determination for the part of the area that is most beneficial to Medicare+Choice enrollees (as identified by the Secretary) apply with respect to all Medicare+Choice enrollees enrolled in the plan.

(3) Supplemental benefits

(A) Benefits included subject to Secretary's approval
Each Medicare+Choice organization may provide to individuals enrolled under this part, other than under an MSA plan (without affording those individuals an option to decline the coverage), supplemental health care benefits that the Secretary may approve. The Secretary shall approve any such supplemental benefits unless the Secretary determines that including such supplemental benefits would substantially discourage enrollment by Medicare+Choice eligible individuals with the organization.

(B) At enrollees' option

(i) In general
Subject to clause (ii), a Medicare+Choice organization may provide to individuals enrolled under this part supplemental health care benefits that the individuals may elect, at their option, to have covered.

(ii) Special rule for MSA plans
A Medicare+Choice organization may not provide, under an MSA plan, supplemental health care benefits that cover the deductible in described in section 1395w–28(b)(2)(B) of this title. In applying the previous sentence, health benefits described in section 1395w(u)(2)(B) of this title shall not be treated as covering such deductible.

(C) Application to Medicare+Choice private fee-for-service plans
Nothing in this paragraph shall be construed as preventing a Medicare+Choice private fee-for-service plan from offering supplemental benefits that include payment for some or all of the balance billing amounts permitted consistent with subsection (k) of this section and coverage of additional services that the plan finds to be medically necessary. Such benefits may include reductions in cost-sharing below the actuarial value specified in section 1395w–24(e)(4)(B) of this title.

(4) Organization as secondary payer
Notwithstanding any other provision of law, a Medicare+Choice organization may (in the case of the provision of items and services to an individual under a Medicare+Choice plan under circumstances in which payment under this subchapter is made secondary pursuant to section 1395y(b)(2) of this title) charge or authorize the provider of such services to charge, in accordance with the charges allowed under a law, plan, or policy described in such section—

(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 individual to the extent that the individual has been paid under such law, plan, or policy for such services.
(5) National coverage determinations and legislative changes in benefits

If there is a national coverage determination or legislative change in benefits required to be provided under this part made in the period beginning on the date of an announcement under section 1395w–23(b) of this title and ending on the date of the next announcement under such section and the Secretary projects that the determination will result in a significant change in the costs to a Medicare+Choice organization of providing the benefits that are the subject of such national coverage determination and that such change in costs was not incorporated in the determination of the annual Medicare+Choice capitation rate under section 1395w–23 of this title included in the announcement made at the beginning of such period, then, unless otherwise required by law—

(A) such determination or legislative change in benefits shall not apply to contracts under this part until the first contract year that begins after the end of such period, and

(B) if such coverage determination or legislative change provides for coverage of additional benefits or coverage under additional circumstances, section 1395w–21(i)(1) of this title shall not apply to payment for such additional benefits or benefits provided under such additional circumstances until the first contract year that begins after the end of such period.

The projection under the previous sentence shall be based on an analysis by the Chief Actuary of the Centers for Medicare & Medicaid Services of the actuarial costs associated with the coverage determination or legislative change in benefits.

(6) Special benefit rules for regional plans

In the case of an MA plan that is a MA regional plan, benefits under the plan shall include the benefits described in paragraphs (1) and (2) of section 1395w–27a(b) of this title.

(7) Limitation on cost-sharing for dual eligibles and qualified medicare beneficiaries

The number, mix, and distribution of plan providers, out-of-network coverage (if any) provided by the plan, and any point-of-service option (including the supplemental premium for such option).

(D) Out-of-area coverage

Out-of-area coverage provided by the plan.

(E) Emergency coverage

Coverage of emergency services, including—

(i) the appropriate use of emergency services, including use of the 911 telephone system or its local equivalent in emergency situations and an explanation of what constitutes an emergency situation;

1 See References in Text note below.
(d) Access to services

(1) In general

A Medicare+Choice organization offering a Medicare+Choice plan may select the providers from whom the benefits under the plan are provided so long as—

(A) the organization makes such benefits available and accessible to each individual electing the plan within the plan service area with reasonable promptness and in a manner which assures continuity in the provision of benefits;

(B) when medically necessary the organization makes such benefits available and accessible 24 hours a day and 7 days a week;

(C) the plan provides for reimbursement with respect to services which are covered under subparagraphs (A) and (B) and which are provided to such an individual other than through the organization, if—

(i) the services were not emergency services (as defined in paragraph (3)), but (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,

(ii) the services were renal dialysis services and were provided other than through the organization because the individual was temporarily out of the plan’s service area, or

(iii) the services are maintenance care or post-stabilization care covered under the guidelines established under paragraph (2);

(D) the organization provides access to appropriate providers, including credentialed specialists, for medically necessary treatment and services; and

(E) coverage is provided for emergency services (as defined in paragraph (3)) without regard to prior authorization or the emergency care provider’s contractual relationship with the organization.

(2) Guidelines respecting coordination of post-stabilization care

A Medicare+Choice plan shall comply with such guidelines as the Secretary may prescribe relating to promoting efficient and timely coordination of appropriate maintenance and post-stabilization care of an enrollee after the enrollee has been determined to be stable under section 1395dd of this title.

(3) “Emergency services” defined

In this subsection—

(A) In general

The term “emergency services” means, with respect to an individual enrolled with an organization, covered inpatient and outpatient services that—

(i) are furnished by a provider that is qualified to furnish such services under this subchapter, and

(ii) are needed to evaluate or stabilize an emergency medical condition (as defined in subparagraph (B)).

(B) Emergency medical condition based on prudent layperson

The term “emergency medical condition” means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention 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.

(4) Assuring access to services in Medicare+Choice private fee-for-service plans

In addition to any other requirements under this part, in the case of a Medicare+Choice pri-
(5) Requirement of certain nonemployer Medicare Advantage private fee-for-service plans to use contracts with providers

(A) In general

For plan year 2011 and subsequent plan years, in the case of a Medicare Advantage private fee-for-service plan not described in paragraph (1) or (2) of section 1395w–27(i) of this title, the plan shall meet the access standards under paragraph (4) only through entering into written contracts as provided for under subparagraph (B) of such paragraph and not, in whole or in part, through the establishment of payment rates meeting the requirements under subparagraph (A) of such paragraph.

(B) Network area defined

For purposes of subparagraph (A), the term "network area" means, for a plan year, an area which the Secretary identifies (in the Secretary’s announcement of the proposed payment rates for the previous plan year under section 1395w–23(b)(1)(B) of this title) as having at least 2 network-based plans (as defined in subparagraph (C)) with enrollment under this part as of the first day of the year in which such announcement is made.

(C) Network-based plan defined

(i) In general

For purposes of subparagraph (B), the term "network-based plan" means—

(I) except as provided in clause (ii), a Medicare Advantage plan that is a coordinated care plan described in section 1395w–21(a)(2)(A)(i) of this title;

(ii) a network-based MSA plan; and

(III) a reasonable cost reimbursement plan under section 1395mm of this title.

(ii) Exclusion of non-network regional PPOS

The term "network-based plan" shall not include an MA regional plan that, with respect to the area, meets access adequacy standards under this part substantially through the authority of section 422.112(a)(1)(ii) of title 42, Code of Federal Regulations, rather than through written contracts.

(6) Requirement of all employer Medicare Advantage private fee-for-service plans to use contracts with providers

For plan year 2011 and subsequent plan years, in the case of a Medicare Advantage private fee-for-service plan that is described in paragraph (1) or (2) of section 1395w–27(i) of this title, the plan shall meet the access standards under paragraph (4) only through entering into written contracts as provided for under subparagraph (B) of such paragraph and not, in whole or in part, through the establishment of payment rates meeting the requirements under subparagraph (A) of such paragraph.

(e) Quality improvement program

(1) In general

Each MA organization shall have an ongoing quality improvement program for the purpose of improving the quality of care provided to enrollees in each MA plan offered by such organization.

(2) Chronic care improvement programs

As part of the quality improvement program under paragraph (1), each MA organization shall have a chronic care improvement program. Each chronic care improvement program shall have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet criteria established by the organization for participation under the program.

(3) Data

(A) Collection, analysis, and reporting

(i) In general

Except as provided in clauses (ii) and (iii) with respect to plans described in such clauses and subject to subparagraph (B), as part of the quality improvement program under paragraph (1), each MA organization shall provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality. With respect to MA private fee-for-service plans and MSA plans, the requirements under the preceding sentence may not exceed the requirements under this subparagraph with respect to MA local plans that are preferred provider organization plans, except that,
for plan year 2010, the limitation under clause (iii) shall not apply and such requirements shall apply only with respect to administrative claims data.

(ii) Special requirements for specialized MA plans for special needs individuals

In addition to the data required to be collected, analyzed, and reported under clause (i) and notwithstanding the limitations under subparagraph (B), as part of the quality improvement program under paragraph (1), each MA organization offering a specialized Medicare Advantage plan for special needs individuals shall provide for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality with respect to the requirements described in paragraphs (2) through (5) of subsection (f). Such data may be based on claims data and shall be at the plan level.

(iii) Application to local preferred provider organizations and MA regional plans

Clause (i) shall apply to MA organizations with respect to MA local plans that are preferred provider organization plans and to MA regional plans only insofar as services are furnished by providers or services, physicians, and other health care practitioners and suppliers that have contracts with such organization to furnish services under such plans.

(iv) Definition of preferred provider organization plan

In this subparagraph, the term “preferred provider organization plan” means an MA plan that—

(I) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(II) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and

(III) is offered by an organization that is not licensed or organized under State law as a health maintenance organization.

(B) Limitations

(i) Types of data

The Secretary shall not collect under subparagraph (A) data on quality, outcomes, and beneficiary satisfaction to facilitate consumer choice and program administration other than the types of data that were collected by the Secretary as of November 1, 2003.

(ii) Changes in types of data

Subject to subclause (iii), the Secretary may only change the types of data that are required to be submitted under subparagraph (A) after submitting to Congress a report on the reasons for such changes that was prepared in consultation with MA organizations and private accrediting bodies.

(iii) Construction

Nothing in the second subsection shall be construed as restricting the ability of the Secretary to carry out the duties under section 1395w–21(d)(4)(D) of this title.

(4) Treatment of accreditation

(A) In general

The Secretary shall provide that a Medicare+Choice organization is deemed to meet all the requirements described in any specific clause of subparagraph (B) if the organization is accredited (and periodically re-accredited) by a private accrediting organization under a process that the Secretary has determined assures that the accrediting organization applies and enforces standards that meet or exceed the standards established under section 1395w–26 of this title to carry out the requirements in such clause.

(B) Requirements described

The provisions described in this subparagraph are the following:

(i) Paragraphs (1) through (3) of this subsection (relating to quality improvement programs).

(ii) Subsection (b) of this section (relating to antibidiscrimination).

(iii) Subsection (d) of this section (relating to access to services).

(iv) Subsection (h) of this section (relating to confidentiality and accuracy of enrollee records).

(v) Subsection (i) of this section (relating to information on advance directives).

(vi) Subsection (j) of this section (relating to provider participation rules).

(vii) The requirements described in section 1395w–104(i) of this title, to the extent such requirements apply under section 1395w–131(c) of this title.

(C) Timely action on applications

The Secretary shall determine, within 210 days after the date the Secretary receives an application by a private accrediting organization and using the criteria specified in section 1395bb(a)(2) of this title, whether the process of the private accrediting organization meets the requirements with respect to any specific clause in subparagraph (B) with respect to which the application is made. The Secretary may not deny such an application on the basis that it seeks to meet the requirements with respect to only one, or more than one, such specific clause.

(D) Construction

Nothing in this paragraph shall be construed as limiting the authority of the Secretary under section 1395w–27 of this title, including the authority to terminate contracts with Medicare+Choice organizations under subsection (c)(2) of such section.

(f) Grievance mechanism

Each Medicare+Choice organization must provide meaningful procedures for hearing and resolving grievances between the organization (in-
§ 1395w–22

(1) Determinations by organization

(A) In general

A Medicare+Choice organization shall have a procedure for making determinations regarding whether an individual enrolled with the plan of the organization under this part is entitled to receive a health service under this section and the amount (if any) that the individual is required to pay with respect to such service. Subject to paragraph (3), such procedures shall provide for such determination to be made on a timely basis.

(B) Explanation of determination

Such a determination that denies coverage, in whole or in part, shall be in writing and shall include a statement in understandable language of the reasons for the denial and a description of the reconsideration and appeals processes.

(2) Reconsiderations

(A) In general

The organization shall provide for reconsideration of a determination described in paragraph (1)(B) upon request by the enrollee involved. The reconsideration shall be made within a time period specified by the Secretary, but shall be made, subject to paragraph (3), not later than 60 days after the date of the receipt of the request for reconsideration.

(B) Physician decision on certain reconsiderations

A reconsideration relating to a determination to deny coverage based on a lack of medical necessity shall be made only by a physician with appropriate expertise in the field of medicine which necessitates treatment who is other than a physician involved in the initial determination.

(3) Expedited determinations and reconsiderations

(A) Receipt of requests

(i) Enrollee requests

An enrollee in a Medicare+Choice plan may request, either in writing or orally, an expedited determination under paragraph (1) or an expedited reconsideration under paragraph (2) by the Medicare+Choice organization.

(ii) Physician requests

A physician, regardless whether the physician is affiliated with the organization or not, may request, either in writing or orally, such an expedited determination or reconsideration.

(B) Organization procedures

(i) In general

The Medicare+Choice organization shall maintain procedures for expediting organization determinations and reconsiderations when, upon request of an enrollee, the organization determines that the application of the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(ii) Expedition required for physician requests

In the case of a request for an expedited determination or reconsideration made under subparagraph (A)(ii), the organization shall expedite the determination or reconsideration if the request indicates that the application of the normal time frame for making a determination (or a reconsideration involving a determination) could seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function.

(iii) Timely response

In cases described in clauses (i) and (ii), the organization shall notify the enrollee (and the physician involved, as appropriate) of the determination or reconsideration under time limitations established by the Secretary, but not later than 72 hours of the time of receipt of the request for the determination or reconsideration (or receipt of the information necessary to make the determination or reconsideration), or such longer period as the Secretary may permit in specified cases.

(4) Independent review of certain coverage denials

The Secretary shall contract with an independent, outside entity to review and resolve in a timely manner reconsiderations that affirm denial of coverage, in whole or in part. The provisions of section 1395ff(c)(5) of this title shall apply to independent outside entities under contract with the Secretary under this paragraph.

(5) Appeals

An enrollee with a Medicare+Choice plan of a Medicare+Choice organization under this part who is dissatisfied by reason of the enrollee's failure to receive any health service to which the enrollee believes the enrollee is entitled and at no greater charge than the enrollee believes the enrollee 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 organization a party. If the amount in controversy is $1,000 or more, the individual or 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 organization shall be entitled to be parties to that judicial review. In applying subsections (b) and (g) of section 405 of this title as provided in this paragraph, and in applying section 405(f) of
of the professional about the health status of the individual or medical care or treatment for the individual’s condition or disease, regardless of whether benefits for such care or treatment are provided under the plan, if the professional is acting within the lawful scope of practice.

(B) Conscience protection

Subparagraph (A) shall not be construed as requiring a Medicare+Choice plan to provide, reimburse for, or provide coverage of a counseling or referral service if the Medicare+Choice organization offering the plan—

(i) objects to the provision of such service on moral or religious grounds; and

(ii) in the manner and through the written instrumentalities such Medicare+Choice organization deems appropriate, makes available information on its policies regarding such service to prospective enrollees before or during enrollment and to enrollees within 90 days after the date that the organization or plan adopts a change in policy regarding such a counseling or referral service.

(C) Construction

Nothing in subparagraph (B) shall be construed to affect disclosure requirements under State law or under the Employee Retirement Income Security Act of 1974 [29 U.S.C. 1001 et seq.].

(D) “Health care professional” defined

For purposes of this paragraph, the term “health care professional” means a physician (as defined in section 1395x(r) of this title) or other health care professional if coverage for the professional’s services is provided under the Medicare+Choice plan for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered nurse anesthetist, and certified nurse-midwife, licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.

(4) Limitations on physician incentive plans

(A) In general

No Medicare+Choice organization may operate any physician incentive plan (as defined in subparagraph (B)) unless the organization provides assurances satisfactory to the Secretary that 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 under this part.

(ii) If the plan places a physician or physician group at substantial financial risk (as determined by the Secretary) for services not provided by the physician or phy-
sician group, the organization 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 group.

(B) “Physician incentive plan” defined

In this paragraph, the term “physician incentive plan” means any compensation arrangement between a Medicare+Choice 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 under this part.

(5) Limitation on provider indemnification

A Medicare+Choice organization may not provide (directly or indirectly) for a health care professional, provider of services, or other entity providing health care services (or group of such professionals, providers, or entities) to indemnify the organization against any liability resulting from a civil action brought for any damage caused to an enrollee with a Medicare+Choice organization under this part by the organization’s denial of medically necessary care.

(6) Special rules for Medicare+Choice private fee-for-service plans

For purposes of applying this part (including subsection (k)(1) of this section) and section 1395cc(a)(1)(O) of this title, a hospital (or other provider of services), a physician or other health care professional, or other entity furnishing health care services is treated as having an agreement or contract in effect with a Medicare+Choice organization (with respect to an individual enrolled in a Medicare+Choice private fee-for-service plan it offers), if—

(A) the provider, professional, or other entity furnishes services that are covered under the plan to such an enrollee; and

(B) before providing such services, the provider, professional, or other entity—

(1) has been informed of the individual’s enrollment under the plan, and

(2) either—

(I) has been informed of the terms and conditions of payment for such services under the plan, or

(II) is given a reasonable opportunity to obtain information concerning such terms and conditions, in a manner reasonably designed to effect informed agreement by a provider.

The previous sentence shall only apply in the absence of an explicit agreement between such a provider, professional, or other entity and the Medicare+Choice organization.

(7) Promotion of e-prescribing by MA plans

(A) In general

An MA–PD plan may provide for a separate payment or otherwise provide for a differential payment for a participating physician that prescribes covered part D drugs in accordance with an electronic prescription drug program that meets standards established under section 1395w–104(e) of this title.

(B) Considerations

Such payment may take into consideration the costs of the physician in implementing such a program and may also be increased for those participating physicians who significantly increase—

(i) formulary compliance;

(ii) lower cost, therapeutically equivalent alternatives;

(iii) reductions in adverse drug interactions; and

(iv) efficiencies in filing prescriptions through reduced administrative costs.

(C) Structure

Additional or increased payments under this subsection may be structured in the same manner as medication therapy management fees are structured under section 1395w–104(c)(2)(E) of this title.

(k) Treatment of services furnished by certain providers

(1) In general

Except as provided in paragraph (2), a physician or other entity (other than a provider of services) that does not have a contract establishing payment amounts for services furnished to an individual enrolled under this part with a Medicare+Choice organization described in section 1395w–21(a)(2)(A) of this title or with an organization offering an MSA plan shall accept as payment in full for covered services under this subchapter that are furnished to such an individual the amounts that the physician or other entity could collect if the individual were not so enrolled. Any penalty or other provision of law that applies to such a payment with respect to an individual entitled to benefits under this subchapter (but not enrolled with a Medicare+Choice organization under this part) also applies with respect to an individual so enrolled.

(2) Application to Medicare+Choice private fee-for-service plans

(A) Balance billing limits under Medicare+Choice private fee-for-service plans in case of contract providers

(i) In general

In the case of an individual enrolled in a Medicare+Choice private fee-for-service plan under this part, a physician, provider of services, or other entity that has a contract (including through the operation of subsection (j)(6) of this section) establishing a payment rate for services furnished to the enrollee shall accept as payment in full for covered services under this subchapter that are furnished to such an individual an amount equal to 115 percent of such payment rate.
(ii) Procedures to enforce limits

The Medicare+Choice organization that offers such a plan shall establish procedures, similar to the procedures described in section 1395w–4(g)(1)(A) of this title, in order to carry out the previous sentence.

(iii) Assuring enforcement

If the Medicare+Choice organization fails to establish and enforce procedures required under clause (ii), the organization is subject to intermediate sanctions under section 1395w–27(g) of this title.

(B) Enrollee liability for noncontract providers

For provision—

(i) establishing minimum payment rate in the case of noncontract providers under a Medicare+Choice private fee-for-service plan, see subsection (a)(2) of this section; or

(ii) limiting enrollee liability in the case of covered services furnished by such providers, see paragraph (1) and section 1395cc(a)(1)(O) of this title.

(C) Information on beneficiary liability

(i) In general

Each Medicare+Choice organization that offers a Medicare+Choice private fee-for-service plan shall provide that enrollees under the plan who are furnished services for which payment is sought under the plan are provided an appropriate explanation of benefits (consistent with that provided under parts A and B of this subchapter and, if applicable, under medicare supplemental policies) that includes a clear statement of the amount of the enrollee’s liability (including any liability for balance billing consistent with this subsection) with respect to payments for such services.

(ii) Advance notice before receipt of inpatient hospital services and certain other services

In addition, such organization shall, in its terms and conditions of payments to hospitals for inpatient hospital services and for other services identified by the Secretary for which the amount of the balance billing under subparagraph (A) could be substantial, require the hospital to provide to the enrollee, before furnishing such services and if the hospital imposes balance billing under subparagraph (A)—

(I) notice of the fact that balance billing is permitted under such subparagraph for such services, and

(II) a good faith estimate of the likely amount of such balance billing (if any), with respect to such services, based upon the presenting condition of the enrollee.

(I) Return to home skilled nursing facilities for covered post-hospital extended care services

(1) Ensuring return to home SNF

(A) In general

In providing coverage of post-hospital extended care services, a Medicare+Choice plan shall provide for such coverage through a home skilled nursing facility if the following conditions are met:

(i) Enrollee election

The enrollee elects to receive such coverage through such facility.

(ii) SNF agreement

The facility has a contract with the Medicare+Choice organization for the provision of such services, or the facility agrees to accept substantially similar payment under the same terms and conditions that apply to similarly situated skilled nursing facilities that are under contract with the Medicare+Choice organization for the provision of such services and through which the enrollee would otherwise receive such services.

(B) Manner of payment to home SNF

The organization shall provide payment to the home skilled nursing facility consistent with the contract or the agreement described in subparagraph (A)(ii), as the case may be.

(2) No less favorable coverage

The coverage provided under paragraph (1) (including scope of services, cost-sharing, and other criteria of coverage) shall be no less favorable to the enrollee than the coverage that would be provided to the enrollee with respect to a skilled nursing facility the post-hospital extended care services of which are otherwise covered under the Medicare+Choice plan.

(3) Rule of construction

Nothing in this subsection shall be construed to do the following:

(A) To require coverage through a skilled nursing facility that is not otherwise qualified to provide benefits under part A of this subchapter for medicare beneficiaries not enrolled in a Medicare+Choice plan.

(B) To prevent a skilled nursing facility from refusing to accept, or imposing conditions upon the acceptance of, an enrollee for the receipt of post-hospital extended care services.

(4) Definitions

In this subsection:

(A) Home skilled nursing facility

The term “home skilled nursing facility” means, with respect to an enrollee who is entitled to receive post-hospital extended care services under a Medicare+Choice plan, any of the following skilled nursing facilities:

(i) SNF residence at time of admission

The skilled nursing facility in which the enrollee resided at the time of admission to the hospital preceding the receipt of such post-hospital extended care services.

(ii) SNF in continuing care retirement community

A skilled nursing facility that is providing such services through a continuing care retirement community (as defined in subparagraph (B)) which provided resi-
dence to the enrollee at the time of such admission.

(iii) SNF residence of spouse at time of discharge

The skilled nursing facility in which the spouse of the enrollee is residing at the time of discharge from such hospital.

(B) Continuing care retirement community

The term “continuing care retirement community” means, with respect to an enrollee in a Medicare+Choice plan, an arrangement under which housing and health-related services are provided (or arranged) through an organization for the enrollee under an agreement that is effective for the life of the enrollee or for a specified period.


Subsec. (d)(4). Pub. L. 110–275, § 162(a)(3)(A), (2)(A), in introductory provisions, substituted “subject to paragraphs (5) and (6), the Secretary” for “the Secretary” in second sentence.

Subsec. (d)(4)(B). Pub. L. 110–275, § 162(a)(3)(A), substituted “a sufficient number and range of providers within such category to meet the access standards in subparagraphs (A) through (D) of paragraph (1)” for “a sufficient number and range of providers within such category to provide covered services under the terms of the plan”.


Subsec. (e)(1). Pub. L. 110–275, § 163(a), struck out “(other than an MA private fee-for-service plan or an MSA plan)” before period at end.

Subsec. (e)(3)(A)(i). Pub. L. 110–275, § 163(b)(1), inserted at end “With respect to MA private fee-for-service plans and MSA plans, the requirements under the preceding sentence may not exceed the requirements under this subparagraph with respect to MA local plans that are preferred provider organization plans, except that, for plan year 2010, the limitation under clause (ii) shall not apply and such requirements shall apply only with respect to administrative claims data.”

Subsec. (e)(3)(A)(ii). Pub. L. 110–275, § 163(b)(2), added (ii) and struck out former cl. (ii). Prior to amendment, text read as follows: “The Secretary shall establish as appropriate by regulation requirements for the collection, analysis, and reporting of data that permits the measurement of health outcomes and other indices of quality for MA organizations with respect to MA regional plans. Such requirements may not exceed the requirements under this subparagraph with respect to MA local plans that are preferred provider organization plans.”


Subsec. (a)(3)(C). Pub. L. 108–173, § 222(a)(3), inserted at end “Such benefits may include reductions in cost sharing below the actuarial value specified in section 1395w–24(e)(4)(B) of this title.”


Subsec. (b)(1)(A). Pub. L. 108–173, § 222(j)(1), inserted at end “The Secretary shall not approve a plan of an organiza-
zation if the Secretary determines that the design of the plan and its benefits are likely to substantially dis-
couragement enrollment by certain MA eligible individuals
who are enrolled with Medicare+Choice organizations.
Subsec. (c)(1)(I). Pub. L. 108–173, § 223(a)(2)(A), inserted “other than deemed contracts or agreements under subsection (j)(6) of this section) to provide covered services under the terms of the plan.”
Subsec. (d)(4). Pub. L. 108–173, § 221(j)(2), inserted “other than deemed contracts or agreements under subsection (j)(6) of this section” after “the plan has contracts or agreements”.
Subsec. (e)(1). Pub. L. 108–173, § 223(a)(2), reenacted heading without change and amended text generally. Prior to amendment, text read as follows: “Each Medicare+Choice organization must have arrangements, consistent with any regulation, for an ongoing quality assurance program for health care services it provides to individuals enrolled with Medicare+Choice plans (other than MSA plans) of the organization.”
Pub. L. 108–173, § 223(a)(1), inserted “other than MSA plans” after “plans”.
Subsec. (e)(3). Pub. L. 108–173, § 223(a)(2), amended par. (3) generally, substituting provisions relating to collection, analysis, and reporting of data for provisions relating to external review by an independent quality review and improvement organization.
Subsec. (e)(4)(B)(1). Pub. L. 108–173, § 223(a)(3)(A), amended cl. (i) generally. Prior to amendment, cl. (i) read as follows: “Paragraphs (1) and (2) of this subsection (relating to quality assurance programs).”
Subsec. (g)(5). Pub. L. 108–173, § 223(b)(2)(A), inserted at end “The provisions of section 1395w–22(a)(1)(B)(iii) of this title shall apply with respect to dollar amounts specified in the first 2 sentences of this paragraph in the same manner as they apply to the dollar amounts specified in section 1395w–22(a)(1)(B)(i) of this title.”
Subsec. (j)(4)(A)(i). Pub. L. 108–173, § 222(h)(2), substituted “the organization” for “the organization—”, struck out subcl. (1) designation before “provides”, sub-
stituted period for “and” at end of subcl. (1), and struck out subcl. (II), which read as follows: “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.”
Subsec. (j)(4)(A)(ii). Pub. L. 108–173, § 222(h)(3), struck out cl. (iii) which read as follows: “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.”
Subsec. (l)(1). Pub. L. 108–173, § 222(c), inserted “or with an organization offering an MSA plan” after “section 1395w–21(a)(2)(A)” of this title.”
Pub. L. 106–554, § 1(a)(6) [title VI, § 611(b)(4)], inserted “or legislative change in benefits” after “National coverage determinations” in heading and inserted “or legislative change in benefits required to be provided under this Act” after “there is a national coverage determination” in introductory provisions.
Subsec. (a)(5)(A). Pub. L. 106–554, § 1(a)(6) [title VI, § 611(b)(3)], inserted “or legislative change in benefits” after “such determination”.
Subsec. (b)(1). Pub. L. 106–554, § 1(a)(6) [title VI, § 616(b)], added par. (5).
Subsec. (g)(4). Pub. L. 106–554, § 1(a)(6) [title V, § 522(1)], inserted at end “The provisions of section 1395w–22 of this title shall apply to independent outside entities under contract with the Secretary under this paragraph.”
Subsec. (e)(2)(A). Pub. L. 106–113, § 1000(a)(6) [title V, § 520(a)(1)], substituted “a, non-network MSA plan, or a preferred provider organization plan” for “a non-network MSA plan” in introductory provisions.
Subsec. (e)(2)(B). Pub. L. 106–113, § 1000(a)(6) [title V, § 520(a)(2)], substituted “, non-network MSA plans, and preferred provider organization plans” for “, and non-network MSA plans” in heading and “, a non-network MSA plan, or a preferred provider organization plan” for “or a non-network MSA plan” in introductory provisions.
Subsec. (e)(5). Pub. L. 106–113, § 1000(a)(6) [title V, § 518], amended heading and text of par. (4) generally. Prior to amendment, text read as follows: “The Secretary shall provide that a Medicare+Choice organization is deemed to meet requirements of paragraphs (1) and (2) of this subsection and subsection (h) of this section (relating to confidentiality and accuracy of enrollee records) if the organization is accredited (and periodically reaccredited) by a private organization under a process that the Secretary has determined assures that the organization, as a condition of accreditation, applies and enforces standards with respect to the requirements involved that are no less stringent than the standards established under section 1395w–26 of this title to carry out the respective requirements.”

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. 106–173, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT


EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 125(b)(6) of Pub. L. 110–275 applicable with respect to accreditations of hospitals granted on or after the date that is 24 months after July 15, 2008, with transition rule, see section 256(d) of Pub. L. 110–275, set out as an Effective Date of 2008 Amendment; Transition Rule note under section 1385b of this title.


Pub. L. 110–275, title I, § 164(b)(2), July 15, 2008, 122 Stat. 2575, provided that: “The amendment made by paragraph (1) [amending this section] shall take effect on a date specified by the Secretary of Health and Human Services (but in no case later than January 1, 2010), and shall apply to all specialized Medicare Advantage plans for special needs individuals regardless of when the plan first entered the Medicare Advantage program under part C of title XVIII of the Social Security Act [this part].”

Pub. L. 110–275, title I, § 165(b), July 15, 2008, 122 Stat. 2575, provided that: “The amendment made by subsection (a) [amending this section] shall apply to plan years beginning on or after January 1, 2010.”

EFFECTIVE AND TERMINATION DATES OF 2003 AMENDMENT

Amendment by sections 221(d)(3) and 222(a)(2), (3), (h), (l)(1) of Pub. L. 106–173 applicable with respect to plan years beginning on or after Jan. 1, 2006, see section 222(a) of Pub. L. 106–173, set out as an Effective Date of 2003 Amendment note under section 1395w–21 of this title.


Amendment by section 948(b)(2) 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. 6601, as enacted by section 1(a)(6) of Public Law 106–554), see section 948(e) of Pub. L. 108–173, set out as an Effective Date of 2003 Amendment note under section 1314 of this title.

EFFECTIVE DATE OF 2000 AMENDMENT

Amendment by section 1(a)(6) [title V, § 521(b)] of Pub. L. 106–554 applicable with respect to initial determinations made on or after Oct. 1, 2002, see section 1(a)(6) [title V, § 521(d)] of Pub. L. 106–554, set out as a note under section 1320c–3 of this title.

Pub. L. 106–554, § 1(a)(6) [title VI, § 611(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–560, provided that: “The amendments made by this section [amending this section and section 1395w–23 of this title] are effective on the date of the enactment of this Act [Dec. 21, 2000], and shall apply to national coverage determinations and legislative changes in benefits occurring on or after such date.”

Pub. L. 106–554, § 1(a)(6) [title VI, § 621(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–565, provided that: “The amendment made by subsection (a) [amending this section] shall apply with respect to contracts entered into or renewed on or after the date of the enactment of this Act [Dec. 21, 2000].”

EFFECTIVE DATE OF 1999 AMENDMENT


(1) The amendments made by subsection (a) [amending this section] apply to contracts years beginning on or after January 1, 2000.

MIDPAC STUDY

Pub. L. 106–554, § 1(a)(6) [title VI, § 621(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–565, provided that:

“(1) STUDY.—The Medicare Payment Advisory Commission shall conduct a study analyzing the effects of the amendments made by subsection (a) [amending this section] on Medicare+Choice organizations. In conducting such study, the Commission shall examine the effects (if any) such amendment has had—

“(A) on the scope of additional benefits provided under the Medicare+Choice program;

“(B) on the administrative and other costs incurred by Medicare+Choice organizations; and

“(C) on the contractual relationships between such organizations and skilled nursing facilities.

“(2) REPORT.—Not later than 2 years 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).”

TRANSITIONAL PASS-THROUGH OF ADDITIONAL COSTS UNDER MEDICARE+CHOICE PROGRAM FOR 2000


“The provisions of subparagraphs (A) and (B) of section 1392(a)(5) of the Social Security Act (42 U.S.C. 1395w–22(a)(5)) shall apply with respect to the coverage of additional benefits for immunosuppressive drugs under the amendments made by this section [amending sections 1395k and 1395x of this title] for drugs furnished in 2000 in the same manner as if such amendments constituted a national coverage determination described in the matter in such section before subparagraph (A).”

§ 1395w–23. Payments to Medicare+Choice organizations

(a) Payments to organizations

(1) Monthly payments

(A) In general

Under a contract under section 1395w–27 of this title and subject to subsections (e), (g), (i), and (l) of this section and section 1395w–28(e)(4) of this title, the Secretary shall make monthly payments under this
section in advance to each Medicare+Choice organization, with respect to coverage of an individual under this part in a Medicare+Choice payment area for a month, in an amount determined as follows:

(i) Payment before 2006

For years before 2006, the payment amount shall be equal to 1/2 of the annual MA capitation rate (as calculated under subsection (c)(1) of this section) with respect to that individual for that area, adjusted under subparagraph (C) and reduced by the amount of any reduction elected under section 1395w–24(f)(1)(E) of this title.

(ii) Payment for original fee-for-service benefits beginning with 2006

For years beginning with 2006, the amount specified in subparagraph (B).

(B) Payment amount for original fee-for-service benefits beginning with 2006

(i) Payment of bid for plans with bids below benchmark

In the case of a plan for which there are average per capita monthly savings described in section 1395w–24(b)(3)(C) or 1395w–24(b)(4)(C) of this title, as the case may be, the amount specified in this subparagraph is equal to the unadjusted MA statutory non-drug monthly bid amount, adjusted under subparagraph (C) and (if applicable) under subparagraphs (F) and (G), plus the amount (if any) of any rebate under subparagraph (E).

(ii) Payment of benchmark for plans with bids at or above benchmark

In the case of a plan for which there are no average per capita monthly savings described in section 1395w–24(b)(3)(C) or 1395w–24(b)(4)(C) of this title, as the case may be, the amount specified in this subparagraph is equal to the MA area-specific non-drug monthly benchmark amount, adjusted under subparagraph (C) and (if applicable) under subparagraphs (F) and (G).

(iii) Payment of benchmark for MSA plans

Notwithstanding clauses (i) and (ii), in the case of an MSA plan, the amount specified in this subparagraph is equal to the MA area-specific non-drug monthly benchmark amount, adjusted under subparagraph (C).

(iv) Authority to apply frailty adjustment under PACE payment rules for certain specialized MA plans for special needs individuals

(I) In general

Notwithstanding the preceding provisions of this paragraph, for plan year 2011 and subsequent plan years, in the case of a plan described in subclause (II), the Secretary may apply the payment rules under section 1395w–24(g)(1) of this title (other than paragraph (3) of such section) rather than the payment rules that would otherwise apply under this part, but only to the extent necessary to reflect the costs of treating high concentrations of frail individuals.

(II) Plan described

A plan described in this subclause is a specialized MA plan for special needs individuals described in section 1395w–24(b)(6)(B)(ii) of this title that is fully integrated with capitated contracts with States for Medicaid benefits, including long-term care, and that have similar average levels of frailty (as determined by the Secretary) as the PACE program.

(C) Demographic adjustment, including adjustment for health status

(i) In general

The Secretary shall adjust the payment amount under subparagraph (A)(i) and the amount specified under subparagraph (B)(i), (B)(ii), and (B)(iii) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Secretary determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Secretary may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

(ii) Application of coding adjustment

For 2006 and each subsequent year:

(I) In applying the adjustment under clause (i) for health status to payment amounts, the Secretary shall ensure that such adjustment reflects changes in treatment and coding practices in the fee-for-service sector and reflects differences in coding patterns between Medicare Advantage plans and providers under part 1 of title 42 that are fully integrated with capitated contracts with States for Medicaid benefits, including long-term care, and that have similar average levels of frailty (as determined by the Secretary) as the PACE program.

(II) In order to ensure payment accuracy, the Secretary shall annually conduct an analysis of the differences described in subclause (I). The Secretary shall complete such analysis by a date necessary to ensure that the results of such analysis are incorporated on a timely basis into the risk scores for 2008 and subsequent years. In conducting such analysis, the Secretary shall use data submitted with respect to 2004 and subsequent years, as available and updated as appropriate.

(III) In calculating each year’s adjustment, the adjustment factor shall be for 2014, not less than the adjustment factor applied for 2010, plus 1.3 percentage points; for each of years 2015 through 2018, not less than the adjustment factor applied for the previous year, plus 0.25 percentage point; and for 2019 and each subsequent year, not less than 5.7 percentage points.

(IV) Such adjustment shall be applied to risk scores until the Secretary imple-
ments risk adjustment using Medicare Advantage diagnostic, cost, and use data.

(iii) Improvements to risk adjustment for special needs individuals with chronic health conditions

(I) In general

For 2011 and subsequent years, for purposes of the adjustment under clause (i) with respect to individuals described in subclause (II), the Secretary shall use a risk score that reflects the known underlying risk profile and chronic health status of similar individuals. Such risk score shall be used instead of the default risk score for new enrollees in Medicare Advantage plans that are not specialized MA plans for special needs individuals (as defined in section 1395w–28(b)(6) of this title).

(II) Individuals described

An individual described in this subclause is a special needs individual described in subsection (b)(6)(B)(iii) who enrolls in a specialized MA plan for special needs individuals on or after January 1, 2011.

(III) Evaluation

For 2011 and periodically thereafter, the Secretary shall evaluate and revise the risk adjustment system under this subparagraph in order to, as accurately as possible, account for higher medical and care coordination costs associated with frailty, individuals with multiple, comorbid chronic conditions, and individuals with a diagnosis of mental illness, and also to account for costs that may be associated with higher concentrations of beneficiaries with those conditions.

(IV) Publication of evaluation and revisions

The Secretary shall publish, as part of an announcement under subsection (b), a description of any evaluation conducted under subclause (III) during the preceding year and any revisions made under such subclause as a result of such evaluation.

(D) Separate payment for Federal drug subsidies

In the case of an enrollee in an MA–PD plan, the MA organization offering such plan also receives—

(i) subsidies under section 1395w–115 of this title (other than under subsection (g)); and

(ii) reimbursement for premium and cost-sharing reductions for low-income individuals under section 1395w–114(c)(1)(C) of this title.

(E) Payment of rebate for plans with bids below benchmark

In the case of a plan for which there are average per capita monthly savings de-

scribed in section 1395w–24(b)(3)(C) or 1395w–24(b)(4)(C) of this title, as the case may be, the amount specified in this subparagraph is the amount of the monthly rebate computed under section 1395w–24(b)(1)(C)(i) of this title for that plan and year (as reduced by the amount of any credit provided under section 1395w–24(b)(1)(C)(iv) of this title).

(F) Adjustment for intra-area variations

(i) Intra-regional variations

In the case of payment with respect to an MA regional plan for an MA region, the Secretary shall also adjust the amounts specified under subparagraphs (B)(i) and (B)(ii) in a manner to take into account variations in MA local payment rates under this part among the different MA local areas included in such region.

(ii) Intra-service area variations

In the case of payment with respect to an MA local plan for a service area that covers more than one MA local area, the Secretary shall also adjust the amounts specified under subparagraphs (B)(i) and (B)(ii) in a manner to take into account variations in MA local payment rates under this part among the different MA local areas included in such service area.

(G) Adjustment relating to risk adjustment

The Secretary shall adjust payments with respect to MA plans as necessary to ensure that—

(i) the sum of—

(I) the monthly payment made under subparagraph (A)(ii); and

(II) the MA monthly basic beneficiary premium under section 1395w–24(b)(2)(A) of this title; equals

(ii) the unadjusted MA statutory non-drug monthly bid amount, adjusted in the manner described in subparagraph (C) and, for an MA regional plan, subparagraph (F).

(H) Special rule for end-stage renal disease

The Secretary shall establish separate rates of payment to a Medicare+Choice organization with respect to classes of individuals determined to have end-stage renal disease and enrolled in a Medicare+Choice plan of the organization. Such rates of payment shall be actuarially equivalent to rates that would have been paid with respect to other enrollees in the MA payment area (or such other area as specified by the Secretary) under the provisions of this section as in effect before December 8, 2003. In accordance with regulations, the Secretary shall provide for the application of the seventh sentence of section 1395rr(b)(7) of this title to payments under this section covering the provision of renal dialysis treatment in the same manner as such sentence applies to composite rate payments described in such sentence. In establishing such rates, the Secretary shall provide for appropriate adjustments to increase each rate to reflect the demonstration rate (including the risk adjustment methodology associated with such
rate) of the social health maintenance organization end-stage renal disease capitation demonstrations (established by section 2355 of the Deficit Reduction Act of 1984, as amended by section 13367(b) of the Omnibus Budget Reconciliation Act of 1993), and shall compute such rates by taking into account such factors as renal treatment modality, age, and the underlying cause of the end-stage renal disease. The Secretary may apply the competitive bidding methodology provided for in this section, with appropriate adjustments to account for the risk adjustment methodology applied to end stage renal disease payments.

(2) Adjustment to reflect number of enrollees

(A) In general

The amount of payment under this subsection may be retroactively adjusted to take into account any difference between the actual number of individuals enrolled with an organization under this part and the number of such individuals estimated to be so enrolled in determining the amount of the advance payment.

(B) Special rule for certain enrollees

(i) In general

Subject to clause (ii), the Secretary may make retroactive adjustments under subparagraph (A) to take into account individuals enrolled during the period beginning on the date on which the individual enrolls with a Medicare+Choice organization under a 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 organization under this part, except that for purposes of making such retroactive adjustments under this subparagraph, such period may not exceed 90 days.

(ii) Exception

No adjustment may be made under clause (i) with respect to any individual who does not certify that the organization provided the individual with the disclosure statement described in section 1395w–22(c) of this title at the time the individual enrolled with the organization.

(3) Establishment of risk adjustment factors

(A) Report

The Secretary shall develop, and submit to Congress by not later than March 1, 1999, a report on the method of risk adjustment of payment rates under this section, to be implemented under subparagraph (C), that accounts for variations in per capita costs based on health status. Such report shall include an evaluation of such method by an outside, independent actuary of the actuarial soundness of the proposal.

(B) Data collection

In order to carry out this paragraph, the Secretary shall require Medicare+Choice organizations (and eligible organizations with risk-sharing contracts under section 1395mm of this title) to submit data regarding inpatient hospital services for periods beginning on or after July 1, 1997, and data regarding other services and other information as the Secretary deems necessary for periods beginning on or after July 1, 1998. The Secretary may not require an organization to submit such data before January 1, 1998.

(C) Initial implementation

(i) In general

The Secretary shall first provide for implementation of a risk adjustment methodology that accounts for variations in per capita costs based on health status and other demographic factors for payments by no later than January 1, 2000.

(ii) Phase-in

Except as provided in clause (iv), such risk adjustment methodology shall be implemented in a phased-in manner so that the methodology insofar as it makes adjustments to capitation rates for health status applies to—

(I) 10 percent of the annual Medicare+Choice capitation rate in 2000 and each succeeding year through 2003;

(II) 50 percent of such capitation rate in 2004;

(III) 50 percent of such capitation rate in 2005;

(IV) 75 percent of such capitation rate in 2006; and

(V) 100 percent of such capitation rate in 2007 and succeeding years.

(iii) Data for risk adjustment methodology

Such risk adjustment methodology for 2004 and each succeeding year, shall be based on data from inpatient hospital and ambulatory settings.

(iv) Full implementation of risk adjustment for congestive heart failure enrollees for 2001

(I) Exemption from phase-in

Subject to subclause (II), the Secretary shall fully implement the risk adjustment methodology described in clause (i) with respect to each individual who has had a qualifying congestive heart failure inpatient diagnosis (as determined by the Secretary under such risk adjustment methodology) during the period beginning on July 1, 1999, and ending on June 30, 2000, and who is enrolled in a coordinated care plan that is the only coordinated care plan offered on January 1, 2001, in the service area of the individual.

(II) Period of application

Subclause (I) shall only apply during the 1-year period beginning on January 1, 2001.
(4) Payment rule for federally qualified health center services

If an individual who is enrolled with an MA plan under this part receives a service from a federally qualified health center that has a written agreement with the MA organization that offers such plan for providing such a service (including any agreement required under section 1395w–27(e)(3) of this title)—

(A) the Secretary shall pay the amount determined under section 1395l(a)(3)(B) of this title directly to the federally qualified health center not less frequently than quarterly; and

(B) the Secretary shall not reduce the amount of the monthly payments under this subsection as a result of the application of subparagraph (A).

(b) Annual announcement of payment rates

(1) Annual announcements

(A) For 2005

The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), not later than the second Monday in May of 2004, with respect to each MA payment area, the following:

(i) MA capitation rates

The annual MA capitation rate for each MA payment area for 2005.

(ii) Adjustment factors

The risk and other factors to be used in adjusting such rates under subsection (a)(1)(C) of this section for payments for months in 2005.

(B) For 2006 and subsequent years

For a year after 2005—

(i) Initial announcement

The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), not later than the first Monday in April before the calendar year concerned, with respect to each MA payment area, the following:

(I) MA capitation rates; MA local area benchmark

The annual MA capitation rate for each MA payment area for the year.

(II) Adjustment factors

The risk and other factors to be used in adjusting such rates under subsection (a)(1)(C) of this section for payments for months in such year.

(ii) Regional benchmark announcement

The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), on a timely basis before the calendar year concerned, with respect to each MA region and each MA regional plan for which a bid was submitted under section 1395w–24 of this title, the MA region-specific non-drug monthly benchmark amount for that region for the year involved.

(iii) Benchmark announcement for CCA local areas

The Secretary shall determine, and shall announce (in a manner intended to provide notice to interested parties), on a timely basis before the calendar year concerned, with respect to each CCA area (as defined in section 1395w–29(b)(1)(A) of this title), the CCA non-drug monthly benchmark amount under section 1395w–29(e)(1) of this title for that area for the year involved.

(2) Advance notice of methodological changes

At least 45 days before making the announcement under paragraph (1) for a year, the Secretary shall provide for notice to Medicare+Choice organizations of proposed changes to be made in the methodology from the methodology and assumptions used in the previous announcement and shall provide such organizations an opportunity to comment on such proposed changes.

(3) Explanation of assumptions

In each announcement made under paragraph (1), the Secretary shall include an explanation of the assumptions and changes in methodology used in such announcement.

(4) Continued computation and publication of county-specific per capita fee-for-service expenditure information

The Secretary, through the Chief Actuary of the Centers for Medicare & Medicaid Services, shall provide for the computation and publication, on an annual basis beginning with 2001 at the time of publication of the annual Medicare+Choice capitation rates under paragraph (1), of the following information for the original medicare fee-for-service program under parts A and B of this subchapter (exclusive of individuals eligible for coverage under section 426–1 of this title) for each Medicare+Choice payment area for the second calendar year ending before the date of publication:

(A) Total expenditures per capita per month, computed separately for part A of this subchapter and for part B of this subchapter.

(B) The expenditures described in subparagraph (A) reduced by the best estimate of the expenditures (such as graduate medical education and disproportionate share hospital payments) not related to the payment of claims.

(C) The average risk factor for the covered population based on diagnoses reported for medicare inpatient services, using the same methodology as is expected to be applied in making payments under subsection (a) of this section.

(D) Such average risk factor based on diagnoses for inpatient and other sites of service, using the same methodology as is expected to be applied in making payments under subsection (a) of this section.

(c) Calculation of annual Medicare+Choice capitation rates

(1) In general

For purposes of this part, subject to paragraphs (6)(C) and (7), each annual
Medicare+Choice capitation rate, for a Medicare+Choice payment area that is an MA local area for a contract year consisting of a calendar year, is equal to the largest of the amounts specified in the following sub-paragraphs (A), (B), (C), or (D):

(A) **Blended capitation rate**

For a year before 2005, the sum of—

(i) the area-specific percentage (as specified under paragraph (2) for the year) of the annual area-specific Medicare+Choice capitation rate for the Medicare+Choice payment area, as determined under paragraph (3) for the year, and

(ii) the national percentage (as specified under paragraph (2) for the year) of the input-price-adjusted annual national Medicare+Choice capitation rate, as determined under paragraph (4) for the year, multiplied (for a year other than 2004) by the budget neutrality adjustment factor determined under paragraph (5).

(B) **Minimum amount**

12 multiplied by the following amount:

(i) For 1998, $367 (but not to exceed, in the case of an area outside the 50 States and the District of Columbia, 150 percent of the annual per capita rate of payment for 1997 determined under section 1395mm(a)(1)(C) of this title for the area).

(ii) For 1999 and 2000, the minimum amount determined under clause (i) or this clause, respectively, for the preceding year, increased by the national per capita Medicare+Choice growth percentage described in paragraph (6)(A) applicable to 1999 or 2000, respectively.

(iii) Subject to subclause (II), for 2001, for any area in a Metropolitan Statistical Area with a population of more than 250,000, $525, and for any other area $475.

(II) In the case of an area outside the 50 States and the District of Columbia, the amount specified in this clause shall not exceed 120 percent of the amount determined under clause (ii) for such area for 2000.

(iv) For 2002, 2003, and 2004, the minimum amount specified in this clause or clause (iii) for the preceding year increased by the national per capita Medicare+Choice growth percentage, described in paragraph (6)(A) for that succeeding year.

(C) **Minimum percentage increase**

(i) For 1998, 102 percent of the annual per capita rate of payment for 1997 determined under section 1395mm(a)(1)(C) of this title for the Medicare+Choice payment area.

(ii) For 1999 and 2000, 102 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for the previous year.

(iii) For 2001, 103 percent of the annual Medicare+Choice capitation rate under this paragraph for the area.

(iv) For 2002 and 2003, 102 percent of the annual Medicare+Choice capitation rate under this paragraph for the area for the previous year.

(v) For 2004 and each succeeding year, the greater of—

(I) 102 percent of the annual MA capitation rate under this paragraph for the area for the previous year; or

(II) the annual MA capitation rate under this paragraph for the area for the previous year increased by the national per capita MA growth percentage, described in paragraph (6) for that succeeding year, but not taking into account any adjustment under paragraph (6)(C) for a year before 2004.

(D) **100 percent of fee-for-service costs**

(i) **In general**

For each year specified in clause (ii), the adjusted average per capita cost for the year involved, determined under section 1395mm(a)(4) of this title and adjusted as appropriate for the purpose of risk adjustment, for the MA payment area for individuals who are not enrolled in an MA plan under this part for the year, but adjusted to exclude costs attributable to payments under sections 1395w–2(a), 1395w–4(o), and 1395ww(n) of this title.

(ii) **Periodic rebasing**

The provisions of clause (i) shall apply for 2004 and for subsequent years as the Secretary shall specify (but not less than once every 3 years).

(iii) **Inclusion of costs of VA and DOD military facility services to medicare-eligible beneficiaries**

In determining the adjusted average per capita cost under clause (i) for a year, such cost shall be adjusted to include the Secretary’s estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this subchapter if individuals entitled to benefits under this subchapter had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.

(2) **Area-specific and national percentages**

For purposes of paragraph (1)(A)—

(A) for 1998, the “area-specific percentage” is 50 percent and the “national percentage” is 10 percent,

(B) for 1999, the “area-specific percentage” is 72 percent and the “national percentage” is 18 percent,

(C) for 2000, the “area-specific percentage” is 74 percent and the “national percentage” is 26 percent,

(D) for 2001, the “area-specific percentage” is 66 percent and the “national percentage” is 34 percent,

(E) for 2002, the “area-specific percentage” is 58 percent and the “national percentage” is 42 percent, and

(F) for a year after 2002, the “area-specific percentage” is 50 percent and the “national percentage” is 50 percent.

*So in original.*
(3) Annual area-specific Medicare+Choice capitation rate

(A) In general

For purposes of paragraph (1)(A), subject to subparagraphs (B) and (E), the annual area-specific Medicare+Choice capitation rate for a Medicare+Choice payment area—

(i) for 1998 is, subject to subparagraph (D), the annual per capita rate of payment for 1997 determined under section 1395mm(a)(1)(C) of this title for the area, increased by the national per capita Medicare+Choice growth percentage for 1998 (described in paragraph (6)(A)); or

(ii) for a subsequent year is the annual area-specific Medicare+Choice capitation rate for the previous year determined under this paragraph for the area, increased by the national per capita Medicare+Choice growth percentage for such subsequent year.

(B) Removal of medical education from calculation of adjusted average per capita cost

(i) In general

In determining the area-specific Medicare+Choice capitation rate under subparagraph (A) for a year (beginning with 1998), the annual per capita rate of payment for 1997 determined under section 1395mm(a)(1)(C) of this title shall be adjusted to exclude from the rate the applicable percent (specified in clause (ii)) of the payment adjustments described in subparagraph (C).

(ii) Applicable percent

For purposes of clause (i), the applicable percent for—

(I) 1999 is 20 percent,

(II) 1998 is 40 percent,

(III) 2000 is 60 percent,

(IV) 2001 is 80 percent, and

(V) a succeeding year is 100 percent.

(C) Payment adjustment

(i) In general

Subject to clause (ii), the payment adjustments described in this subparagraph are payment adjustments which the Secretary estimates were payable during 1997—

(I) for the indirect costs of medical education under section 1395ww(d)(5)(B) of this title, and

(II) for direct graduate medical education costs under section 1395ww(h) of this title.

(ii) Treatment of payments covered under State hospital reimbursement system

To the extent that the Secretary estimates that an annual per capita rate of payment for 1997 described in clause (i) reflects payments to hospitals reimbursed under section 1395f(b)(3) of this title, the Secretary shall estimate a payment adjustment that is comparable to the payment adjustment that would have been made under clause (i) if the hospitals had not been reimbursed under such section.

(D) Treatment of areas with highly variable payment rates

In the case of a Medicare+Choice payment area for which the annual per capita rate of payment determined under section 1395mm(a)(1)(C) of this title for 1997 varies by more than 20 percent from such rate for 1996, for purposes of this subsection the Secretary may substitute for such rate for 1997 a rate that is more representative of the costs of the enrollees in the area.

(E) Inclusion of costs of DOD and VA military facility services to Medicare-eligible beneficiaries

In determining the area-specific MA capitation rate under subparagraph (A) for a year (beginning with 2004), the annual per capita rate of payment for 1997 determined under section 1395mm(a)(1)(C) of this title shall be adjusted to include in the rate the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this subchapter if individuals entitled to benefits under this subchapter had not received services from facilities of the Department of Defense or the Department of Veterans Affairs.

(4) Input-price-adjusted annual national Medicare+Choice capitation rate

(A) In general

For purposes of paragraph (1)(A), the input-price-adjusted annual national Medicare+Choice capitation rate for a Medicare+Choice payment area for a year is equal to the sum, for all the types of Medicare services (as classified by the Secretary), of the product (for each such type of service) of—

(i) the national standardized annual Medicare+Choice capitation rate (determined under subparagraph (B)) for the year,

(ii) the proportion of such rate for the year which is attributable to such type of services, and

(iii) an index that reflects (for that year and that type of services) the relative input price of such services in the area compared to the national average input price of such services.

In applying clause (iii), the Secretary may, subject to subparagraph (C), apply those indices under this subchapter that are used in applying (or updating) national payment rates for specific areas and localities.

(B) National standardized annual Medicare+Choice capitation rate

In subparagraph (A)(i), the “national standardized annual Medicare+Choice capitation rate” for a year is equal to—

(I) the sum (for all Medicare+Choice payment areas) of the product of—

(a) the annual area-specific Medicare+Choice capitation rate for that year for the area under paragraph (3), and

(b) the average number of Medicare beneficiaries residing in that area in the
year, multiplied by the average of the risk factor weights used to adjust payments under subsection (a)(1)(A) of this section for such beneficiaries in such area; divided by

(ii) the sum of the products described in clause (i)(II) for all areas for that year.

(C) Special rules for 1998

In applying this paragraph for 1998—

(I) Medicare+Choice services shall be divided into 2 types of services: part A services and part B services;

(ii) the proportions described in subparagraph (A)(i) are

(I) for part A services shall be the ratio (expressed as a percentage) of the national average annual per capita rate of payment for part A of this subchapter for 1997 to the total national average annual per capita rate of payment for parts A and B of this subchapter for 1997, and

(ii) for part B services shall be 100 percent minus the ratio described in subclause (I);

(iii) for part A services, 70 percent of payments attributable to such services shall be adjusted by the index used under section 1395w(d)(3)(E) of this title to adjust payment rates for relative hospital wage levels for hospitals located in the payment area involved;

(iv) for part B services—

(I) 66 percent of payments attributable to such services shall be adjusted by the index of the geographic area factors under section 1395w–4(e) of this title to adjust payment rates for physicians’ services furnished in the payment area,

and

(II) of the remaining 34 percent of the amount of such payments, 40 percent shall be adjusted by the index described in clause (iii); and

(v) the index values shall be computed based only on the beneficiary population who are 65 years of age or older and who are not determined to have end-stage renal disease.

The Secretary may continue to apply the rules described in this subparagraph (or similar rules) for 1999.

(5) Payment adjustment budget neutrality factor

For purposes of paragraph (1)(A), for each year (other than 2004), the Secretary shall determine a budget neutrality adjustment factor so that the aggregate of the payments under this part (other than those attributable to subsections (a)(3)(C)(iv), (a)(4), and (i) of this section) shall equal the aggregate payments that would have been made under this part if payment were based entirely on area-specific capitation rates.

(6) “National per capita Medicare+Choice growth percentage” defined

(A) In general

In this part, the “national per capita Medicare+Choice growth percentage” for a year is the percentage determined by the Secretary, by March 1st before the beginning of the year involved, to reflect the Secretary’s estimate of the projected per capita rate of growth in expenditures under this subchapter for an individual entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter, excluding expenditures attributable to subsections (a)(7) and (o) of section 1395w–4 of this title and subsections (b)(3)(B)(ix) and (n) of section 1395ww of this title, reduced by the number of percentage points specified in subparagraph (B) for the year. Separate determinations may be made for aged enrollees, disabled enrollees, and enrollees with end-stage renal disease.

(B) Adjustment

The number of percentage points specified in this subparagraph is—

(i) for 1998, 0.8 percentage points,

(ii) for 1999, 0.5 percentage points,

(iii) for 2000, 0.5 percentage points,

(iv) for 2001, 0.5 percentage points,

(v) for 2002, 0.3 percentage points, and

(vi) for a year after 2002, 0 percentage points.

(C) Adjustment for over or under projection of national per capita Medicare+Choice growth percentage

Beginning with rates calculated for 1999, before computing rates for a year as described in paragraph (1), the Secretary shall adjust all area-specific and national Medicare+Choice capitation rates (and beginning in 2000, the minimum amount) for the previous year for the differences between the projections of the national per capita Medicare+Choice growth percentage for that year and previous years and the current estimate of such percentage for such years, except that for purposes of paragraph (1)(C)(v)(II), no such adjustment shall be made for a year before 2004.

(7) Adjustment for national coverage determinations and legislative changes in benefits

If the Secretary makes a determination with respect to coverage under this subchapter and there is a change in benefits required to be provided under this part that the Secretary projects will result in a significant increase in the costs to Medicare+Choice of providing benefits under contracts under this part (for periods after any period described in section 1395w–22(a)(5) of this title), the Secretary shall adjust appropriately the payments to such organizations under this part. Such projection and adjustment shall be based on an analysis by the Chief Actuary of the Centers for Medicare & Medicaid Services of the actuarial costs associated with the new benefits.

d) MA payment area; MA local area; MA region defined

(1) MA payment area

In this part, except as provided in this subsection, the term “MA payment area” means—

A) with respect to an MA local plan, an MA local area (as defined in paragraph (2)); and
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(B) with respect to an MA regional plan, an MA region (as established under section 1395w–27(a)(2) of this title).

(2) MA local area

The term “MA local area” means a county or equivalent area specified by the Secretary.

(3) Rule for ESRD beneficiaries

In the case of individuals who are determined to have end stage renal disease, the Medicare+Choice payment area shall be a State or such other payment area as the Secretary specifies.

(4) Geographic adjustment

(A) In general

Upon written request of the chief executive officer of a State for a contract year (beginning after 1998) made by not later than February 1 of the previous year, the Secretary shall make a geographic adjustment to a Medicare+Choice payment area in the State otherwise determined under paragraph (1) for MA local plans—

(i) to a single statewide Medicare+Choice payment area,

(ii) to the metropolitan based system described in subparagraph (C), or

(iii) to consolidating into a single Medicare+Choice payment area noncontiguous counties (or equivalent areas described in paragraph (1)(A)) within a State. Such adjustment shall be effective for payments for months beginning with January of the year following the year in which the request is received.

(B) Budget neutrality adjustment

In the case of a State requesting an adjustment under this paragraph, the Secretary shall initially (and annually thereafter) adjust the payment rates otherwise established under this section with respect to MA local plans for Medicare+Choice payment areas in the State in a manner so that the aggregate payments that would have been made under this section for such plans in the State shall not exceed the aggregate payments that would have been made under this section for Medicare+Choice payment areas in the State in the absence of the adjustment under this paragraph.

(C) Metropolitan based system

The metropolitan based system described in this subparagraph is one in which—

(i) all the portions of each metropolitan statistical area in the State or in the case of a consolidated metropolitan statistical area, all of the portions of each primary metropolitan statistical area within the consolidated area within the State, are treated as a single Medicare+Choice payment area, and

(ii) all areas in the State that do not fall within a metropolitan statistical area are treated as a single Medicare+Choice payment area.

(D) Areas

In subparagraph (C), the terms “metropolitan statistical area”, “primary metropolitan statistical area”, and “primary metropolitan statistical area” mean any area designated as such by the Secretary of Commerce.

(e) Special rules for individuals electing MSA plans

(1) In general

If the amount of the Medicare+Choice monthly MSA premium (as defined in section 1395w–23(b)(2)(C) of this title) for an MSA plan for a year is less than $12 of the annual Medicare+Choice capitation rate applied under this section for the area and year involved, the Secretary shall deposit an amount equal to 100 percent of such difference in a Medicare+Choice MSA established (and, if applicable, designated) by the individual under paragraph (2).

(2) Establishment and designation of Medicare+Choice medical savings account as requirement for payment of contribution

In the case of an individual who has elected coverage under an MSA plan, no payment shall be made under paragraph (1) on behalf of an individual for a month unless the individual—

(A) has established before the beginning of the month (or by such other deadline as the Secretary may specify) a Medicare+Choice MSA (as defined in section 139(b)(2) of the Internal Revenue Code of 1986), and

(B) if the individual has established more than one such Medicare+Choice MSA, has designated one of such accounts as the individual’s Medicare+Choice MSA for purposes of this part.

Under rules under this section, such an individual may change the designation of such account under subparagraph (B) for purposes of this part.

(3) Lump-sum deposit of medical savings account contribution

In the case of an individual electing an MSA plan effective beginning with a month in a year, the amount of the contribution to the Medicare+Choice MSA on behalf of the individual for that month and all successive months in the year shall be deposited during that first month. In the case of a termination of such an election as of a month before the end of a year, the Secretary shall provide for a procedure for the recovery of deposits attributable to the remaining months in the year.

(f) Payments from Trust Funds

The payment to a Medicare+Choice organization under this section for individuals enrolled under this part with the organization and for payments under subsection (l) and subsection (m) and payments to a Medicare+Choice MSA under subsection (e)(1) of this section shall be made from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in such proportion as the Secretary determines reflects the relative weight that benefits under part A of this subchapter and under part B of this subchapter represent of the actuarial value of the total bene-
fits under this subchapter. Payments to MA organizations for statutory drug benefits provided under this subchapter are made from the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund. Monthly payments otherwise payable under this section for October 2000 shall be paid on the first business day of such month. Monthly payments otherwise payable under this section for October 2001 shall be paid on the last business day of September 2001. Monthly payments otherwise payable under this section for October 2006 shall be paid on the first business day of October 2006.

(g) Special rule for certain inpatient hospital stays

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), a rehabilitation hospital described in section 1395ww(d)(1)(B) of this title, or a long-term care hospital (described in section 1395ww(d)(1)(B)(iv) of this title) as of the effective date of the individual’s—

(1) election under this part of a Medicare+Choice plan offered by a Medicare+Choice organization—

(A) payment for such services until the date of the individual’s discharge shall be made under this subchapter through the Medicare+Choice plan or the original medical fee-for-service program option described in section 1395w–21(a)(1)(A) of this title (as the case may be) elected before the election with such organization.

(B) the elected organization shall not be financially responsible for payment for such services until the date after the date of the individual’s discharge, and

(C) the organization shall nonetheless be paid the full amount otherwise payable to the organization under this part; or

(2) termination of election with respect to a Medicare+Choice organization under this part—

(A) the organization shall be financially responsible for payment for such services after such date and until the date of the individual’s discharge,

(B) payment for such services during the stay shall not be made under section 1395ww(d) of this title or other payment provision under this subchapter for inpatient services for the type of facility, hospital, or unit involved, described in the matter preceding paragraph (1), as the case may be, or by any succeeding Medicare+Choice organization, and

(C) the terminated organization shall not receive any payment with respect to the individual under this part during the period the individual is not enrolled.

(h) Special rule for hospice care

(1) Information

A contract under this part shall require the Medicare+Choice organization to inform each individual enrolled under this part with a Medicare+Choice plan offered by the organization about the availability of hospice care if—

(A) a hospice program participating under this subchapter is located within the organization’s service area; or

(B) it is common practice to refer patients to hospice programs outside such service area.

(2) Payment

If an individual who is enrolled with a Medicare+Choice organization under this part makes an election under section 1395d(d)(1) of this title to receive hospice care from a particular hospice program—

(A) payment for the hospice care furnished to the individual shall be made to the hospice program elected by the individual by the Secretary;

(B) payment for other services for which the individual is eligible notwithstanding the individual’s election of hospice care under section 1395d(d)(1) of this title, including services not related to the individual’s terminal illness, shall be made by the Secretary to the Medicare+Choice organization or the provider or supplier of the service instead of payments calculated under subsection (a) of this section; and

(C) the Secretary shall continue to make monthly payments to the Medicare+Choice organization in an amount equal to the value of the additional benefits required under section 1395w–24(f)(1)(A) of this title.

(i) New entry bonus

(1) In general

Subject to paragraphs (2) and (3), in the case of Medicare+Choice payment area in which a Medicare+Choice plan has not been offered since 1997 (or in which all organizations that offered a plan since such date have filed notice with the Secretary, as of October 13, 1999, that they will not be offering such a plan as of January 1, 2000, or filed notice with the Secretary as of October 3, 2000, that they will not be offering such a plan as of January 1, 2001), the amount of the monthly payment otherwise made under this section shall be increased—

(A) only for the first 12 months in which any Medicare+Choice plan is offered in the area, by 5 percent of the total monthly payment otherwise computed for such payment area; and

(B) only for the subsequent 12 months, by 3 percent of the total monthly payment otherwise computed for such payment area.

(2) Period of application

Paragraph (1) shall only apply to payment for Medicare+Choice plans which are first offered in a Medicare+Choice payment area during the 2-year period beginning on January 1, 2000.

(3) Limitation to organization offering first plan in an area

Paragraph (1) shall only apply to payment to the first Medicare+Choice organization that offers a Medicare+Choice plan in each Medicare+Choice payment area, except that if more than one such organization first offers
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such a plan in an area on the same date, paragraph (1) shall apply to payment for such organizations.

(4) Construction

Nothing in paragraph (1) shall be construed as affecting the calculation of the annual Medicare+Choice capitation rate under subsection (c) of this section for any payment area or as applying to payment for any period not described in such paragraph and paragraph (2).

(5) Offered defined

In this subsection, the term “offered” means, with respect to a Medicare+Choice plan as of a date, that a Medicare+Choice eligible individual may enroll with the plan on that date, regardless of when the enrollment takes effect or when the individual obtains benefits under the plan.

(j) Computation of benchmark amounts

For purposes of this part, subject to subsection (o), the term “MA area-specific non-drug monthly benchmark amount” means for a month in a year—

(1) with respect to—

(A) a service area that is entirely within an MA local area, subject to section 1395w–29(d)(2)(A) [1] of this title, an amount equal to 1/12 of the annual MA capitation rate under subsection (c)(1)(D) for the area for the year (or, for 2007, 2008, 2009, and 2010, 1/3 of the applicable amount determined under subsection (k)(1) for the area for the year; for 2011, 1/12 of the applicable amount determined under subsection (k)(1) for the area for the year; and, beginning with 2012, 1/12 of the blended benchmark amount determined under subsection (n)(1) for the area for the year), adjusted as appropriate (for years before 2007) for the purpose of risk adjustment; or

(B) a service area that includes more than one MA local area, an amount equal to the average of the amounts described in subparagraph (A) for each such local MA area, weighted by the projected number of enrollees in the plan residing in the respective local MA areas (as used by the plan for purposes of the bid and disclosed to the Secretary under section 1395w–24(a)(6)(A)(iii) of this title), adjusted as appropriate (for years before 2007) for the purpose of risk adjustment; or

(2) with respect to an MA region for a month in a year, the MA region-specific non-drug monthly benchmark amount, as defined in section 1395w–27a(i) of this title for the region for the year.

(k) Determination of applicable amount for purposes of calculating the benchmark amounts

(1) Applicable amount defined

For purposes of subsection (j), subject to paragraphs (2) and (4), the term “applicable amount” means for an area—

(A) for 2007—

(i) if such year is not specified under subsection (c)(1)(D)(ii), an amount equal to the amount specified in subsection (c)(1)(C) for the area for 2006—

(I) first adjusted by the rescaling factor for 2006 for the area (as made available by the Secretary in the announcement of the rates on April 4, 2005, under subsection (b)(1), but excluding any national adjustment factors for coding intensity and risk adjustment budget neutrality that were included in such factor); and

(II) then increased by the national per capita MA growth percentage, described in subsection (c)(6) for 2007, but not taking into account any adjustment under subparagraph (C) of such subsection for a year before 2004;

(ii) if such year is specified under subsection (c)(1)(D)(ii), an amount equal to the greater of—

(I) the amount determined under clause (i) for the area for the year; or

(II) the amount specified in subsection (c)(1)(D) for the area for the year;

and

(B) for a subsequent year—

(i) if such year is not specified under subsection (c)(1)(D)(ii), an amount equal to the amount determined under this paragraph for the area for the previous year (determined without regard to paragraphs (2) and (4)), increased by the national per capita MA growth percentage, described in subsection (c)(6) for that succeeding year, but not taking into account any adjustment under subparagraph (C) of such subsection for a year before 2004; and

(ii) if such year is specified under subsection (c)(1)(D)(ii), an amount equal to the greater of—

(I) the amount determined under clause (i) for the area for the year; or

(II) the amount specified in subsection (c)(1)(D) for the area for the year.

(2) Phase-out of budget neutrality factor

(A) In general

Except as provided in subparagraph (D), in the case of 2007 through 2010, the applicable amount determined under paragraph (1) shall be multiplied by a factor equal to 1 plus the product of—

(i) the percent determined under subparagraph (B) for the year; and

(ii) the applicable phase-out factor for the year under subparagraph (C).

(B) Percent determined

(i) In general

For purposes of subparagraph (A)(i), subject to clause (iv), the percent determined under this subparagraph for a year is a percent equal to a fraction the numerator of which is described in clause (ii) and the denominator of which is described in clause (iii).

(ii) Numerator based on difference between demographic rate and risk rate

(I) In general

The numerator described in this clause is an amount equal to the amount by which the demographic rate described in
The term “applicable phase-out factor” means—

(C) Applicable phase-out factor

For purposes of subparagraph (A)(ii), the term “applicable phase-out factor” means—

(i) for 2007, 0.55;

(ii) for 2008, 0.40;

(iii) for 2009, 0.25; and

(iv) for 2010, 0.05.

(D) Termination of application

Subparagraph (A) shall not apply in a year if the amount estimated under subparagraph (B)(ii)(III) for the year is equal to or greater than the amount estimated under subparagraph (B)(ii)(II) for the year.

(3) No revision in percent

(A) In general

The Secretary may not make any adjustment to the percent determined under paragraph (2)(B) for any year.

(B) Rule of construction

Nothing in this subsection shall be construed to limit the authority of the Secretary to make adjustments to the applicable amounts determined under paragraph (1) as appropriate for purposes of updating data or for purposes of adopting an improved risk adjustment methodology.

(4) Phase-out of the indirect costs of medical education from capitation rates

(A) In general

After determining the applicable amount for an area for a year under paragraph (1) (beginning with 2010), the Secretary shall adjust such applicable amount to exclude from such applicable amount the phase-in percentage (as defined in subparagraph (B)(i)) for the year of the Secretary’s estimate of the standardized costs for payments under section 1395ww(d)(5)(B) of this title in the area for the year. Any adjustment under the preceding sentence shall be made prior to the application of paragraph (2).

(B) Percentages defined

For purposes of this paragraph:

(i) Phase-in percentage

The term “phase-in percentage” means, for an area for a year, the ratio (expressed as a percentage, but in no case greater than 100 percent) of—

(I) the maximum cumulative adjustment percentage for the year (as defined in clause (ii)); to

(II) the standardized IME cost percentage (as defined in clause (iii)) for the area and year.

(ii) Maximum cumulative adjustment percentage

The term “maximum cumulative adjustment percentage” means, for—

(I) 2010, 0.60 percent; and

(II) a subsequent year, the maximum cumulative adjustment percentage for the previous year increased by 0.60 percentage points.

(iii) Standardized IME cost percentage

The term “standardized IME cost percentage” means, for an area for a year, the per capita costs for payments under section 1395ww(d)(5)(B) of this title (expressed as a percentage of the fee-for-service amount specified in subparagraph (C)) for the area and the year.
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(C) Fee-for-service amount

The fee-for-service amount specified in this subparagraph for an area for a year is the amount specified under subsection (c)(1)(D) for the area and the year.

(l) Application of eligible professional incentives for certain MA organizations for adoption and meaningful use of certified EHR technology

(1) In general

Subject to paragraphs (3) and (4), in the case of a qualifying MA organization, the provisions of sections 1395w–4(o) and 1395w–4(a)(7) of this title shall apply with respect to eligible professionals described in paragraph (2) of the organization who the organization attests under paragraph (6) to be meaningful EHR users in a similar manner as they apply to eligible professionals under such sections. Incentive payments under paragraph (3) shall be made to and payment adjustments under paragraph (4) shall apply to such qualifying organizations.

(2) Eligible professional described

With respect to a qualifying MA organization, an eligible professional described in this paragraph is an eligible professional (as defined for purposes of section 1395w–4(o) of this title) who—

(A)(i) is employed by the organization; or

(ii)(I) is employed by, or is a partner of, an entity that through contract with the organization furnishes at least 80 percent of the entity’s Medicare patient care services to enrollees in the organization; and

(II) furnishes at least 80 percent of the professional services of the eligible professional covered under this subchapter to enrollees of the organization; and

(B) furnishes, on average, at least 20 hours per week of patient care services.

(3) Eligible professional incentive payments

(A) In general

In applying section 1395w–4(o) of this title under paragraph (1), instead of the additional payment amount under section 1395w–4(o)(1)(A) of this title and subject to subparagraph (B), the Secretary may substitute an amount determined by the Secretary to the extent feasible and practical to be similar to the estimated amount in the aggregate that would be payable if payment for services furnished by such professionals was payable under part B instead of this part.

(B) Avoiding duplication of payments

(i) In general

In the case of an eligible professional described in paragraph (2)—

(I) that is eligible for the maximum incentive payment under section 1395w–4(o)(1)(A) of this title for the same payment period, the payment incentive shall be made only under such section and not under section 1395w–4(o)(1)(A) of this title.

(ii) Methods

In the case of an eligible professional described in paragraph (2) who is eligible for an incentive payment under section 1395w–4(o)(1)(A) of this title but is not described in clause (i) for the same payment period, the Secretary shall develop a process—

(I) to ensure that duplicate payments are not made with respect to an eligible professional both under this subsection and under section 1395w–4(o)(1)(A) of this title; and

(II) to collect data from Medicare Advantage organizations to ensure against such duplicate payments.

(C) Fixed schedule for application of limitation on incentive payments for all eligible professionals

In applying section 1395w–4(o)(1)(B)(ii) of this title under subparagraph (A), in accordance with rules specified by the Secretary, a qualifying MA organization shall specify a year (not earlier than 2011) that shall be treated as the first payment year for all eligible professionals with respect to such organization.

(4) Payment adjustment

(A) In general

In applying section 1395w–4(a)(7) of this title under paragraph (1), instead of the payment adjustment being an applicable percent of the fee schedule amount for a year under such section, subject to subparagraph (D), the payment adjustment under paragraph (1) shall be equal to the percent specified in subparagraph (B) for such year of the payment amount otherwise provided under this section for such year.

(B) Specified percent

The percent specified under this subparagraph for a year is 100 percent minus a number of percentage points equal to the product of—

(i) the number of percentage points by which the applicable percent (under section 1395w–4(a)(7)(A)(ii) of this title) for the year is less than 100 percent; and

(ii) the Medicare physician expenditure proportion specified in subparagraph (C) for the year.

(C) Medicare physician expenditure proportion

The Medicare physician expenditure proportion under this subparagraph for a year is the Secretary’s estimate of the proportion, of the expenditures under parts A and B that are not attributable to this part, that are attributable to expenditures for physicians’ services.

(D) Application of payment adjustment

In the case that a qualifying MA organization attests that not all eligible profes-
sionals of the organization are meaningful EHR users with respect to a year, the Secretary shall apply the payment adjustment under this paragraph based on the proportion of all such eligible professionals of the organization that are not meaningful EHR users for such year.

(5) Qualifying MA organization defined

In this subsection and subsection (m), the term “qualifying MA organization” means a Medicare Advantage organization that is organized as a health maintenance organization (as defined in section 300gg–91(b)(3) of this title).

(6) Meaningful EHR user attestations

For purposes of this subsection and subsection (m), a qualifying MA organization shall submit an attestation in a form and manner specified by the Secretary which may include the submission of such attestation as part of submission of the initial bid under section 1395w–24(a)(1)(A) of this title, identifying—

(A) whether each eligible professional described in paragraph (2), with respect to such organization is a meaningful EHR user (as defined in section 1395w–4(o)(2) of this title) for a year specified by the Secretary; and

(B) whether each eligible hospital described in paragraph (2), with respect to such organization, is a meaningful EHR user (as defined in section 1395w–4(n)(3) of this title) for an applicable period specified by the Secretary.

(7) 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, business addresses, and business phone numbers of—

(A) each qualifying MA organization receiving an incentive payment under this subsection for eligible professionals of the organization; and

(B) the eligible professionals of such organization for which such incentive payment is based.

(8) 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—

(A) the methodology and standards for determining payment amounts and payment adjustments under this subsection, including avoiding duplication of payments under section 1395ff(b) and the specification of rules for the fixed schedule for application of limitation on incentive payments for all eligible professionals under section 1395w–4(o)(2); and

(B) the methodology and standards for determining eligible professionals under paragraph (2); and

(C) the methodology and standards for determining a meaningful EHR user under section 1395w–4(o)(2) of this title, including specification of the means of demonstrating meaningful EHR use under section 1395w–4(o)(3)(C) of this title and selection of measures under section 1395w–4(o)(3)(B) of this title.

(m) Application of eligible hospital incentives for certain MA organizations for adoption and meaningful use of certified EHR technology

(1) Application

Subject to paragraphs (3) and (4), in the case of a qualifying MA organization, the provisions of sections 1395ww(n) and 1395ww(b)(3)(B) of this title shall apply with respect to eligible hospitals described in paragraph (2) of the organization which the organization attests under subsection (l)(6) to be meaningful EHR users in a similar manner as they apply to eligible hospitals under such sections. Incentive payments under paragraph (3) shall be made to and payment adjustments under paragraph (4) shall apply to such qualifying organizations.

(2) Eligible hospital described

With respect to a qualifying MA organization, an eligible hospital described in this paragraph is an eligible hospital (as defined in section 1395ww(n)(6)(A) of this title) that is under common corporate governance with such organization and serves individuals enrolled under an MA plan offered by such organization.

(3) Eligible hospital incentive payments

(A) In general

In applying section 1395ww(n)(2) of this title under paragraph (1), instead of the additional payment amount under section 1395ww(n)(2) of this title, there shall be substituted an amount determined by the Secretary to be similar to the estimated amount in the aggregate that would be payable if payment for services furnished by such hospitals was payable under part A instead of this Part. In implementing the previous sentence, the Secretary—

(i) shall, insofar as data to determine the discharge related amount under section 1395ww(n)(2)(C) of this title for an eligible hospital are not available to the Secretary, use such alternative data and methodology to estimate such discharge related amount as the Secretary determines appropriate; and

(ii) shall, insofar as data to determine the medicare share described in section 1395ww(n)(2)(D) of this title for an eligible hospital are not available to the Secretary, use such alternative data and methodology to estimate such discharge related amount as the Secretary determines appropriate; and

So in original. Probably should be “1395w–4(o)(2)(C)”.

So in original. Probably should be “1395w–4(o)(2)(B)”.

So in original. Probably should be “1395ww(n)(6)(B)”.

So in original. Probably should be “(m)(2),”.

So in original. Probably should be “(m)(1),”.

So in original. Section 1395w–24(a)(1)(A) of this title does not contain a cl. (iv).
or individuals enrolled in an MA plan under a Medicare Advantage organization under this part as a proportion of the estimated total number of patient-bed-days (or discharges) with respect to such hospital during such period.

(B) Avoiding duplication of payments

(i) In general

In the case of a hospital that for a payment year is an eligible hospital described in paragraph (2) and also is eligible for an incentive payment under section 1395ww(n) of this title but is not described in clause (i) for the same payment period, the Secretary shall develop a process—

(I) to ensure that duplicate payments are not made with respect to an eligible hospital both under this subsection and under section 1395ww(n) of this title; and

(II) to collect data from Medicare Advantage organizations to ensure against such duplicate payments.

(4) Payment adjustment

(A) In general

Subject to paragraph (3), in the case of a qualifying MA organization (as defined in subparagraph (A) of such section) that also is eligible for an incentive payment under this section for such organization for such payment period, the payment amount payable under this section for such organization for such period shall be made only under section 1395ww(w)(n) of this title and not under this subsection.

(ii) Methods

In the case of a hospital that is an eligible hospital described in paragraph (2) and is not described in clause (i) for the same payment period, the Secretary shall develop a process—

(I) to ensure that duplicate payments are not made with respect to an eligible hospital both under this subsection and under section 1395ww(n) of this title; and

(II) to collect data from Medicare Advantage organizations to ensure against such duplicate payments.

(5) Posting on website

The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format—

(A) a list of the names, business addresses, and business phone numbers of each qualifying MA organization receiving an incentive payment under this subsection for eligible hospitals described in paragraph (2); and

(B) a list of the names of the eligible hospitals for which such incentive payment is based.

(6) Limitations on review

There shall be no administrative or judicial review under section 1395fi of this title, section 1395oo of this title, or otherwise, of—

(A) the methodology and standards for determining payment amounts and payment adjustments under this subsection, including avoiding duplication of payments under paragraph (3)(B); and

(B) the methodology and standards for determining eligible hospitals under paragraph (2); and

(C) the methodology and standards for determining a meaningful EHR user under section 1395ww(n)(3) of this title, including specification of the means of demonstrating meaningful EHR use under subparagraph (C) of such section and selection of measures under subparagraph (B) of such section.

(n) Determination of blended benchmark amount

(1) In general

For purposes of subsection (j), subject to paragraphs (3), (4), and (5), the term "blended benchmark amount" means for an area—

(A) for 2012 the sum of—

(i) ½ of the applicable amount for the area and year; and

(ii) ⅓ of the amount specified in paragraph (2)(A) for the area and year; and

(B) for a subsequent year the amount specified in paragraph (2)(A) for the area and year.

(2) Specified amount

(A) In general

The amount specified in this subparagraph for an area and year is the product of—

(i) the base payment amount specified in subparagraph (E) for the area and year adjusted to take into account the phase-out in the indirect costs of medical education from capitation rates described in subsection (k)(4); and

(ii) the Medicare hospital expenditure proportion specified in subparagraph (C) for the year.

(C) Medicare hospital expenditure proportion

The Medicare hospital expenditure proportion under this subparagraph for a year is the Secretary’s estimate of the proportion of the expenditures under parts A and B that are attributable to expenditures for inpatient hospital services.

(D) Application of payment adjustment

In the case that a qualifying MA organization attests that not all eligible hospitals are meaningful EHR users with respect to an applicable period, the Secretary shall apply the payment adjustment under this paragraph based on a methodology specified by the Secretary, taking into account the proportion of such eligible hospitals, or discharges from such hospitals, that are not meaningful EHR users for such period.

(5) Posting on website

The Secretary shall post on the Internet website of the Centers for Medicare & Medicaid Services, in an easily understandable format—

(A) a list of the names, business addresses, and business phone numbers of each qualifying MA organization receiving an incentive payment under this subsection for eligible hospitals described in paragraph (2); and

(B) a list of the names of the eligible hospitals for which such incentive payment is based.

(6) Limitations on review

There shall be no administrative or judicial review under section 1395fi of this title, section 1395oo of this title, or otherwise, of—

(A) the methodology and standards for determining payment amounts and payment adjustments under this subsection, including avoiding duplication of payments under paragraph (3)(B); and

(B) the methodology and standards for determining eligible hospitals under paragraph (2); and

(C) the methodology and standards for determining a meaningful EHR user under section 1395ww(n)(3) of this title, including specification of the means of demonstrating meaningful EHR use under subparagraph (C) of such section and selection of measures under subparagraph (B) of such section.
(ii) the applicable percentage for the area for the year specified under subparagraph (B).

(B) Applicable percentage

Subject to subparagraph (D), the applicable percentage specified in this subparagraph for an area for a year in the case of an area that is ranked—

(i) in the highest quartile under subparagraph (C) for the previous year is 95 percent;

(ii) in the second highest quartile under such subparagraph for the previous year is 100 percent;

(iii) in the third highest quartile under such subparagraph for the previous year is 107.5 percent; or

(iv) in the lowest quartile under such subparagraph for the previous year is 115 percent.

(C) Periodic ranking

For purposes of this paragraph in the case of an area located—

(i) in 1 of the 50 States or the District of Columbia, the Secretary shall rank such area in each year specified under subsection (C)(1)(D)(ii) based upon the level of the amount specified in subparagraph (A)(i) for such areas; or

(ii) in a territory, the Secretary shall rank such areas in each such year based upon the level of the amount specified in subparagraph (A)(i) for such area relative to quartile rankings computed under clause (i).

(D) 1-year transition for changes in applicable percentage

If, for a year after 2012, there is a change in the quartile in which an area is ranked compared to the previous year, the applicable percentage for the area in the year shall be the average of—

(i) the applicable percentage for the area for the previous year; and

(ii) the applicable percentage that would otherwise apply for the area for the year.

(E) Base payment amount

Subject to subparagraph (F), the base payment amount specified in this subparagraph—

(i) for 2012 is the amount specified in subsection (c)(1)(D) for the area for the year; or

(ii) for a subsequent year that—

(I) is not specified under subsection (c)(1)(D)(ii), is the base amount specified in this subparagraph for the area for the previous year, increased by the national per capita MA growth percentage, described in subsection (c)(6) for that succeeding year, but not taking into account any adjustment under subparagraph (C) of such subsection for a year before 2004; and

(II) is specified under subsection (c)(1)(D)(ii), is the amount specified in subsection (c)(1)(D) for the area for the year.

(F) Application of indirect medical education phase-out

The base payment amount specified in subparagraph (E) for a year shall be adjusted in the same manner under paragraph (4) of subsection (k) as the applicable amount is adjusted under such subsection.

(3) Alternative phase-ins

(A) 4-year phase-in for certain areas

If the difference between the applicable amount (as defined in subsection (k)) for an area for 2010 and the projected 2010 benchmark amount (as defined in subparagraph (C)) for the area is at least $30 but less than $50, the blended benchmark amount for the area is—

(i) for 2012 the sum of—

(I) ¼ of the applicable amount for the area and year; and

(II) ¼ of the amount specified in paragraph (2)(A) for the area and year;

(ii) for 2013 the sum of—

(I) ½ of the applicable amount for the area and year; and

(II) ¼ of the amount specified in paragraph (2)(A) for the area and year;

(iii) for 2014 the sum of—

(I) ¼ of the applicable amount for the area and year; and

(II) ¾ of the amount specified in paragraph (2)(A) for the area and year; and

(iv) for a subsequent year the amount specified in paragraph (2)(A) for the area and year.

(B) 6-year phase-in for certain areas

If the difference between the applicable amount (as defined in subsection (k)) for an area for 2010 and the projected 2010 benchmark amount (as defined in subparagraph (C)) for the area is $50, the blended benchmark amount for the area is—

(i) for 2012 the sum of—

(I) ½ of the applicable amount for the area and year; and

(II) ¼ of the amount specified in paragraph (2)(A) for the area and year;

(ii) for 2013 the sum of—

(I) ½ of the applicable amount for the area and year; and

(II) ¼ of the amount specified in paragraph (2)(A) for the area and year;

(iii) for 2014 the sum of—

(I) ¾ of the applicable amount for the area and year; and

(II) ¼ of the amount specified in paragraph (2)(A) for the area and year;

(iv) for 2015 the sum of—

(I) ¼ of the applicable amount for the area and year; and

(II) ¾ of the amount specified in paragraph (2)(A) for the area and year;

(v) for 2016 the sum of—

(I) ¼ of the applicable amount for the area and year; and

(II) ¾ of the amount specified in paragraph (2)(A) for the area and year; and

(III) the amount specified under subsection (c)(1)(D)(ii) for the area and year.
(vi) for a subsequent year the amount specified in paragraph (2)(A) for the area and year.

(C) Projected 2010 benchmark amount
The projected 2010 benchmark amount described in this subparagraph for an area is equal to the sum of—
(I) ½ of the applicable amount (as defined in subsection (k)) for the area for 2010; and
(ii) ½ of the amount specified in paragraph (2)(A) for the area for 2010 but determined as if there were substituted for the applicable percentage specified in clause (ii) of such paragraph the sum of—
(I) the applicable percent that would be specified under subparagraph (B) of paragraph (2) (determined without regard to subparagraph (D) of such paragraph) for the area for 2010 if any reference in such paragraph to “the previous year” were deemed a reference to 2010; and
(II) the applicable percentage increase that would apply to a qualifying plan in the area under subsection (o) as if any reference in such subsection to 2012 were deemed a reference to 2010 and as if the determination of a qualifying county under paragraph (3)(B) of such subsection were made for 2010.

(4) Cap on benchmark amount
In no case shall the blended benchmark amount for an area for a year (determined taking into account subsection (o)) be greater than the applicable amount that would (but for the application of this subsection) be determined under subsection (k) for the area for 2010.

(5) Non-application to PACE plans
This subsection shall not apply to payments to a PACE program under section 1395eee of this title.

(o) Applicable percentage quality increases
(1) In general
Subject to the succeeding paragraphs, in the case of a qualifying plan with respect to a year beginning with 2012, the applicable percentage under subsection (n)(2)(B) shall be increased on a plan or contract level, as determined by the Secretary—
(A) for 2012, by 1.5 percentage points;
(B) for 2013, by 3.0 percentage points; and
(C) for 2014 or a subsequent year, by 5.0 percentage points.

(2) Increase for qualifying plans in qualifying counties
The increase applied under paragraph (1) for a qualifying plan located in a qualifying county for a year shall be doubled.

(3) Qualifying plans and qualifying county defined; application of increases to low enrollment and new plans
For purposes of this subsection:
(A) Qualifying plan
(i) In general
The term “qualifying plan” means, for a year and subject to paragraph (4), a plan that had a quality rating under paragraph (4) of 4 stars or higher based on the most recent data available for such year.

(ii) Application of increases to low enrollment plans
(I) 2012
For 2012, the term “qualifying plan” includes an MA plan that the Secretary determines is not able to have a quality rating under paragraph (4) because of low enrollment.

(II) 2013 and subsequent years
For 2013 and subsequent years, for purposes of determining whether an MA plan with low enrollment (as defined by the Secretary) is included as a qualifying plan, the Secretary shall establish a method to apply to MA plans with low enrollment (as defined by the Secretary) the computation of quality rating and the rating system under paragraph (4).

(iii) Application of increases to new plans
(I) In general
A new MA plan that meets criteria specified by the Secretary shall be treated as a qualifying plan, except that in applying paragraph (1), the applicable percentage under subsection (n)(2)(B) shall be increased—
(aa) for 2012, by 1.5 percentage points;
(bb) for 2013, by 2.5 percentage points; and
(cc) for 2014 or a subsequent year, by 3.5 percentage points.

(II) New MA plan defined
The term “new MA plan” means, with respect to a year, a plan offered by an organization or sponsor that has not had a contract as a Medicare Advantage organization in the preceding 3-year period.

(B) Qualifying county
The term “qualifying county” means, for a year, a county—
(i) that has an MA capitation rate that, in 2004, was based on the amount specified in subsection (c)(1)(B) for a Metropolitan Statistical Area with a population of more than 250,000;
(ii) for which, as of December 2009, of the Medicare Advantage eligible individuals residing in the county at least 25 percent of such individuals were enrolled in Medicare Advantage plans; and
(iii) that has per capita fee-for-service spending that is lower than the national monthly per capita cost for expenditures for individuals enrolled under the original Medicare fee-for-service program for the year.

(4) Quality determinations for application of increase
(A) Quality determination
The quality rating for a plan shall be determined according to a 5-star rating system (based on the data collected under section 1395w–22(e) of this title).
(B) Plans that failed to report

An MA plan which does not report data that enables the Secretary to rate the plan for purposes of this paragraph shall be counted as having a rating of fewer than 3.5 stars.

(5) Exception for PACE plans

This subsection shall not apply to payments to a PACE program under section 1395see of this title.


REFERENCES IN TEXT

Parts A and B of this subchapter, referred to in subsec. (a)(3)(B), (b)(4), (c), (4)(C), (6)(A), (f), (k)(2)(B)(iv)(III), (b)(3)(A), (4)(C), and (m)(3)(A), (B)(i), (4)(C), are classified to section 1395c et seq., and section 1395(e) et seq., respectively, of this title.


“(ii) for 2012 and succeeding years, a service area that is an entire urban or rural area, as applicable (as described in paragraph (5)); and

for purposes of subdividing a local plan, an MA local plan, an MA local area (as defined in paragraph (2)); and”, was repealed by Pub. L. 111–152, §1102(a). See Effective Date of 2010 Amendment note below.

Subsec. (d)(5). Pub. L. 111–148, §3201(a)(1)(C)(ii), which directed the addition of par. (5), was repealed by Pub. L. 111–152, §1102(a). As enacted, text read as follows: “For 2012 and succeeding years, the service area for an MA local plan shall be an entire urban or rural area in each State as follows:

“(A) **U**RBAN AREAS.—

“(1) **I**N **G**ENERAL.—Subject to clause (ii) and subparagaphs (C) and (D), the service area for an MA local plan in an urban area shall be the Core Based Statistical Area (in this paragraph referred to as a ‘CBSA’) or, if applicable, a conceptually similar alternative classification, as defined by the Director of the Office of Management and Budget.

“(1) CBSA covering more than one State.—In the case of a CBSA (or alternative classification) that covers more than one State, the Secretary shall divide the CBSA (or alternative classification) into separate service areas with respect to each State covered by the CBSA (or alternative classification).

“(B) **R**URAL AREAS.—Subject to subparagraphs (C) and (D), the service area for an MA local plan in a rural area shall be an entire county that does not qualify for inclusion in a CBSA (or alternative classification), as defined by the Director of the Office of Management and Budget.

“(C) **R**EFINEMENTS TO SERVICE AREAS.—For 2015 and succeeding years, in order to reflect actual patterns of health care service utilization, the Secretary may adjust the boundaries of service areas for MA local plans in urban areas and rural areas under subparagraphs (A) and (B), respectively, but may only do so based on recent analyses of actual patterns of care.

“(D) **A**DDITIONAL AUTHORITIES TO MAKE LIMITED EXCEPTIONS TO SERVICE AREA REQUIREMENTS FOR MA LOCAL PLANS.—The Secretary may, in addition to any adjustments under subparagraph (C), make limited exceptions to service area requirements otherwise applicable under this part for MA local plans that have in effect (as of March 23, 2010)—

“(1) agreements with another MA organization or MA plan that preclude the offering of benefits throughout an entire service area; or

“(2) limitations in their structural capacity to support adequate networks throughout an entire service area as a result of the delivery system model of the MA local plan.”

See Effective Date of 2010 Amendment note below.

Subsec. (d)(6). Pub. L. 111–148, §3201(a)(2), which directed the addition of par. (6), was repealed by Pub. L. 111–152, §1102(a). As enacted, text read as follows: “For years beginning with 2012, in the case of a PACE program under section 1395ee of this title, the MA payment area shall be the MA local area (as defined in paragraph (2)).” See Effective Date of 2010 Amendment note below.

Subsec. (j). Pub. L. 111–152, §1102(c)(1), inserted “subject to subsection (c),” after “For purposes of this part,” in introductory provisions.

Pub. L. 111–148, §3201(a)(1)(A)–(C)(i), which directed the designation of existing provisions as pars. (1), the insertion with respect to an MA local plan, an MA local area (as defined in paragraph (2)); and”, was repealed by Pub. L. 111–152, §1102(a). See Effective Date of 2010 Amendment note below.

Subsec. (j)(1)(A). Pub. L. 111–152, §1102(b)(1), substituted “for the area for the year (or, for 2007, 2008, 2009, and 2010, ¼ of the applicable amount determined under subsection (k)(1) for the area for the year; for 2011, ¼ of the applicable amount determined under subsection (k)(1) for the area for the year; and, beginning with 2012, ¼ of the blended benchmark amount determined under subsection (n)(1) for the area for the year)’’ for “(or, beginning with 2007, ¼ of the applicable amount determined under subsection (k)(1) for the area for the year)”.

Pub. L. 111–148, §3201(a)(1)(C)(ii), (iii), which, in cl. (i), directed substitution of “section 1395w–29(d)(2)(A) of this title, an amount equal to—” for “section 1395w–29(d)(2)(A) of this title, an amount equal to”, subcls. (i) to (VI) for “¼ of the annual MA capitation rate under subsection (c)(1) (or, beginning with 2007, ¼ of the applicable amount determined under subsection (k)(1)) for the area for the year, adjusted as appropriate for years before 2007 for the purpose of risk adjustment; or”, and, in cl. (ii), directed substitution of “clause (i)” for “subsection (A)’’ was repealed by Pub. L. 111–152, §1102(a). As enacted, subcls. (i) to (VI) read as follows: “(I) for years before 2007, ¼ of the annual MA capitation rate under subsection (c)(1) for the area for the year, adjusted as appropriate for the purpose of risk adjustment; (II) for 2007 through 2011, ¼ of the applicable amount determined under subsection (k)(1) for the area for the year; (III) for 2012, the sum of—

“(aa) ½ of the quotients of—

“(AA) the applicable amount determined under subsection (k)(1) for the area for the year; and

“(BB) 12; and

“(bb) ½ of the MA competitive benchmark amount (determined under paragraph (2)) for the area for the month;”

“(IV) for 2013, the sum of—

“(aa) ½ of the quotients of—

“(AA) the applicable amount determined under subsection (k)(1) for the area for the year; and

“(BB) 12; and

“(bb) ½ of the MA competitive benchmark amount (as so determined) for the area for the month;”

“(V) for 2014, the MA competitive benchmark amount for the area for a month in 2013 (as so determined), increased by the national per capita MA growth percentage, described in subsection (c)(6) for 2014, but not taking into account any adjustment under subparagraph (C) of such subsection for a year before 2004; and

“(VI) for 2015 and each subsequent year, the MA competitive benchmark amount (as so determined) for the area for the month, or’’.

See Effective Date of 2010 Amendment note below.

Subsec. (j)(2), (3). Pub. L. 111–148, §3201(a)(1)(D), which directed addition of pars. (2) and (3), was repealed by Pub. L. 111–152, §1102(a). As enacted, pars. (2) and (3) read as follows:

“(2) **C**OMPUTATION OF MA COMPETITIVE BENCHMARK AMOUNT

“(A) **I**N **G**ENERAL.—Subject to subparagraph (B), for purposes of paragraphs (1) and (2) for each MA payment area the Secretary shall compute an MA competitive benchmark amount equal to the weighted average of the unadjusted MA statutory non-drug monthly bid amount (as defined in section 1395w–29(d)(2)(E) of this title) for each MA plan in the area, with the weight for each plan being equal to the average number of beneficiaries enrolled under such plan in the reference month (as defined in section 1395w–27a(c)(4) of this title, except that, in applying such definition for purposes of this paragraph, ’to compute the MA competitive benchmark amount under section 1395w–23(k)(2) of this title’ shall be substituted for ’to compute the percentage specified in subparagraph (A)’ and other relevant percentages under this part’).

“(B) **W**EIGHTING RULES.—

“(1) **S**INGLE PLAN RULE.—In the case of an MA payment area in which only a single MA plan is being offered, the weight under subparagraph (A) shall be equal to 1.
"(ii) Use of simple average among multiple plans if no plans offered in previous year.—In the case of an MA payment area in which no MA plan was offered in the previous year and more than 1 MA plan is offered in the current year, the Secretary shall use a simple average of the unadjusted MA statutory non-drug monthly bid amount (as so defined) for purposes of computing the MA competitive benchmark amount under subparagraph (A).

"(iii) Cap on MA competitive benchmark amount.—In no case shall the MA competitive benchmark amount be greater than the applicable amount that would (but for the application of this subsection) be determined under subsection (k)(1) for the area for the month in the year." See Effective Date of 2010 Amendment note below.


"(A) I

"N GENERAL

"For years beginning with 2014, subject to subparagraph (B), in the case of an MA plan that conducts 1 or more programs described in subparagraph (C) with respect to the year, the Secretary shall, in addition to any other payment provided under this part, make monthly payments, with respect to coverage of an individual under this part, to an MA plan that achieves at least a 3 star rating under such subparagraph.

"(B) LIMITATION.—In no case may the total amount of payment with respect to a year under subparagraph (A) be greater than 2 percent of the national monthly per capita cost for expenditures for individuals enrolled under the original medicare fee-for-service program for the year; and

"(i) the total number of programs described in clauses (i) through (ix) of subparagraph (C) that the Secretary determines the plan is conducting for the year; and

"(ii) the number of eligible beneficiaries identified by the Secretary that are enrolled in the plan.

"(C) PROGRAMS DESCRIBED.—The following programs are described in this paragraph:

"(i) Care management programs that—

"(1) target individuals with 1 or more chronic conditions;

"(2) identify gaps in care; and

"(3) facilitate improved care by using additional resources like nurses, nurse practitioners, and physician assistants.

"(ii) Programs that focus on patient education and self-management of health conditions, including interventions that—

"(1) help manage chronic conditions;

"(2) reduce declines in health status; and

"(3) foster patient and provider collaboration.

"(iii) Transitional care interventions that focus on care provided around a hospital inpatient episode, including programs that target post-discharge patient care in order to reduce unnecessary health complications and readmissions.

"(iv) Patient safety programs, including programs for hospital-based patient safety programs in contracts that the Medicare Advantage organization offering the MA plan has with hospitals.

"(v) Financial policies that promote systematic coordination of care by primary care physicians across the full spectrum of specialties and sites of care, such as medical homes, capitation arrangements, or pay-for-performance programs.

"(vi) Programs that address, identify, and ameliorate health care disparities among principal at-risk subpopulations.

"(vii) Medication therapy management programs that are more extensive than is required under section 1395w–104(c) of this title (as determined by the Secretary).

"(viii) Health information technology programs, including clinical decision support and other tools to facilitate data collection and ensure patient-centered, appropriate care.

"(ix) Such other care management and coordination programs as the Secretary determines appropriate.

"(D) CONDUCT OF PROGRAM IN URBAN AND RURAL AREAS.—An MA plan may conduct a program described in subparagraph (C) in a manner appropriate for an urban or rural area as applied under the original medicare fee-for-service program for the year.

"(E) REPORTING OF DATA.—Each Medicare Advantage organization shall provide to the Secretary the information needed to determine whether they are eligible for a care coordination and management performance bonus at a time and in a manner specified by the Secretary.

"(F) PERIODIC AUDITING.—The Secretary shall monitor auditing activities conducted under this subparagraph.

"(2) QUALITY PERFORMANCE BONUSES.—

"(A) QUALITY BONUS.—For years beginning with 2014, the Secretary shall, in addition to any other payment provided under this part, make monthly payments, with respect to coverage of an individual under this part, to an MA plan that achieves at least a 4 or 5 star rating (or comparable rating) on a rating system described in subparagraph (C) in an amount equal to—

"(i) in the case of a plan that achieves a 4 star rating (or comparable rating) on such system, 2 percent of the national monthly per capita cost for expenditures for individuals enrolled under the original medicare fee-for-service program for the year; and

"(ii) in the case of a plan that achieves a 5 star rating (or comparable rating) on such system, 4 percent of such national monthly per capita cost for the year.

"(B) IMPROVED QUALITY BONUS.—For years beginning with 2014, in the case of an MA plan that does not receive a quality bonus under subparagraph (A) and is an improved quality MA plan with respect to the year (as identified by the Secretary), the Secretary shall, in addition to any other payment provided under this part, make monthly payments, with respect to coverage of an individual under this part, to the MA plan in an amount equal to 1 percent of such national monthly per capita cost for the year.

"(C) USE OF RATING SYSTEM.—For purposes of subparagraph (A), a rating system described in this paragraph is—

"(i) a rating system that uses up to 5 stars to rate clinical quality and enrollment satisfaction and performance at the Medicare Advantage contract or MA plan level; or

"(ii) such other system established by the Secretary that provides for the determination of a comparable quality performance rating to the rating system described in clause (i).

"(D) DATA USED IN DETERMINING SCORE.—

"(i) IN GENERAL.—The rating of an MA plan under the rating system described in subparagraph (C) with respect to a year shall be based on the most recent data available.
"(1) PLANS THAT FAIL TO REPORT DATA.—An MA plan which does not report data that enables the Secretary to rate the plan for purposes of subparagraph (A) or identify the plan for purposes of subparagraph (B) shall be counted, for purposes of such rating or identification, as having the lowest plan performance rating and the lowest percentage improvement, respectively.

"(2) QUALITY BONUS FOR NEW AND LOW ENROLLMENT MA PLANS.—

"(A) NEW MA PLANS.—For years beginning with 2014, in the case of an MA plan that first submits a bid under section 1395w-24(a)(1)(A) of this title for 2012 or a subsequent year, only receives enrollments made during the coverage election periods described in section 1395w-21(e) of this title, and is not able to receive a bonus under subparagraph (A) or (B) of paragraph (2) for the year, the Secretary shall, in addition to any other payment provided under this part, make monthly payments, with respect to coverage of an individual under this part, to the MA plan in an amount equal to 2 percent of national monthly per capita cost for expenditures for individuals enrolled under the original medicare fee-for-service program for the year. In its fourth year of operation, the MA plan shall be paid in the same manner as other MA plans with comparable enrollment.

"(B) LOW ENROLLMENT PLANS.—For years beginning with 2014, in the case of an MA plan that has low enrollment (as defined by the Secretary) and would not otherwise be able to receive a bonus under subparagraph (A) or (B) of paragraph (2) or subparagraph (A) of this paragraph for the year (referred to in this subparagraph as a 'low enrollment plan'), the Secretary shall use a regional or local mean of the rating of all MA plans in the region or local area, as determined appropriate by the Secretary, on measures used to determine whether MA plans are eligible for a quality or an improved quality bonus, as applicable, to determine whether the low enrollment plan is eligible for a bonus under such a subparagraph.

"(4) RISK ADJUSTMENT.—The Secretary shall risk adjust just a performance bonus under this subsection in the same manner as the Secretary risk adjusts beneficiary rebates described in section 1395w-24(b)(1)(C) of this title.

"(5) NOTIFICATION.—The Secretary, in the annual announcement required under subsection (b)(1)(B) for 2014 and each succeeding year, shall notify the Medicare Advantage organization of any performance bonus (including a risk adjustment) bonus under paragraph (1), a quality performance bonus under paragraph (2), and a quality bonus for new and low enrollment plans under paragraph (3) that the organization will receive under this section for the preceding year. The Secretary shall provide for the publication of the information described in the previous sentence on the Internet website of the Centers for Medicare & Medicaid Services.

See Effective Date of 2010 Amendment note below.

Subsec. (h)(2)(B). Pub. L. 111–152, §1102(c)(2), directed insertion of “subject to subsection (o)” after “as follows” could not be executed because “as follows” did not appear in text.

Subsec. (h)(6). Pub. L. 111–148, §3202(b)(2), which directed that subsec. (n), as added by Pub. L. 111–148, §3201(f), be amended by adding a par. (6), was not executed to reflect the probable intent of Congress and the subsequent repeal of §3201(f) by Pub. L. 111–152, §1102(a).

See Amendment note above.


Pub. L. 111–148, §3201(g), which directed addition of subsec. (o) relating to grandfathering supplemental benefits for current enrollees after implementation of competitive bidding, was repealed by Pub. L. 111–152, §1102(a). As enacted, text read as follows:

"(4) RISK ADJUSTMENT.—The Secretary shall identify MA local areas in which, with respect to 2009, average bids submitted by an MA organization under section 1395w-24(a) of this title for MA local plans in the area are not greater than 75 percent of the adjusted average per capita cost for the year involved, determined under section 1395w-4(a)(4) of this title, for the area for individuals who are not enrolled in an MA plan under this part for the year, but adjusted to exclude costs attributable to payments under section 1395w-4(o), 1395w(w), and 1395w(b) of this title.

"(2) ELECTION TO PROVIDE REBATES TO GRANDFATHERED ENROLLERS.—

"(A) IN GENERAL.—For years beginning with 2012, each Medicare Advantage organization offering an MA local plan in an area identified by the Secretary under paragraph (1) may elect to provide rebates to grandfathered enrollees under section 1395w-24(b)(1)(C) of this title. In the case where an MA organization makes such an election, the monthly per capita dollar amount of such rebates shall not exceed the applicable amount for the year (as defined in subparagraph (B)).

"(B) APPLICABLE AMOUNT.—For purposes of this subsection, the term 'applicable amount' means—

"(i) for 2012, the monthly per capita dollar amount of such rebates provided to enrollees under the MA local plan with respect to 2011; and

"(ii) for a subsequent year, the amount determined under this subparagraph for the preceding year.

"(3) SPECIAL RULES FOR PLANS IN IDENTIFIED AREAS.—Notwithstanding any other provision of this part, the following shall apply with respect to each Medicare Advantage organization offering an MA local plan in an area identified by the Secretary under paragraph (1) that makes an election described in paragraph (A) of this subsection:

"(A) PAYMENTS.—The amount of the monthly payment under this section to the Medicare Advantage organization, with respect to coverage of a grandfathered enrollee under this part in the area for a month, shall be equal to—

"(i) for 2012 and 2013, the sum of—

"(I) the bid amount under section 1395w-24(a) of this title for the MA local plan; and

"(II) the applicable amount (as defined in paragraph (3)(B)) for the MA local plan for the year.

"(ii) for 2014 and subsequent years, the sum of—

"(I) the MA competitive benchmark amount under subsection (j)(1)(A)(i) for the area for the month, adjusted, only to the extent the Secretary determines necessary, to account for induced utilization as a result of rebates provided to grandfathered enrollees (except that such adjustment shall not exceed 0.5 percent of such MA competitive benchmark amount); and

"(II) the applicable amount (as so defined) for the MA local plan for the year.

"(B) REQUIREMENT TO SUBMIT BIDS UNDER COMPETITIVE BIDDING.—The Medicare Advantage organization shall submit a single bid amount under section 1395w-24(a) of this title for the MA local plan. The Medicare Advantage organization shall remove from such bid amount any effects of induced demand for care that may result from the higher rebates available to grandfathered enrollees under this subsection.

"(C) NONAPPLICATION OF BONUS PAYMENTS AND ANY OTHER REBATES.—The Medicare Advantage organization offering the MA local plan shall not be eligible for any bonus payment under subsection (n) or any rebate under this part (other than as provided under this subsection) with respect to grandfathered enrollees.

"(D) NONAPPLICATION OF UNIFORM BID AND PREMIUM AMOUNTS TO GRANDFATHERED ENROLLERS.—Section 1395w-24(c) of this title shall not apply with respect to the MA local plan.

"(E) NONAPPLICATION OF LIMITATION ON APPLICATION OF PLAN REBATES TOWARD PAYMENT OF PART B PREMIUM.—Notwithstanding clause (ii) of section 1395w-24(b)(1)(C) of this title, in the case of a grandfathered enrollee, a rebate under such section may be used for the purpose described in clause (ii)(III) of such section.
“(F) RISK ADJUSTMENT.—The Secretary shall risk adjust rebates to grandfathered enrollees under this subsection in the same manner as the Secretary risk adjusts beneficiary rebates described in section 1395w–24(b)(1)(C) of this title.

“(4) DEFINITION OF GRANDFATHERED ENROLLEE.—In this subsection, the term ‘grandfathered enrollee’ means an individual who is enrolled (effective as of March 23, 2010) in an MA local plan in an area that is identified by the Secretary under paragraph (1).”

See Effective Date of 2010 Amendment note below.

2009—Subsec. (a)(1)(A). Pub. L. 111–5, § 4101(e)(1), substituted “(i), and (iii)” for “(i)”.

Subsec. (c)(1)(D)(i). Pub. L. 111–5, § 4102(d)(3)(A)(i), substituted “1395w–4(o), and 1395ww(n)” for “1395w–4(o)”. Pub. L. 111–5, § 4101(e)(2)(A), substituted “sections 1395w–4(o) and 1395ww(h) of this title” for “section 1395ww(h) of this title”.

Subsec. (c)(6)(B). Pub. L. 111–5, § 4102(d)(3)(A)(ii), inserted “and subsections (b)(3)(B)(ix) and (n) of section 1395ww of this title” after “1395w–4 of this title”. Pub. L. 111–5, § 4101(e)(2)(B), inserted “excluding expenditures attributable to subsections (a)(7) and (o) of section 1395w–4 of this title,” after “under part B of this subchapter.”

Subsec. (f). Pub. L. 111–5, § 4102(d)(3)(B), inserted “and subsection (m)” after “under subsection (l)”. Pub. L. 111–5, § 4101(e)(3), inserted “and for payments under subsection (l)” after “with the organization”.

Subsec. (i). Pub. L. 111–5, § 4101(c), added subsec. (i).

Subsec. (m). Pub. L. 111–5, § 4102(c), added subsec. (m).

2008—Subsec. (k)(1). Pub. L. 110–275, § 161(a)(1), (b), substituted “paragraphs (2) and (4)” for “paragraph (2)” in introductory provisions of this subsection as a result of competitive bidding under this part (as determined by the Secretary).


Subsec. (j)(1)(A). Pub. L. 109–171, § 5301(a)(1)(A), inserted “(or, beginning with 2007, ¼ of the applicable amount determined under subsection (k)(1))” after “subsection (c)(1)” and “(for years before 2007)” after “adjusted as appropriate”.


2005—Subsec. (a)(1)(A). Pub. L. 108–173, § 222(e)(1)(A), redesignated subpar. (B) as (A) and added subpars. (B) to (G).

Subsec. (b). Pub. L. 108–173, § 222(d)(3)(B), inserted “amount determined as follows:” and cls. (i) and (ii) for “amount” and provisions describing amount equal to ¼ of the annual Medicare+Choice capitation rate, reduced by the amount of any reduction elected under section 1395w–24(f)(1)(E) of this title and adjusted for certain factors.


Subsec. (k)(1). Pub. L. 110–275, § 161(a)(1), (b), redesignated cl. (i) and (ii) for “amount” and provisions relating to actuarial equivalence of rates of payment to rates that would have been paid with respect to other enrollees in the MA payment area under this section as in effect before Dec. 8, 2003, for provisions relating to actuarial equivalence of rates of payment to rates paid to other enrollees in the Medicare+Choice payment area and inserted sentence at end authorizing application of the competitive bidding methodology provided for in this section, with appropriate adjustments to account for the risk adjustment methodology applied to end stage renal disease payments.


Subsec. (b)(3). Pub. L. 108–173, § 222(c)(2), substituted “in such announcement” for “in the announcement in sufficient detail so that Medicare+Choice organizations can compute monthly adjusted Medicare+Choice capitation rates for individuals in each Medicare+Choice payment area which is in whole or in part within the service area of such an organization.”
Pub. L. 108–173, § 211(a)(2), substituted “(C), or (D)” for “or (C)” in introductory provisions.
Pub. L. 108–173, § 237(b)(2)(B), substituted “subsections (a)(3)(C)(iii), (a)(4), and (i)” for “subsections (a)(3)(C)(iii) and (i)”.
Pub. L. 108–173, § 211(b)(2), inserted “(other than 2004)” after “for each year”.
Subsec. (d). Pub. L. 108–173, § 221(d)(1)(A), substituted “MA payment area; MA local area; MA region defined” for “Health Care Financing Administration”.
Subsec. (d)(1). Pub. L. 108–173, § 221(d)(1)(A), substituted heading and text of par. (1) generally. Prior to amendment, text read as follows: “In this part, except as provided in paragraph (1)(C)(v)(II), no such adjustment shall be made for a year before 2004” before period at end.
Pub. L. 108–173, § 211(a)(2), substituted “(C), or (D)” for “or (C)” in introductory provisions.
Subsec. (d)(2), (3). Pub. L. 108–173, § 221(d)(1)(B), (D), added par. (2) and redesignated former par. (2) as (3). Former par. (3) redesignated (4).
Subsec. (d)(4)(B). Pub. L. 108–173, § 221(d)(1)(E)(iii), inserted “with respect to MA local plans” after “established under this section” and “for such plans” after “payments under this section” and “made under this section”.
Subsec. (g). Pub. L. 108–173, § 211(e)(1)(A), inserted “a rehabilitation hospital described in section 1395ww(d)(1)(B)(i) of this title or a distinct part rehabilitation unit described in the matter following clause (v) of section 1395ww(d)(1)(B) of this title, or a long-term care hospital described in section 1395ww(d)(1)(B)(iv) of this title” after “1395ww(d)(1)(B) of this title)” in introductory provisions.
Subsec. (g)(2)(B). Pub. L. 108–173, § 211(e)(1)(B), inserted “or other payment provision under this subchapter for inpatient services for the type of facility, hospital, or unit involved, described in the matter preceding paragraph (1), as the case may be,” after “1395ww(d) of this title.”


1995—Pub. L. 104–193, § 601(a)(1), (3), redesignated cl. (ii) as (iv) and substituted “2001 and each succeeding year” for “and 2000 and after the calendar year concerned” for 2004 and 2005 not later than the second Monday in May before the respective calendar year for “not later than March 1 before the calendar year concerned”.


Subsec. (c)(7). Pub. L. 106–554, § 1(a)(6) [title VI, § 611(a)], amended heading and text of par. (7) generally. Prior to amendment, text read as follows: “If the Secretary makes a determination, with respect to coverage under this subchapter that the Secretary projects will result in a significant increase in the costs to Medicare+Choice of providing benefits under contracts under this part (for periods after any period described in section 1395w–22(a)(5) of this title), the Secretary shall adjust appropriately the payments to such organizations under this part.”

Subsec. (1)(i). Pub. L. 106–554, § 1(a)(6) [title VI, § 608(a)], in introductory provisions, inserted “, or filed notice with the Secretary as of October 3, 2000, that they will not be offering such a plan as of January 1, 2001.”

1999—Subsec. (a)(1)(A). Pub. L. 106–113, § 1000(a)(6) [title V, § 512(1)], substituted “subsections (e) and (f) of this section” for “subsections (e), (g), and (h) of this section”.


Subsec. (c)(5). Pub. L. 106–113, § 1000(a)(6) [title V, § 512(2)], inserted “other than those attributable to subsection (l) of this section” after “payments under this part”.


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

Section 201 of Pub. L. 108–173 mulled out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2003 AMENDMENT


Amendment by section 221(d)(1), (4) and 222(d)(1), (4) of Pub. L. 108–173 applicable with respect to plan years beginning on or after Jan. 1, 2006, and contract years beginning on or after such date, see section 237(e) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

Amendment by section 221(d)(1), (2) of Pub. L. 108–173 applicable to services provided on or after Jan. 1, 2006, and contract years beginning on or after such date, see section 237(e) of Pub. L. 108–173, set out as a note under section 1320a–7b of this title.

EFFECTIVE DATE OF 2002 AMENDMENT


EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–554, § 1(a)(6) [title VI, § 605(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–556, provided that: “The amendment made by subsection (a) (amending this section) shall apply to payments for months beginning with January 2002.”

Amendment by section 1(a)(6) [title VI, § 606(a)(2)(A)] of Pub. L. 106–554 applicable to years beginning with 2003, see section 1(a)(6) [title VI, § 606(b)] of Pub. L. 106–554, set out as a note under section 1395w–23 of this title.

Pub. L. 106–554, § 1(a)(6) [title VI, § 608(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–559, provided that: “The amendment made by subsection (a) [amending this section] shall apply as if included in the enactment of BBRA [Pub. L. 106–113, 1000(a)(6)].”

Amendment by section 1(a)(6) [title VI, § 611(a)] of Pub. L. 106–554 effective Dec. 21, 2000, and applicable to national coverage determinations and legislative changes in benefits occurring on or after such date, see section 1(a)(6) [title VI, § 611(c)] of Pub. L. 106–554, set out as a note under section 1395w–22 of this title.

MEDPAC STUDY OF AAPCC

Pub. L. 108–173, title II, § 211(f), Dec. 8, 2003, 117 Stat. 2178, directed the Medicare Payment Advisory Commission to conduct a study that would assess the methods used for determining the adjusted average per capita cost (AAPCC) under section 1395mm(a)(4) of this title, as applied under subsection (c)(1)(A) of this section, and to submit to Congress a report on such study not later than 18 months after Dec. 8, 2003.

IMPLEMENTATION OF 2003 AMENDMENT


“(1) ANNOUNCEMENT OF REVISED MEDICARE ADVANTAGE PAYMENT RATES.—Within 6 weeks after the date of the enactment of this Act [Dec. 8, 2003], the Secretary [of Health and Human Services] shall determine, and shall announce (in a manner intended to provide notice to interested parties) MA capitation rates under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) for 2004, revised in accordance with the provisions of this section [amending this section and section 1395w–22 of this title and enacting provisions set out as notes under this section], effective as if such notes had not been enacted.

“(2) TRANSITION TO REVISED PAYMENT RATES.—The provisions of section 604 of BIPA (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, set out as a note under this section) (114 Stat. 2763A–555) (other than subsection (a)) shall apply to the provisions of subsections (a) through (d) of this section [amending this section] for 2004 in the same manner as the provisions of such section 604 applied to the provisions of BIPA for 2001.

“(3) SPECIAL RULE FOR PAYMENT RATES IN 2004.—

“(A) JANUARY AND FEBRUARY.—Notwithstanding the amendments made by subsections (a) through (d) [amending this section] for purposes of making payments under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) for January and February 2004, the annual capitation rate for a payment area shall be calculated and the excess amount under section 1854(c)(1)(B) of such Act (42 U.S.C. 1395w–24(1)(B)) shall be determined as if such amendments had not been enacted.

“(B) MARCH THROUGH DECEMBER.—Notwithstanding the amendments made by subsections (a) through (d) [amending this section], for purposes of making payments under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) for March through December 2004, the annual capitation rate for a payment area shall be calculated and the excess amount under section 1854(c)(1)(B) of such Act (42 U.S.C. 1395w–24(1)(B)) shall be determined as such estimates will ensure that the total of such payments with respect to 2004 is the same as the amounts that would have been if subparagraph (A) had not been enacted.

“(C) CONSTRUCTION.—Subparagraphs (A) and (B) shall not be taken into account in computing such capitation rate for 2005 and subsequent years.

“(D) PLANS REQUIRED TO PROVIDE NOTICE OF CHANGES IN PLAN BENEFITS.—In the case of an organization offering a plan under part C of title XVII of the Social Security Act...
Act [this part] that revises its submission of the information described in section 1854(a)(1) of such Act (42 U.S.C. 1395w–23(a)(1) [1395w–24(a)(1)]) for a plan pursuant to the application of paragraph (2), if such revision results in changes in beneficiary premiums, beneficiary cost-sharing, or benefits under the plan, then by not later than 3 weeks after the date the Secretary approves such revised information, the organization offering the plan shall provide each beneficiary enrolled in the plan with written notice of such changes.

(5) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1899 or section 1878 of the Social Security Act (42 U.S.C. 1395ff and 1395oo), or otherwise of any determination made by the Secretary under this subsection or the application of the payment rates determined pursuant to this subsection.

SPECIAL RULE FOR JANUARY AND FEBRUARY OF 2001

Pub. L. 106–554, §1(a)(6) [title VI, §601(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–554, provided that:

"(1) IN GENERAL.—Notwithstanding the amendments made by subsection (a) [amending this section], for purposes of making payments under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) for January and February 2001, the annual Medicare+Choice capitation rate for purposes of applying section 1852(a)(5) of the Social Security Act (42 U.S.C. 1395w–22(a)(5)), the announcement of revised rates under subsection (a) shall not be treated as an announcement under section 1853(b) of such Act (42 U.S.C. 1395w–23(b))."

TRANSITION TO REVISED MEDICARE+CHOICE PAYMENT RATES

Pub. L. 106–554, §1(a)(6) [title VI, §604], Dec. 21, 2000, 114 Stat. 2763, 2763A–554, provided that:

"(a) ANNOUNCEMENT OF REVISED MEDICARE+CHOICE PAYMENT RATES.—Within 2 weeks after the date of the enactment of this Act [Dec. 21, 2000], the Secretary of Health and Human Services shall determine, and shall announce in a manner intended to provide notice to interested parties) Medicare+Choice capitation rates under section 1853 of the Social Security Act (42 U.S.C. 1395w–23) for 2001, revised in accordance with the provisions of this Act.

"(b) REENTRY INTO PROGRAM PERMITTED FOR MEDICARE+CHOICE PROGRAMS.—A Medicare+Choice organization that previously submitted a report on a timely basis consistent with subsection (b) [set out as a note above],"
The Secretary shall consult with representatives of Medicare+Choice organizations in conducting the study. The study shall address the following issues:

(A) The ability of the average risk adjustment factor applied to a Medicare+Choice plan to explain variations in plans' average per capita Medicare costs, as reported by Medicare+Choice plans in the plans' adjusted community rate filings.

(B) The year-to-year stability of the risk factors applied to each Medicare+Choice plan and the potential for substantial changes in payment for small Medicare+Choice plans.

(C) For Medicare beneficiaries newly enrolled in Medicare+Choice plans in a given year, the correspondence between the average risk factor calculated from medicare fee-for-service data for those individuals from the period prior to their enrollment in a Medicare+Choice plan and the average risk factor calculated for such individuals during their initial year of enrollment in a Medicare+Choice plan.

(D) For Medicare beneficiaries disenrolling from or switching among Medicare+Choice plans in a given year, the correspondence between the average risk factor calculated from data pertaining to the period prior to their disenrollment from a Medicare+Choice plan and the average risk factor calculated from data pertaining to the period after disenrollment.

(E) An evaluation of the exclusion of 'discretional' hospitalizations from consideration in the risk adjustment methodology.

(F) Suggestions for changes or improvements in the risk adjustment methodology.

Not later than December 1, 2000, the Commission shall submit a report to Congress on the study conducted under paragraph (1), together with any recommendations for legislation that the Commission determines to be appropriate as a result of such study.

Study and Report Regarding Reporting of Encounter Data

Pub. L. 106-113, div. B, § 1000(a)(6) [title V, § 511(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A-381, provided that:

(1) STUDY.—The Medicare Payment Advisory Commission shall conduct a study to evaluate the methods and burdens on Medicare+Choice organizations of capturing and reporting requirements for encounter data imposed by the Secretary in establishing and implementing a risk adjustment methodology used in making payments to such organizations under section 1833 of the Social Security Act (42 U.S.C. 1395w-23). The Medicare Payment Advisory Commission shall consult with representatives of Medicare+Choice organizations in conducting the study.

The study shall address the following issues:

(A) Limiting the number and types of sites of services (that are in addition to inpatient sites) for which encounter data must be reported.

(B) Establishing alternative risk adjustment methods that would require submission of less data.

(C) The potential for Medicare+Choice organizations to misreport, overreport, or underreport prevalence of diagnoses in outpatient sites of care, the potential for increases in payments to Medicare+Choice organizations from changes in Medicare+Choice plan coding practices (commonly known as 'coding creep') and proposed methods for detecting and adjusting for such variations in diagnosis coding as part of the risk adjustment methodology using encounter data from multiple sites of care.

(D) The impact of such requirements on the willingness of insurers to offer Medicare+Choice MSA plans and options for modifying encounter data reporting requirements to accommodate such plans.

(E) Differences in the ability of Medicare+Choice organizations to report encounter data, and the potential for adverse competitive impacts on group and staff model health maintenance organizations or other integrated providers of care based on data reporting capabilities.

(2) REPORT.—Not later than January 1, 2001, the Secretary shall submit a report to Congress on the study conducted under this subsection, together with any recommendations for legislation that the Secretary determines to be appropriate as a result of such study.

Special Rule for 2001

Pub. L. 106-113, div. B, § 1000(a)(6) [title V, § 552(a)], Nov. 29, 1999, 113 Stat. 1536, 1501A-382, provided that:

(1) STUDY.—The Medicare Payment Advisory Commission shall conduct a study on the development of a payment methodology under the Medicare+Choice program for frail elderly Medicare+Choice beneficiaries enrolled in a Medicare+Choice plan under a specialized program for the frail elderly that—

(A) accounts for the prevalence, mix, and severity of chronic conditions among such frail elderly Medicare+Choice beneficiaries;

(B) includes medical diagnostic factors from all provider settings (including hospital and nursing facility settings); and

(C) includes functional indicators of health status and such other factors as may be necessary to achieve appropriate payments for plans serving such beneficiaries.

(2) REPORT.—Not later than 1 year 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 paragraph (1), together with any recommendations for legislation that the Commission determines to be appropriate as a result of such study.

Publication of New Capitation Rates

Section 4002(l) of Pub. L. 105-33 provided that: "Not later than 4 weeks after the date of the enactment of this Act (Aug. 5, 1997), the Secretary of Health and Human Services shall announce the annual Medicare+Choice capitation rates for 1998 under section 1833(b) of the Social Security Act (subsec. (b) of this section)."

Medicare+Choice Competitive Pricing Demonstration Project


SEC. 4011. MEDICARE PREPAID COMPETITIVE PRICING DEMONSTRATION PROJECT.

(a) Establishment of Project.—

(1) In general.—Subject to the succeeding provisions of this subsection, the Secretary of Health and Human Services (in this subsection [subchapter A (§§ 4011–4012) of chapter 2 of subtitle A of title IV of Pub. L. 105-33) referred to as the "Secretary") shall establish a demonstration project (in this subsection referred to as the "project") under which payments to Medicare+Choice organizations in medicare payment
areas in which the project is being conducted are determined in accordance with a competitive pricing methodology established under this subchapter.

"(2) DELAY IN IMPLEMENTATION.—The Secretary shall not implement the project until January 1, 2002, or, if later, 6 months after the date the Competitive Pricing Advisory Committee has submitted to Congress a report on each of the following topics:

(A) INCORPORATION OF ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM INTO PROJECT.—What changes would be required in the project to feasibly incorporate the original medicare fee-for-service program into the project in the areas in which the project is operational.

(B) QUALITY ACTIVITIES.—The nature and extent of the quality reporting and monitoring activities that should be required of plans participating in the project, the estimated costs that plans will incur as a result of these requirements, and the current ability of the Health Care Financing Administration to collect and report comparable data, sufficient to support comparable quality reporting and monitoring activities with respect to beneficiaries enrolled in the original medicare fee-for-service program generally.

(C) RURAL PROJECT.—The current viability of initiating a project in a rural area, given the site specific budget neutrality requirements of the project under subsection (g), and insofar as the Committee decides that the addition of such a site is not viable, recommendations on how the project might best be changed so that such a site is viable.

(D) BENEFIT STRUCTURE.—The nature and extent of the benefit structure that should be required of plans participating in the project, the rationale for such benefit structure, the potential implications that any benefit standardization requirement may have on the number of plan choices available to a beneficiary in an area designated under the project, the potential implications of requiring participating plans to offer variations on any standardized benefit package the committee might recommend, such that a beneficiary could elect to pay a higher percentage of out-of-pocket costs in exchange for a lower premium (or premium rebate as the case may be), and the potential implications of expanding the project (in conjunction with the potential inclusion of the original medicare fee-for-service program) to require medicare supplemental insurance plans operating in an area designated under the project to offer a coordinated and comparable standardized benefit package.

(3) CONFORMING DEADLINES.—Any dates specified in the preceding provisions of this section shall be delayed (as specified by the Secretary) in a manner consistent with the delay effected under paragraph (2).

(b) DESIGNATION OF 7 MEDICARE PAYMENT AREAS COVERED BY PROJECT.

(1) IN GENERAL.—The Secretary shall designate, in accordance with the recommendations of the Competitive Pricing Advisory Committee under paragraphs (2) and (3), medicare payment areas as areas in which the project under this subchapter will be conducted. In this section, the term 'Competitive Pricing Advisory Committee' means the Competitive Pricing Advisory Committee established under section 4012(a).

(2) INITIAL DESIGNATION OF 4 AREAS.

(A) IN GENERAL.—The Competitive Pricing Advisory Committee shall recommend to the Secretary, consistent with subparagraph (B), the designation of 4 specific areas as medicare payment areas to be included in the project. Such recommendations shall be made in a manner so as to ensure that payments under the project in 2 such areas will begin on January 1, 1999, and in 2 such areas will begin on January 1, 2000.

(B) LOCATION OF DESIGNATION.—Of the 4 areas recommended under subparagraph (A), 3 shall be in urban areas and 1 shall be in a rural area.

(3) DESIGNATION OF ADDITIONAL 3 AREAS.—Not later than December 31, 2001, the Competitive Pricing Advisory Committee may recommend to the Secretary the designation of up to 3 additional, specific medicare payment areas to be included in the project.

(c) PROJECT IMPLEMENTATION.

(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall for each medicare payment area designated under subsection (b)—

(A) in accordance with the recommendations of the Competitive Pricing Advisory Committee—

(i) establish the benefit design among plans offered in such area,

(ii) structure the method for selecting plans offered in such area; and

(iii) establish beneficiary premiums for plans offered in such area in a manner such that a beneficiary who enrolls in an offered plan the per capita bid for which is less than the standard per capita government contribution (as established by the competitive pricing methodology established for such area) may, at the plan's election, be offered a rebate of some or all of the medicare part B premium that such individual must otherwise pay in order to participate in a Medicare+Choice plan under the Medicare+Choice program; and

(B) in consultation with such Committee—

(i) establish methods for setting the price to be paid to plans, including, if the Secretaries determines appropriate, the rewarding and penalizing of Medicare+Choice plans in the area on the basis of the attainment of, or failure to attain, applicable quality standards, and

(ii) provide for the publication of plan information (including information concerning quality and access to care), the dissemination of information, and the methods of evaluating the results of the project.

(2) CONSULTATION.—The Secretary shall take into account the recommendations of the area advisory committee established in section 4012(b), in implementing a project design for any area, except that no modifications may be made in the project design without consultation with the Competitive Pricing Advisory Committee. In no case may the Secretary change the designation of an area based on recommendations of any area advisory committee.

(d) MONITORING AND REPORT.

(1) MONITORING IMPACT.—Taking into consideration the recommendations of the Competitive Pricing Advisory Committee and the area advisory committees, the Secretary shall closely monitor and measure the impact of the project on the different areas on the price and quality of, and access to, medicare covered services, choice of health plans, changes in enrollment, and other relevant factors.

(2) REPORT.—Not later than December 31, 2002, the Secretary shall submit to Congress a report on the progress under the project under this subchapter, including a comparison of the matters monitored under paragraph (1) among the different designated areas. The report may include any legislative recommendations for extending the project to the entire medicare population.

(e) WAIVER AUTHORITY.—The Secretary of Health and Human Services may waive such requirements of title XVIII of the Social Security Act (this subchapter) (as amended by this Act) as may be necessary for the purposes of carrying out the project.

(f) RELATIONSHIP TO OTHER AUTHORITY.—Except pursuant to this subchapter, the Secretary of Health and Human Services may not conduct or continue any project or activity relating to payment of health maintenance organizations, Medicare+Choice organizations, or similar prepaid managed care entities on the basis of a competitive bidding process or pricing system described in subsection (a).

(g) NO ADDITIONAL COSTS TO MEDICARE PROGRAM.—The aggregate payments to Medicare+Choice organiz-
sections under the project for any designated area for a fiscal year may not exceed the aggregate payments to such organizations that would have been made under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), as amended by section 4001 (enacting this part and redesignating former part C of this subchapter as part D), if the project had not been conducted.

"(B) Definitions.—Any term used in this subchapter which is also used in part C of title XVIII of the Social Security Act [this part], as amended by section 4001, shall have the same meaning as when used in such part.

"SEC. 602. ADVISORY COMMITTEES.

"(a) COMPETITIVE PRICING ADVISORY COMMITTEE.—

"(1) IN GENERAL.—Before implementing the project under this subchapter [subchapter A (§§ 4011–4012) of chapter 2 of subtitle A of title IV of Pub. L. 105–33], the Secretary shall appoint the Competitive Pricing Advisory Committee, including independent actuaries, individuals with expertise in competitive health plan pricing, and an employee of the Office of Personnel Management with expertise in the administration of the Federal Employees Health Benefit Program, to make recommendations to the Secretary concerning the designation of areas for inclusion in the project and appropriate research design for implementing the project.

"(2) INITIAL RECOMMENDATIONS.—The Competitive Pricing Advisory Committee initially shall submit recommendations regarding the area selection, benefit design among plans offered, structuring choice among health plans offered, methods for setting the price to be paid to plans, collection of plan information (including information concerning quality and access to care), information dissemination, and methods of evaluating the results of the project.

"(3) QUALITY RECOMMENDATION.—The Competitive Pricing Advisory Committee shall study and make recommendations regarding the feasibility of providing financial incentives and penalties to plans operating under the project that meet, or fail to meet, applicable quality standards.

"(4) ADVICE DURING IMPLEMENTATION.—Upon implementation of the project, the Competitive Pricing Advisory Committee shall continue to advise the Secretary on the application of the design in different areas and changes in the project based on experience with its operations.


"(b) APPOINTMENT OF AREA ADVISORY COMMITTEE.—

Upon the designation of an area for inclusion in the project, the Secretary shall appoint an area advisory committee, composed of representatives of health plans, providers, and medicare beneficiaries in the area, to advise the Secretary concerning how the project will be implemented in the area. Such advice may include advice concerning the marketing and pricing of plans in the area and other salient factors. The duration of such a committee for an area shall be for the duration of the operation of the project in the area.

"(c) SPECIAL APPLICATION.—Notwithstanding section 9(c) of the Federal Advisory Committee Act (5 U.S.C. App.), the Competitive Pricing Advisory Commission and any area advisory committee (described in subsection (b)) may meet as soon as the members of the commission or committee, respectively, are appointed.

§ 1395w–24. Premiums and bid amounts

(a) Submission of proposed premiums, bid amounts, and related information

(1) In general

(A) Initial submission

Not later than the second Monday in September of 2002, 2003, and 2004 (or the first Monday in June of each subsequent year), each MA organization shall submit to the Secretary, in a form and manner specified by the Secretary and for each MA plan for the service area (or segment of such an area if permitted under subsection (h) of this section) in which it intends to be offered in the following year the following:

(i) The information described in paragraph (2), (3), (4), or (6)(A) for the type of plan and year involved.

(ii) The plan type for each plan.

(iii) The enrollment capacity (if any) in relation to the plan and area.

(B) Beneficiary rebate information

In the case of a plan required to provide a monthly rebate under subsection (b)(1)(C) of this section for a year, the MA organization offering the plan shall submit to the Secretary, in such form and manner and at such time as the Secretary specifies, information on—

(i) the manner in which such rebate will be provided under clause (ii) of such subsection; and

(ii) the MA monthly prescription drug beneficiary premium (if any) and the MA monthly supplemental beneficiary premium (if any).

(C) Paperwork reduction for offering of MA regional plans nationally or in multi-region areas

The Secretary shall establish requirements for information submission under this subsection in a manner that promotes the offering of MA regional plans in more than one region (including all regions) through the filing of consolidated information.

(2) Information required for coordinated care plans before 2006

For a Medicare+Choice plan described in section 1395w–22(a)(1)(A) of this title for a year before 2006, the information described in this paragraph is as follows:

(A) Basic (and additional) benefits

For benefits described in section 1395w–22(a)(1)(A) of this title—

(i) the adjusted community rate (as defined in subsection (f)(3) of this section);

(ii) the Medicare+Choice monthly basic beneficiary premium (as defined in subsection (b)(2)(A) of this section);

(iii) a description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of such deductibles, coinsurance, and copayments, described in subsection (e)(1)(A) of this section; and

(iv) if required under subsection (f)(1) of this section, a description of the additional benefits to be provided pursuant to such subsection and the value determined for such proposed benefits under such subsection.

(B) Supplemental benefits

For benefits described in section 1395w–22(a)(3) of this title—

(i) the adjusted community rate (as defined in subsection (f)(3) of this section);

(ii) the Medicare+Choice monthly supplemental beneficiary premium (as defined in subsection (b)(2)(B) of this section); and
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(5) Review

Subject to subparagraph (B), the Secretary shall review the adjusted community rates, the amounts of the basic and supplemental premiums, and values filed under paragraphs (2) and (4) of this subsection and shall approve or disapprove such rates, amounts, and values so submitted. The Chief Actuary of the Centers for Medicare & Medicaid Services shall review the actuarial assumptions and data used by the Medicare+Choice organization with respect to such rates, amounts, and values so submitted to determine the appropriateness of such assumptions and data.

(B) Exception

The Secretary shall not review, approve, or disapprove the amounts submitted under paragraph (3) or, in the case of an MA private fee-for-service plan, subparagraphs (A)(ii) and (B) of paragraph (4).

(C) Rejection of bids

(i) In general

Nothing in this section shall be construed as requiring the Secretary to accept any or every bid submitted by an MA organization under this subsection.

(ii) Authority to deny bids that propose significant increases in cost sharing or decreases in benefits

The Secretary may deny a bid submitted by an MA organization for an MA plan if it proposes significant increases in cost sharing or decreases in benefits offered under the plan.

(6) Submission of bid amounts by MA organizations beginning in 2006

(A) Information to be submitted

For an MA plan (other than an MSA plan) for a plan year beginning on or after January 1, 2006, the information described in this paragraph is as follows:

(A) Basic (and additional) benefits

For benefits described in section 1395w–22(a)(1)(A) of this title and section 300e–1(8) of this title (as specified by the Secretary), a description of the additional benefits to be provided pursuant to such subsection and the value determined for such proposed benefits under such subsection.

(B) Supplemental benefits

For benefits described in section 1395w–22(a)(3) of this title and section 300e–1(8) of this title (as specified by the Secretary), a description of the basic and supplemental benefits, and values so submitted to determine the appropriateness of such assumptions and data.

(B) Exception

The Secretary shall not review, approve, or disapprove the amounts submitted under paragraph (3) or, in the case of an MA private fee-for-service plan, subparagraphs (A)(ii) and (B) of paragraph (4).

(C) Rejection of bids

(i) In general

Nothing in this section shall be construed as requiring the Secretary to accept any or every bid submitted by an MA organization under this subsection.

(ii) Authority to deny bids that propose significant increases in cost sharing or decreases in benefits

The Secretary may deny a bid submitted by an MA organization for an MA plan if it proposes significant increases in cost sharing or decreases in benefits offered under the plan.

(6) Submission of bid amounts by MA organizations beginning in 2006

(A) Information to be submitted

For an MA plan (other than an MSA plan) for a plan year beginning on or after January 1, 2006, the information described in this paragraph is as follows:

(i) The monthly aggregate bid amount for the provision of all items and services under the plan, which amount shall be based on average revenue requirements (as used for purposes of section 300e–1(8) of this title) in the payment area for an enrollee with a national average risk profile for the factors described in section 1395w–23(a)(1)(C) of this title (as specified by the Secretary).

(ii) The proportions of such bid amount that are attributable to—

(I) the provision of benefits under the original medicare fee-for-service program option (as defined in section 1395w–22(a)(1)(B) of this title);

(II) the provision of basic prescription drug coverage; and

(III) the provision of supplemental health care benefits.

(iii) The actuarial basis for determining the amount under clause (i) and the proportions described in clause (ii) and such additional information as the Secretary may require to verify such actuarial bases and the projected number of enrollees in each MA local area.

(iv) A description of deductibles, coinsurance, and copayments applicable under the plan and the actuarial value of such deductibles, coinsurance, and copayments, described in subsection (e)(4)(A) of this section.

(v) With respect to qualified prescription drug coverage, the information required under section 1395w–104 of this title, as incorporated under section 1395w–111(b)(2) of this title, with respect to such coverage.

In the case of a specialized MA plan for special needs individuals, the information de-
scribed in this subparagraph is such information as the Secretary shall specify.

(B) Acceptance and negotiation of bid amounts

(i) Authority

Subject to clauses (iii) and (iv), the Secretary has the authority to negotiate regarding monthly bid amounts submitted under subparagraph (A) (and the proportions described in subparagraph (A)(ii)), including supplemental benefits provided under subsection (b)(1)(C)(ii)(I) of this section and in exercising such authority the Secretary shall have authority similar to the authority of the Director of the Office of Personnel Management with respect to health benefits plans under chapter 89 of title 5.

(ii) Application of FEHBP standard

Subject to clause (iv), the Secretary may only accept such a bid amount or proportion if the Secretary determines that such amount and proportions are supported by the actuarial bases provided under subparagraph (A) and reasonably and equitably reflects the revenue requirements (as used for purposes of section 300e–1(8) of this title) of benefits provided under that plan.

(iii) Noninterference

In order to promote competition under this part and part D of this subchapter and in carrying out such parts, the Secretary may not require any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services under this subchapter or require a particular price structure for payment under such a contract to the extent consistent with the Secretary’s authority under this part.

(iv) Exception

In the case of a plan described in section 1395w–21(a)(2)(C) of this title, the provisions of clauses (i) and (ii) shall not apply and the provisions of paragraph (5)(B), prohibiting the review, approval, or disapproval of amounts described in such paragraph, shall apply to the negotiation and rejection of the monthly bid amounts and the proportions referred to in subparagraph (A).

(b) Monthly premium charged

(1) In general

(A) Rule for other than MSA plans

Subject to the rebate under subparagraph (C), the monthly amount (if any) of the premium charged to an individual enrolled in a Medicare+Choice plan (other than an MSA plan) offered by a Medicare+Choice organization shall be equal to the sum of the Medicare+Choice monthly basic beneficiary premium, the Medicare+Choice monthly supplementary beneficiary premium (if any), and, if the plan provides qualified prescription drug coverage, the MA monthly prescription drug beneficiary premium.

(B) MSA plans

The monthly amount of the premium charged to an individual enrolled in an MSA plan offered by a Medicare+Choice organization shall be equal to the Medicare+Choice monthly supplemental beneficiary premium (if any).

(C) Beneficiary rebate rule

(i) Requirement

The MA plan shall provide to the enrollee a monthly rebate equal to 75 percent (or the applicable rebate percentage specified in clause (iii) in the case of plan years beginning on or after January 1, 2012) of the average per capita savings (if any) described in paragraph (3)(C) or (4)(C), as applicable to the plan and year involved.

(ii) Form of rebate for plan years before 2012

For plan years before 2012, a rebate required under this subparagraph shall be provided through the application of the amount of the rebate toward one or more of the following:

(I) Provision of supplemental health care benefits and payment for premium for supplemental benefits

The provision of supplemental health care benefits described in section 1395w–22(a)(3) of this title in a manner specified under the plan, which may include the reduction of cost-sharing otherwise applicable as well as additional health care benefits which are not benefits under the original medicare fee-for-service program option, or crediting toward an MA monthly supplemental beneficiary premium (if any).

(II) Payment for premium for prescription drug coverage

Crediting toward the MA monthly prescription drug beneficiary premium.

(III) Payment toward part B premium

Crediting toward the premium imposed under part B of this subchapter (determined without regard to the application of subsections (b), (h), and (i) of section 1395r of this title).

(iii) Applicable rebate percentage

The applicable rebate percentage specified in this clause for a plan for a year, based on the system under section 1395w–23(o)(4)(A), is the sum of—

(I) the product of the old phase-in proportion for the year under clause (iv) and 75 percent; and

(II) the product of the new phase-in proportion for the year under clause (iv) and the final applicable rebate percentage under clause (v).

(iv) Old and new phase-in proportions

For purposes of clause (iv)—

(I) for 2012, the old phase-in proportion is \(\frac{1}{3}\) and the new phase-in proportion is \(\frac{1}{5}\); and

(II) for 2013, the old phase-in proportion is \(\frac{1}{3}\) and the new phase-in proportion is \(\frac{2}{5}\); and
(II) for 2014 and any subsequent year, the old phase-in proportion is 0 and the new phase-in proportion is 1.

(v) Final applicable rebate percentage

Subject to clause (vi), the final applicable rebate percentage under this clause is—

(I) in the case of a plan with a quality rating under such system of at least 4.5 stars, 70 percent; and

(II) in the case of a plan with a quality rating under such system of at least 3.5 stars and less than 4.5 stars, 65 percent; and

(III) in the case of a plan with a quality rating under such system of less than 3.5 stars, 50 percent.

(vi) Treatment of low enrollment and new plans

For purposes of clause (v)—

(I) for 2012, in the case of a plan described in subclause (I) of subsection (o)(3)(A)(i), the plan shall be treated as having a rating of 4.5 stars; and

(II) for 2012 or a subsequent year, in the case of a new MA plan (as defined under subsection (III) of subsection (o)(3)(A)(iii)) that is treated as a qualifying plan pursuant to subclause (I) of such subsection, the plan shall be treated as having a rating of 3.5 stars.

(vii) Disclosure relating to rebates

The plan shall disclose to the Secretary information on the form and amount of the rebate provided under this subparagraph or the actuarial value in the case of supplemental health care benefits.

(viii) Application of part B premium reduction

Insofar as an MA organization elects to provide a rebate under this subparagraph under a plan as a credit toward the part B premium under clause (ii)(III), the Secretary shall apply such credit to reduce the premium under section 1395r of this title of each enrollee in such plan as provided in section 1395w–23(a)(1) of this title.

(2) Premium and bid terminology defined

For purposes of this part:

(A) MA monthly basic beneficiary premium

The term “MA monthly basic beneficiary premium” means, with respect to an MA plan—

(i) described in section 1395w–23(a)(1)(B)(I) of this title relating to plans providing rebates, zero; or

(ii) described in section 1395w–23(a)(1)(B)(II) of this title, the amount (if any) by which the unadjusted MA statutory non-drug monthly bid amount (as defined in subparagraph (E)) exceeds the applicable unadjusted MA area-specific non-drug monthly benchmark amount (as defined in section 1395w–23(j) of this title).

(B) MA monthly prescription drug beneficiary premium

The term “MA monthly prescription drug beneficiary premium” means, with respect to an MA plan, the base beneficiary premium (as determined under section 1395w–113(a)(2) of this title and as adjusted under section 1395w–113(a)(1)(B) of this title), less the amount of rebate credited toward such amount under subsection (b)(1)(C)(ii)(II) of this section.

(C) MA monthly supplemental beneficiary premium

(i) In general

The term “MA monthly supplemental beneficiary premium” means, with respect to an MA plan, the portion of the aggregate monthly bid amount submitted under clause (i) of subsection (a)(6)(A) of this section for the year that is attributable under clause (ii)(III) of such subsection to the provision of supplemental health care benefits, less the amount of rebate credited toward such portion under subsection (b)(1)(C)(ii)(I) of this section.

(ii) Application of MA monthly supplemental beneficiary premium

For plan years beginning on or after January 1, 2012, any MA monthly supplemental beneficiary premium charged to an individual enrolled in an MA plan shall be used for the purposes, and in the priority order, described in subclauses (I) through (III) of paragraph (1)(C)(iii).

(D) Medicare+Choice monthly MSA premium

The term “Medicare+Choice monthly MSA premium” means, with respect to a Medicare+Choice plan, the amount of such premium filed under subsection (a)(3)(A) of this section for the plan.

(E) Unadjusted MA statutory non-drug monthly bid amount

The term “unadjusted MA statutory non-drug monthly bid amount” means the portion of the bid amount submitted under clause (i) of subsection (a)(6)(A) of this section for the year that is attributable under clause (ii)(I) of such subsection to the provision of benefits under the original medicare fee-for-service program option (as defined in section 1395w–22(a)(1)(B) of this title).

(3) Computation of average per capita monthly savings for local plans

For purposes of paragraph (1)(C)(i), the average per capita monthly savings referred to in such paragraph for an MA local plan and year is computed as follows:

(A) Determination of statewide average risk adjustment for local plans

(i) In general

Subject to clause (iii), the Secretary shall determine, at the same time rates

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1 So in original. Probably means subclause (I) of section 1395w–23(a)(1)(B)(I) of this title.

2 So in original. Probably means subclause (II) of section 1395w–23(a)(1)(B)(II) of this title.

3 See References in Text note below.
are promulgated under section 1395w–23(b)(1) of this title (beginning with 2006) for each State, the average of the risk adjustment factors to be applied under section 1395w–23(a)(1)(C) of this title to payment for enrollees in that State for MA local plans.

(ii) Treatment of States for first year in which local plan offered
In the case of a State in which no MA local plan was offered in the previous year, the Secretary shall estimate such average. In making such estimate, the Secretary may use average risk adjustment factors applied to comparable States or applied on a national basis.

(iii) Authority to determine risk adjustment for areas other than States
The Secretary may provide for the determination and application of risk adjustment factors under this subparagraph on the basis of areas other than States or on a plan-specific basis.

(B) Determination of risk-adjusted benchmark and risk-adjusted bid for local plans
For each MA plan offered in a local area in a State, the Secretary shall—

(i) adjust the applicable MA area-specific non-drug monthly benchmark amount (as defined in section 1395w–23(j)(1) of this title) for the area by the average risk adjustment factor computed under subparagraph (A); and

(ii) adjust the unadjusted MA statutory non-drug monthly bid amount by such applicable average risk adjustment factor.

(C) Determination of average per capita monthly savings
The average per capita monthly savings described in this subparagraph for an MA regional plan is equal to the amount (if any) by which—

(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i); exceeds

(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

(4) Computation of average per capita monthly savings for regional plans
For purposes of paragraph (1)(C)(i), the average per capita monthly savings referred to in such paragraph for an MA regional plan and year is computed as follows:

(A) Determination of regionwide average risk adjustment for regional plans

(i) In general
The Secretary shall determine, at the same time rates are promulgated under section 1395w–23(b)(1) of this title (beginning with 2006) for each MA region the average of the risk adjustment factors to be applied under section 1395w–23(a)(1)(C) of this title to payment for enrollees in that region for MA regional plans.

(ii) Treatment of regions for first year in which regional plan offered
In the case of an MA region in which no MA regional plan was offered in the previous year, the Secretary shall estimate such average. In making such estimate, the Secretary may use average risk adjustment factors applied to comparable regions or applied on a national basis.

(iii) Authority to determine risk adjustment for areas other than regions
The Secretary may provide for the determination and application of risk adjustment factors under this subparagraph on the basis of areas other than MA regions or on a plan-specific basis.

(B) Determination of risk-adjusted benchmark and risk-adjusted bid for regional plans
For each MA regional plan offered in a region, the Secretary shall—

(i) adjust the applicable MA area-specific non-drug monthly benchmark amount (as defined in section 1395w–23(j)(2) of this title) for the region by the average risk adjustment factor computed under subparagraph (A); and

(ii) adjust the unadjusted MA statutory non-drug monthly bid amount by such applicable average risk adjustment factor.

(C) Determination of average per capita monthly savings
The average per capita monthly savings described in this subparagraph for an MA regional plan is equal to the amount (if any) by which—

(i) the risk-adjusted benchmark amount computed under subparagraph (B)(i); exceeds

(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

(c) Uniform premium and bid amounts
Except as permitted under section 1395w–27(i) of this title, the MA monthly bid amount submitted under subsection (a)(6) of this section, the amounts of the MA monthly basic, prescription drug, and supplemental beneficiary premiums, and the MA monthly MSA premium charged under subsection (b) of this section of an MA organization under this part may not vary among individuals enrolled in the plan.

(d) Terms and conditions of imposing premiums

(1) In general
Each Medicare+Choice organization shall permit the payment of Medicare+Choice monthly basic, prescription drug, and supplemental beneficiary premiums on a monthly basis, may terminate election of individuals for a Medicare+Choice plan for failure to make premium payments only in accordance with section 1395w–21(g)(3)(B)(i) of this title, and may not provide for cash or other monetary rebates as an inducement for enrollment or otherwise.

(2) Beneficiary’s option of payment through withholding from social security payment or use of electronic funds transfer mechanism
In accordance with regulations, an MA organization shall permit each enrollee, at the enrollee’s option, to make payment of premiums
(if any) under this part to the organization through—

(A) withholding from benefit payments in the manner provided under section 1395s of this title with respect to monthly premiums under section 1395r of this title;

(B) an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account); or

(C) such other means as the Secretary may specify, including payment by an employer or under employment-based retiree health coverage (as defined in section 1395w–132(c)(1) of this title) on behalf of an employee or former employee (or dependent).

All premium payments that are withheld under subparagraph (A) shall be credited to the appropriate Trust Fund (or Account thereof), as specified by the Secretary, under this subchapter and shall be paid to the MA organization involved. No charge may be imposed under an MA plan with respect to the election of the payment option described in subparagraph (A). The Secretary shall consult with the Commissioner of Social Security and the Secretary of the Treasury regarding methods for allocating premiums withheld under subparagraph (A) among the appropriate Trust Funds and Account.

(3) Information necessary for collection

In order to carry out paragraph (2)(A) with respect to an enrollee who has elected such paragraph to apply, the Secretary shall transmit to the Commissioner of Social Security—

(A) by the beginning of each year, the name, social security account number, consolidated monthly beneficiary premium described in paragraph (4) owed by such enrollee for each month during the year, and other information determined appropriate by the Secretary in consultation with the Commissioner of Social Security; and

(B) periodically throughout the year, information to update the information previously transmitted under this paragraph for the year.

(4) Consolidated monthly beneficiary premium

In the case of an enrollee in an MA plan, the Secretary shall provide a mechanism for the consolidation of—

(A) the MA monthly basic beneficiary premium (if any);

(B) the MA monthly supplemental beneficiary premium (if any); and

(C) the MA monthly prescription drug beneficiary premium (if any).

(e) Limitation on enrollee liability

(1) For basic and additional benefits before 2006

For periods before 2006, in no event may—

(A) the Medicare+Choice monthly basic beneficiary premium (multiplied by 12) charged and the actuarial value of the deductibles, coinsurance, and copayments charged with respect to such benefits may not exceed the adjusted community rate for such benefits (as defined in subsection (c)(1) of this section).

(B) the actuarial value of the deductibles, coinsurance, and copayments that would be applicable on average to individuals enrolled under the MA monthly prescription drug beneficiary premium (if any).

(2) For supplemental benefits before 2006

For periods before 2006, if the Medicare+Choice organization provides to its members enrolled under this part in a Medicare+Choice plan described in section 1395w–21(a)(2)(A) of this title with respect to supplemental benefits described in section 1395w–22(a)(3) of this title, the sum of the Medicare+Choice monthly supplemental beneficiary premium (multiplied by 12) charged and the actuarial value of its deductibles, coinsurance, and copayments charged with respect to such benefits may not exceed the adjusted community rate for such benefits (as defined in subsection (c)(1) of this section).

(3) Determination on other basis

If the Secretary determines that adequate data are not available to determine the actuarial value under paragraph (1)(A), (2), or (4), the Secretary may determine such amount with respect to all individuals in same geographic area, the State, or in the United States, eligible to enroll in the Medicare+Choice plan involved under this part or on the basis of other appropriate data.

(4) Special rule for private fee-for-service plans and for basic benefits beginning in 2006

With respect to a Medicare+Choice private fee-for-service plan (other than a plan that is an MSA plan) and for periods beginning with 2006, with respect to an MA plan described in section 1395w–21(a)(2)(A) of this title, in no event may—

(A) the actuarial value of the deductibles, coinsurance, and copayments applicable on average to individuals enrolled under this part with such a plan of an organization with respect to benefits under the original Medicare+Choice private fee-for-service program option, exceed

(B) the actuarial value of the deductibles, coinsurance, and copayments that would be applicable with respect to such benefits on average to individuals enrolled under part A of this subchapter and enrolled under part B of this subchapter if they were not members of a Medicare+Choice organization for the year.

(f) Requirement for additional benefits before 2006

(1) Requirement

(A) In general

For years before 2006, each Medicare+Choice organization (in relation to a Medicare+Choice plan, other than an MSA plan) shall provide a mechanism for the consolidation of—

(A) the Medicare+Choice monthly supplemental beneficiary premium (multiplied by 12) charged and the actuarial value of the deductibles, coinsurance, and copayments that would be applicable on average to individuals enrolled under this part with a Medicare+Choice plan described in section 1395w–21(a)(2)(A) of this title of an organization with respect to required benefits described in section 1395w–22(a)(1)(A) of this title and additional benefits (if any) required under subsection (f)(1)(A) of this section for a year, exceed

(B) the actuarial value of the deductibles, coinsurance, and copayments that would be applicable on average to individuals entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter if they were not members of a Medicare+Choice organization for the year.
plan, it offers) shall provide that if there is an excess amount (as defined in subparagraph (B)) for the plan for a contract year, subject to the succeeding provisions of this subsection, the organization shall provide to individuals such additional benefits (as the organization may specify) in a value which the Secretary determines is at least equal to the adjusted excess amount (as defined in subparagraph (C)).

(B) Excess amount

For purposes of this paragraph, the "excess amount", for an organization for a plan, is the amount (if any) by which—

(i) the average of the capitation payments made to the organization under section 1395w–23 of this title for the plan at the beginning of contract year, exceeds

(ii) the actuarial value of the required benefits described in section 1395w–22(a)(1)(A) of this title under the plan for individuals under this part, as determined based upon an adjusted community rate described in paragraph (3) (as reduced for the actuarial value of the coinsurance, copayments, and deductibles under parts A and B of this subchapter).

(C) Adjusted excess amount

For purposes of this paragraph, the "adjusted excess amount", for an organization for a plan, is the excess amount reduced to reflect any amount withheld and reserved for the organization for the year under paragraph (2).

(D) Uniform application

This paragraph shall be applied uniformly for all enrollees for a plan.

(E) Premium reductions

(i) In general

Subject to clause (ii), as part of providing any additional benefits required under subparagraph (A), a Medicare+Choice organization may elect a reduction in its payments under section 1395w–23(a)(1)(A) of this title with respect to a Medicare+Choice plan and the Secretary shall apply such reduction to reduce the premium under section 1395r of this title of each enrollee in such plan as provided in section 1395s(i) of this title.

(ii) Amount of reduction

The amount of the reduction under clause (i) with respect to any enrollee in a Medicare+Choice plan—

(I) may not exceed 125 percent of the premium described under section 1395r(a)(3) of this title; and

(II) shall apply uniformly to each enrollee of the Medicare+Choice plan to which such reduction applies.

(F) Construction

Nothing in this subsection shall be construed as preventing a Medicare+Choice organization from providing supplemental benefits (described in section 1395w–22(a)(3) of this title) that are in addition to the health care benefits otherwise required to be provided under this paragraph and from imposing a premium for such supplemental benefits.

(2) Stabilization fund

A Medicare+Choice organization may provide that a part of the value of an excess amount described in paragraph (1) be withheld and reserved in the Federal Hospital Insurance Trust Fund and in the Federal Supplementary 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 subsequent periods by the organization in accordance with this paragraph. Any of such value of the amount reserved which is not provided as additional benefits described in paragraph (1)(A) to individuals electing the Medicare+Choice plan of the organization in accordance with such paragraph prior to the end of such periods, shall revert for the use of such trust funds.

(3) Adjusted community rate

For purposes of this subsection, subject to paragraph (4), the term "adjusted community rate" for a service or services means, at the election of a Medicare+Choice organization, either—

(A) the rate of payment for that service or services which the Secretary annually determines would apply to an individual electing a Medicare+Choice plan under this part 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 such an individual, as the Secretary annually estimates is attributable to that service or services, but adjusted for differences between the utilization characteristics of the individuals electing coverage under this part and the utilization characteristics of the other enrollees with the plan (or, if the Secretary finds that adequate data are not available to adjust for those differences, the differences between the utilization characteristics of individuals selecting other Medicare+Choice coverage, Medicare+Choice eligible individuals in the area, in the State, or in the United States, eligible to elect Medicare+Choice coverage under this part and the utilization characteristics of the rest of the population in the area, in the State, or in the United States, respectively).

(4) Determination based on insufficient data

For purposes of this subsection, if the Secretary finds that there is insufficient enrollment experience to determine an average of the capitation payments to be made under this part at the beginning of a contract period or to determine (in the case of a newly provider-sponsored organization or other new organization) the adjusted community rate for the organization, the Secretary may determine such an average based on the enrollment
experience of other contracts entered into under this part and may determine such a rate using data in the general commercial marketplace.

(g) Prohibition of State imposition of premium taxes

No State may impose a premium tax or similar tax with respect to payments to Medicare+Choice organizations under section 1395w–23 of this title or premiums paid to such organizations under this part.

(h) Permitting use of segments of service areas

The Secretary shall permit a Medicare+Choice organization to elect to apply the provisions of this section uniformly to separate segments of a service area (rather than uniformly to an entire service area) as long as such segments are composed of one or more Medicare+Choice payment areas.


REFERENCES IN TEXT

Part D of this subchapter, referred to in subsec. (a)(6)(B)(iii), is classified to section 1395w–101 et seq. of this title.

Parts A and B of this subchapter, referred to in subsecs. (b)(1)(C)(iii), (viii), (e)(1)(B), (d)(B), and (f)(1)(B)(ii), are classified to section 1395c et seq. and section 1385 et seq., respectively, of this title.

Cl. (i)(C), referred to in subsec. (b)(2)(C)(ii), was struck out and a new cl. (iii) was added by Pub. L. 111–152, §1102(d)(2). See 2010 Amendment note below. As so amended, par. (1)(C)(iii) no longer relates to purposes of rebates and no longer contains a subcl. (III).

AMENDMENTS


Subsec. (a)(6)(A). Pub. L. 111–148, §3201(d)(1), which directed insertion of “Information to be submitted under this paragraph shall be certified by a qualified member of the American Academy of Actuaries and shall meet actuarial guidelines and rules established by the Secretary under subparagraph (B)(v).” at end of concluding provisions, was repealed by Pub. L. 111–152, §1102(a). See Effective Date of 2010 Amendment note below.

Subsec. (a)(6)(B)(i). Pub. L. 111–148, §3201(d)(2)(A), which directed substitution of “(III) and (IV)” for “(I) and (IV)”, was repealed by Pub. L. 111–152, §1102(a). See Effective Date of 2010 Amendment note below.

Subsec. (a)(6)(B)(v). Pub. L. 111–148, §3201(d)(2)(B), which directed addition of cl. (v), was repealed by Pub. L. 111–152, §1102(a). As enacted, front text as follows: “(I) IN GENERAL.—In order to establish fair MA competitive benchmarks under section 1395w–23(1)(A)(i) of this title, the Secretary, acting through the Chief Actuary of the Centers for Medicare & Medicaid Services (in this clause referred to as the ‘Chief Actuary’), shall establish—

‘‘(aa) actuarial guidelines for the submission of bid information under this paragraph; and
‘‘(bb) bidding rules that are appropriate to ensure accurate bids and fair competition among MA plans.

‘‘(II) DENIAL OF BID AMOUNTS.—The Secretary shall deny monthly bid amounts submitted under subparagraph (A) that do not meet the actuarial guidelines and rules established under subclause (I).

‘‘(III) REFUSAL TO ACCEPT CERTAIN BIDS DUE TO MISREPRESENTATIONS AND FAILURES TO ADEQUATELY MEET REQUIREMENTS.—In the case where the Secretary determines that the actuaries of the organization were complicit in those misrepresentations and failures, report those actuaries to the Actuarial Board for Counseling and Discipline.” See Effective Date of 2010 Amendment note below.


Subsec. (b)(1)(C)(ii). Pub. L. 111–148, §3201(d)(2)(B), added cl. (ii) and struck out former cl. (iii). Prior to amendment, text read as follows: “For plan years beginning on or after January 1, 202, a rebate required under this subparagraph may not be used for the purpose described in clause (i)(II) and shall be provided through the application of the amount of the rebate in the following priority order:

‘‘(I) First, to use the most significant share to meaningfully reduce cost-sharing otherwise applicable for benefits under the original medicare fee-for-service program under parts A and B and for qualified prescription drug coverage under part D, including the reduction of any deductibles, copayments, and maximum limitations on out-of-pocket expenses otherwise applicable. Any reduction of maximum limitations on out-of-pocket expenses under the preceding sentence shall apply to all benefits under the original medicare fee-for-service program option. The Secretary may provide guidance on meaningfully reducing cost-sharing under this subclause, except that such guidance may not require a particular amount of cost-sharing or reduction in cost-sharing.

‘‘(II) Second, to use the next most significant share to meaningfully provide coverage of preventive and wellness health care benefits (as defined by the Secretary) which are not benefits under the original medicare fee-for-service program, such as smoking cessation, a free flu shot, and an annual physical examination.

‘‘(III) Third, to use the remaining share to meaningfully provide coverage of other health care benefits which are not benefits under the original medicare fee-for-service program, such as eye examinations and dental coverage, and are not benefits described in subclause (II).


Subsec. (a)(4). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(6)(C)(iii)(I)], which directed insertion of “section” after “described in”, was executed by making the insertion after “described in” the second time appearing in introductory provisions to reflect the probable intent of Congress.


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. 106–113, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Repeal of sections 3201 and 3203 of Pub. L. 111–148 and the amendments made by such sections, 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.


EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 222(a)(1), (b), (c), (g) of Pub. L. 108–173 applicable with respect to plan years beginning on or after Jan. 1, 2006, see section 222(a) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

Pub. L. 108–173, title II, §222(c), Dec. 8, 2003, 117 Stat. 2298, provided that: “The amendments made by this subsection [probably should be “this section”] amending this section and section 1395w–26 of this title shall take effect on the date of the enactment of this Act [Dec. 8, 2003].”

EFFECTIVE DATE OF 2002 AMENDMENT


EFFECTIVE DATE OF 2000 AMENDMENT

Amendment by section 1(a)(6) [title VI, §606(a)(1)] of Pub. L. 106–554 applicable to years beginning with 2003, see section 1(a)(6) [title VI, §606(b)] of Pub. L. 106–554, set out as a note under section 1395w of this title.

Pub. L. 106–554, §1(a)(6) [title VI, §622(b)], Dec. 21, 2000, 114 Stat. 2763, 2783A–566, provided that: “The amendments made by subsection (a) [amending this section] shall apply to submissions made on or after May 1, 2001.”

EFFECTIVE DATE OF 1999 AMENDMENT


§1395w–25. Organizational and financial requirements for Medicare+Choice organizations; provider-sponsored organizations

(a) Organized and licensed under State law

(1) In general

Subject to paragraphs (2) and (3), a Medicare+Choice organization shall be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a Medicare+Choice plan.

(2) Special exception for provider-sponsored organizations

(A) In general

In the case of a provider-sponsored organization that seeks to offer a Medicare+Choice plan in a State, the Secretary shall waive the requirement of paragraph (1) that the organization be licensed in that State if—

(i) the organization files an application for such waiver with the Secretary by not later than November 1, 2002, and

(ii) the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for approval of the application described in subparagraph (B), (C), or (D) has been met.

(B) Failure to act on licensure application on a timely basis

The ground for approval of such a waiver application described in this subparagraph is that the State has failed to complete action on a licensing application of the organization within 90 days of the date of the State’s receipt of a substantially complete application. No period before August 5, 1997, shall be included in determining such 90-day period.

(C) Denial of application based on discriminatory treatment

The ground for approval of such a waiver application described in this subparagraph is that the State has denied such a licensing application and—

(i) the standards or review process imposed by the State as a condition of approval of the license imposes any material requirements, procedures, or standards (other than solvency requirements) to such organizations that are not generally applicable to other entities engaged in a substantially similar business, or

(ii) the State requires the organization, as a condition of licensure, to offer any product or plan other than a Medicare+Choice plan.
(D) Denial of application based on application of solvency requirements

With respect to waiver applications filed on or after the date of publication of solvency standards under section 1395w–26(a) of this title, the ground for approval of such a waiver application described in this subparagraph is that the State has denied such a licensing application based (in whole or in part) on the organization's failure to meet applicable solvency requirements and—

(i) such requirements are not the same as the solvency standards established under section 1395w–26(a) of this title; or

(ii) the State has imposed as a condition of approval of the license documentation or information requirements relating to solvency or other material requirements, procedures, or standards relating to solvency that are different from the requirements, procedures, and standards applied by the Secretary under subsection (d)(2) of this section.

For purposes of this paragraph, the term "solvency requirements" means requirements relating to solvency and other matters covered under the standards established under section 1395w–26(a) of this title.

(E) Treatment of waiver

In the case of a waiver granted under this paragraph for a provider-sponsored organization with respect to a State—

(i) Limitation to State

The waiver shall be effective only with respect to that State and does not apply to any other State.

(ii) Limitation to 36-month period

The waiver shall be effective only for a 36-month period and may not be renewed.

(iii) Conditioned on compliance with consumer protection and quality standards

The continuation of the waiver is conditioned upon the organization's compliance with the requirements described in subparagraph (G).

(iv) Preemption of State law

Any provisions of law of that State which relate to the licensing of the organization and which prohibit the organization from providing coverage pursuant to a contract under this part shall be superseded.

(F) Prompt action on application

The Secretary shall grant or deny such a waiver application within 60 days after the date the Secretary determines that a substantially complete waiver application has been filed. Nothing in this section shall be construed as preventing an organization which has had such a waiver application denied from submitting a subsequent waiver application.

(G) Application and enforcement of State consumer protection and quality standards

(i) In general

A waiver granted under this paragraph to an organization with respect to licens-

ing under State law is conditioned upon the organization's compliance with all consumer protection and quality standards insofar as such standards—

(I) would apply in the State to the organization if it were licensed under State law;

(II) are generally applicable to other Medicare+Choice organizations and plans in the State; and

(III) are consistent with the standards established under this part.

Such standards shall not include any standard preempted under section 1395w–26(b)(3)(B) of this title.

(ii) Incorporation into contract

In the case of such a waiver granted to an organization with respect to a State, the Secretary shall incorporate the requirement that the organization (and Medicare+Choice plans it offers) comply with standards under clause (i) as part of the contract between the Secretary and the organization under section 1395w–27 of this title.

(iii) Enforcement

In the case of such a waiver granted to an organization with respect to a State, the Secretary may enter into an agreement with the State under which the State agrees to provide for monitoring and enforcement activities with respect to compliance of such an organization and its Medicare+Choice plans with such standards. Such monitoring and enforcement shall be conducted by the State in the same manner as the State enforces such standards with respect to other Medicare+Choice organizations and plans, without discrimination based on the type of organization to which the standards apply. Such an agreement shall specify or establish mechanisms by which compliance activities are undertaken, while not lengthening the time required to review and process applications for waivers under this paragraph.

(H) Report

By not later than December 31, 2001, the Secretary shall submit to the Committee on Ways and Means and the Committee on Commerce of the House of Representatives and the Committee on Finance of the Senate a report regarding whether the waiver process under this paragraph should be continued after December 31, 2002. In making such recommendation, the Secretary shall consider, among other factors, the impact of such process on beneficiaries and on the long-term solvency of the program under this subchapter.

(3) Licensure does not substitute for or constitute certification

The fact that an organization is licensed in accordance with paragraph (1) does not deem the organization to meet other requirements imposed under this part.
(b) Assumption of full financial risk

The Medicare+Choice organization shall assume full financial risk on a prospective basis for the provision of the health care services for which benefits are required to be provided under section 1395w–22(a)(1) of this title, except that the organization—

(1) may obtain insurance or make other arrangements for the cost of providing to any enrolled member such services the aggregate value of which exceeds such aggregate level as the Secretary specifies from time to time,

(2) may obtain insurance or make other arrangements for the cost of such services provided to its enrolled members other than through the organization because medical necessity required their provision before they could be secured through the organization,

(3) may 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 exceed 115 percent of its income for such fiscal year, and

(4) may make arrangements with physicians or other health care 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.

(c) Certification of provision against risk of insolvency for unlicensed PSOs

(1) In general

Each Medicare+Choice organization that is a provider-sponsored organization, that is not licensed by a State under subsection (a) of this section, and for which a waiver application has been approved under subsection (a)(2) of this section, shall meet standards established under section 1395w–26(a) of this title relating to the financial solvency and capital adequacy of the organization.

(2) Certification process for solvency standards for PSOs

The Secretary shall establish a process for the receipt and approval of applications of a provider-sponsored organization described in paragraph (1) for certification (and periodic recertification) of the organization as meeting such solvency standards. Under such process, the Secretary shall act upon such a certification application not later than 60 days after the date the application has been received.

(d) “Provider-sponsored organization” defined

(1) In general

In this part, the term “provider-sponsored organization” means a public or private entity—

(A) that is established or organized, and operated, by a health care provider, or group of affiliated health care providers,

(B) that provides a substantial proportion (as defined by the Secretary in accordance with paragraph (2)) of the health care items and services under the contract under this part directly through the provider or affiliated group of providers, and

(C) with respect to which the affiliated providers share, directly or indirectly, substantial financial risk with respect to the provision of such items and services and have at least a majority financial interest in the entity.

(2) Substantial proportion

In defining what is a “substantial proportion” for purposes of paragraph (1)(B), the Secretary—

(A) shall take into account the need for such an organization to assume responsibility for providing—

(i) significantly more than the majority of the items and services under the contract under this section through its own affiliated providers; and

(ii) most of the remainder of the items and services under the contract through providers with which the organization has an agreement to provide such items and services,

in order to assure financial stability and to address the practical considerations involved in integrating the delivery of a wide range of service providers;

(B) shall take into account the need for such an organization to provide a limited proportion of the items and services under the contract through providers that are neither affiliated with nor have an agreement with the organization; and

(C) may allow for variation in the definition of substantial proportion among such organizations based on relevant differences among the organizations, such as their location in an urban or rural area.

(3) Affiliation

For purposes of this subsection, a provider is “affiliated” with another provider if, through contract, ownership, or otherwise—

(A) one provider, directly or indirectly, controls, is controlled by, or is under common control with the other,

(B) both providers are part of a controlled group of corporations under section 1563 of the Internal Revenue Code of 1986,

(C) each provider is a participant in a lawful combination under which each provider shares substantial financial risk in connection with the organization’s operations, or

(D) both providers are part of an affiliated service group under section 414 of such Code.

(4) Control

For purposes of paragraph (3), control is presumed to exist if one party, directly or indirectly, owns, controls, or holds the power to vote, or proxies for, not less than 51 percent of the voting rights or governance rights of another.

(5) “Health care provider” defined

In this subsection, the term “health care provider” means—

(A) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, and
(B) any entity that is engaged in the delivery of health care services in a State and that, if it is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, is so licensed.

(6) Regulations

The Secretary shall issue regulations to carry out this subsection


REFERENCES IN TEXT

The Internal Revenue Code of 1986, referred to in subsec. (d)(3)(B), (D), is classified generally to Title 26, Internal Revenue Code.

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate internal Revenue Code.

sec. (d)(3)(B), (D), is classified generally to Title 26, Internal Revenue Code.

§ 1395w–26. Establishment of standards

(a) Establishment of solvency standards for provider-sponsored organizations

(1) Establishment

(A) In general

The Secretary shall establish, on an expedited basis and using a negotiated rulemaking process under subchapter III of chapter 5 of title 5, standards described in section 1395w–25(c)(1) of this title (relating to the financial solvency and capital adequacy of the organization) that entities must meet to qualify as provider-sponsored organizations under this part.

(B) Factors to consider for solvency standards

In establishing solvency standards under subparagraph (A) for provider-sponsored organizations, the Secretary shall consult with interested parties and shall take into account—

(i) the delivery system assets of such an organization and ability of such an organization to provide services directly to enrollees through affiliated providers,

(ii) alternative means of protecting against insolvency, including reinsurance, unrestricted surplus, letters of credit, guarantees, organizational insurance coverage, partnerships with other licensed entities, and valuation attributable to the ability of such an organization to meet its service obligations through direct delivery of care, and

(iii) any standards developed by the National Association of Insurance Commissioners specifically for risk-based health care delivery organizations.

(C) Enrollee protection against insolvency

Such standards shall include provisions to prevent enrollees from being held liable to any person or entity for the Medicare+Choice organization’s debts in the event of the organization’s insolvency.

(2) Publication of notice

In carrying out the rulemaking process under this subsection, the Secretary, after consultation with the National Association of Insurance Commissioners, the American Academy of Actuaries, organizations representative of medicare beneficiaries, and other interested parties, shall publish the notice provided for under section 564(a) of title 5 not later than 45 days after August 5, 1997.

(3) Target date for publication of rule

As part of the notice under paragraph (2), and for purposes of this subsection, the “target date for publication” (referred to in section 564(a)(5) of such title) shall be April 1, 1998.

(4) Abbreviated period for submission of comments

In applying section 564(c) of such title under this subsection, “15 days” shall be substituted for “30 days”.

(5) Appointment of negotiated rulemaking committee and facilitator

The Secretary shall provide for—

(A) the appointment of a negotiated rulemaking committee under section 565(a) of such title by not later than 30 days after the end of the comment period provided for under section 564(c) of such title (as shortened under paragraph (4)), and

(B) the nomination of a facilitator under section 566(c) of such title by not later than 10 days after the date of appointment of the committee.

(6) Preliminary committee report

The negotiated rulemaking committee appointed under paragraph (5) shall report to the Secretary, by not later than January 1, 1998, regarding the committee’s progress on achieving a consensus with regard to the rulemaking proceeding and whether such consensus is likely to occur before 1 month before the target date for publication of the rule. If the committee reports that the committee has failed to make significant progress towards such consensus or is unlikely to reach such consensus by the target date, the Secretary may terminate such process and provide for the publication of a rule under this subsection through such other methods as the Secretary may provide.

(7) Final committee report

If the committee is not terminated under paragraph (6), the rulemaking committee shall submit a report containing a proposed rule by not later than 1 month before the target date of publication.

(8) Interim, final effect

The Secretary shall publish a rule under this subsection in the Federal Register by not later
than the target date of publication. Such rule shall be effective and final immediately on an interim basis, but is subject to change and revision after public notice and opportunity for a period (of not less than 60 days) for public comment. In connection with such rule, the Secretary shall specify the process for the timely review and approval of applications of entities to be certified as provider-sponsored organizations pursuant to such rules and consistent with this subsection.

(9) Publication of rule after public comment

The Secretary shall provide for consideration of such comments and republication of such rule by not later than 1 year after the target date of publication.

(b) Establishment of other standards

(1) In general

The Secretary shall establish by regulation other standards (not described in subsection (a) of this section) for Medicare+Choice organizations and plans consistent with, and to carry out, this part. The Secretary shall publish such regulations by June 1, 1998. In order to carry out this requirement in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

(2) Use of current standards

Consistent with the requirements of this part, standards established under this subsection shall be based on standards established under section 1395mm of this title to carry out analogous provisions of such section.

(3) Relation to State laws

The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.

(4) Prohibition of midyear implementation of significant new regulatory requirements

The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a Medicare+Choice organization or plan.

(9) Publication of rule after public comment

The Secretary shall provide for consideration of such comments and republication of such rule by not later than 1 year after the target date of publication.

(b) Establishment of other standards

(1) In general

The Secretary shall establish by regulation other standards (not described in subsection (a) of this section) for Medicare+Choice organizations and plans consistent with, and to carry out, this part. The Secretary shall publish such regulations by June 1, 1998. In order to carry out this requirement in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

(2) Use of current standards

Consistent with the requirements of this part, standards established under this subsection shall be based on standards established under section 1395mm of this title to carry out analogous provisions of such section.

(3) Relation to State laws

The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.

(4) Prohibition of midyear implementation of significant new regulatory requirements

The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a Medicare+Choice organization or plan.


§ 1395w–27. Contracts with Medicare+Choice organizations

(a) In general

The Secretary shall not permit the election under section 1395w–21 of this title of a Medicare+Choice plan offered by a Medicare+Choice organization under this part, and no payment shall be made under section 1395w–23 of this title to an organization, unless the Secretary has entered into a contract under this section with the organization with respect to the offering of such plan. Such a contract with an organization may cover more than 1 Medicare+Choice plan. Such contract shall provide that the organization agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(b) Minimum enrollment requirements

(1) In general

Subject to paragraph (2), the Secretary may not enter into a contract under this section with a Medicare+Choice organization unless the organization has—

(A) at least 5,000 individuals (or 1,500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization, or

(B) at least 1,500 individuals (or 500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization primarily serves individuals residing outside of urbanized areas.

(2) Application to MSA plans

In applying paragraph (1) in the case of a Medicare+Choice organization that is offering an MSA plan, paragraph (1) shall be applied by substituting covered lives for individuals.

(3) Allowing transition

The Secretary may waive the requirement of paragraph (1) during the first 3 contract years with respect to an organization.

(c) Contract period and effectiveness

(1) Period

Each contract under this section shall be for a term of at least 1 year, as determined by the
Secretary, and may be made automatically renew-able from term to term in the absence of notice by either party of intention to terminate at the end of the current term.

(2) Termination authority

In accordance with procedures established under subsection (h) of this section, the Secretary may at any time terminate any such contract 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 inconsistent with the efficient and effective administration of this part; or

(C) no longer substantially meets the applicable conditions of this part.

(3) Effective date of contracts

The effective date of any contract executed pursuant to this section shall be specified in the contract, except that in no case shall a contract under this section which provides for coverage under an MSA plan be effective before January 1999 with respect to such coverage.

(4) Previous terminations

(A) In general

The Secretary may not enter into a contract with a Medicare+Choice organization if a previous contract with that organization under this section was terminated at the request of the organization within the preceding 2-year period, except as provided in subparagraph (B) and except in such other circumstances which warrant special consideration, as determined by the Secretary.

(B) Earlier re-entry permitted where change in payment policy

Subparagraph (A) shall not apply with respect to the offering by a Medicare+Choice organization of a Medicare+Choice plan in a Medicare+Choice payment area if during the 6-month period beginning on the date the organization notified the Secretary of the intention to terminate the most recent previous contract, there was a legislative change enacted (or a regulatory change adopted) that has the effect of increasing payment amounts under section 1395w–23 of this title for that Medicare+Choice payment area.

(5) Contracting authority

The authority vested in the Secretary by this part 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.

(d) Protections against fraud and beneficiary protections

(1) Periodic auditing

The Secretary shall provide for the annual auditing of the financial records (including data relating to medicare utilization and costs, including allowable costs under section 1395w–27a(c) of this title) of at least one-third of the Medicare+Choice organizations offering Medicare+Choice plans under this part. The Comptroller General shall monitor auditing activities conducted under this subsection.

(2) Inspection and audit

Each contract under this section shall provide that the Secretary, or any person or organization designated by the Secretary—

(A) shall have the right to timely 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

(B) shall have the right to timely audit and inspect any records of the Medicare+Choice organization that pertain to services performed or determinations of amounts payable under the contract.

(3) Enrollee notice at time of termination

Each contract under this section shall require the organization 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 with the organization under this part.

(4) Disclosure

(A) In general

Each Medicare+Choice organization shall, in accordance with regulations of the Secretary, report to the Secretary financial information which shall include the following:

(i) Such information as the Secretary may require demonstrating that the organization has a fiscally sound operation.

(ii) A copy of the report, if any, filed with the Secretary containing the information required to be reported under section 1320a–3 of this title by disclosing entities.

(iii) A description of transactions, as specified by the Secretary, between the organization and a party in interest. Such transactions shall include—

(I) any sale or exchange, or leasing of any property between the organization and a party in interest;

(II) any furnishing for consideration of goods, services (including management services), or facilities between the organization and a party in interest, but not including salaries paid to employees for services provided in the normal course of their employment and health services provided to members by hospitals and other providers and by staff, medical group (or groups), individual practice association (or associations), or any combination thereof; and

(III) any lending of money or other extension of credit between an organization and a party in interest.

The Secretary may require that information reported respecting an organization which
controls, is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(B) “Party in interest” defined

For the purposes of this paragraph, the term “party in interest” means—

(i) any director, officer, partner, or employee responsible for management or administration of a Medicare+Choice organization, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the organization, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the organization, and, in the case of a Medicare+Choice organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

(ii) any entity in which a person described in clause (i)—

(I) is an officer or director;

(II) is a partner (if such entity is organized as a partnership);

(III) has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(IV) has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(iii) any person directly or indirectly controlling, controlled by, or under common control with an organization; and

(iv) any spouse, child, or parent of an individual described in clause (i).

(C) Access to information

Each Medicare+Choice organization shall make the information reported pursuant to subparagraph (A) available to its enrollees upon reasonable request.

(5) Loan information

The contract 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.

(6) Review to ensure compliance with care management requirements for specialized medicare advantage plans for special needs individuals

In conjunction with the periodic audit of a specialized Medicare Advantage plan for special needs individuals under paragraph (1), the Secretary shall conduct a review to ensure that such organization offering the plan meets the requirements described in section 1395w–29(f)(5) of this title.

(e) Additional contract terms

(1) In general

The contract shall contain such other terms and conditions not inconsistent with this part (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.

(2) Cost-sharing in enrollment-related costs

(A) In general

A Medicare+Choice organization and a PDP sponsor under part D of this subchapter shall pay the fee established by the Secretary under subparagraph (B).

(B) Authorization

The Secretary is authorized to charge a fee to each Medicare+Choice organization with a contract under this part and each PDP sponsor with a contract under part D of this subchapter that is equal to the organization’s or sponsor’s pro rata share (as determined by the Secretary) of the aggregate amount of fees which the Secretary is directed to collect in a fiscal year. Any amounts collected shall be available without further appropriation to the Secretary for the purpose of carrying out section 1395w–21 of this title (relating to enrollment and dissemination of information), section 1395w–101(c) of this title, and section 1395b–4 of this title (relating to the health insurance counseling and assistance program).

(C) Authorization of appropriations

There are authorized to be appropriated for the purposes described in subparagraph (B) for each fiscal year beginning with fiscal year 2001 and ending with fiscal year 2006 an amount equal to $100,000,000, and for each fiscal year beginning with fiscal year 2006 an amount equal to $200,000,000, reduced by the amount of fees authorized to be collected under this paragraph and section 1395w–112(b)(3)(D) of this title for the fiscal year.

(D) Limitation

In any fiscal year the fees collected by the Secretary under subparagraph (B) shall not exceed the lesser of—

(i) the estimated costs to be incurred by the Secretary in the fiscal year in carrying out the activities described in section 1395w–21 of this title and section 1395w–101(c) of this title and section 1395b–4 of this title; or

(ii)(I) $200,000,000 in fiscal year 1998;

(II) $150,000,000 in fiscal year 1999;

(III) $100,000,000 in fiscal year 2000;

(IV) the Medicare+Choice portion (as defined in subparagraph (E)) of $100,000,000 in fiscal year 2001 and each succeeding fiscal year before fiscal year 2006; and

(V) the applicable portion (as defined in subparagraph (F)) of $200,000,000 in fiscal year 2006 and each succeeding fiscal year.

(E) Medicare+Choice portion defined

In this paragraph, the term “Medicare+Choice portion” means, for a fiscal year, the ratio, as estimated by the Secretary, of—

(i) the average number of individuals enrolled in Medicare+Choice plans during the fiscal year, to

(ii) the average number of individuals entitled to benefits under part A of this subchapter, and enrolled under part B of this subchapter, during the fiscal year.
(F) Applicable portion defined
In this paragraph, the term "applicable portion" means, for a fiscal year—
(i) with respect to MA organizations, the Secretary's estimate of the total proportion of expenditures under this subchapter that are attributable to expenditures made under this part (including payments under part D of this subchapter that are made to such organizations); or
(ii) with respect to PDP sponsors, the Secretary's estimate of the total proportion of expenditures under this subchapter that are attributable to expenditures made to such sponsors under part D of this subchapter.

(3) Agreements with federally qualified health centers
(A) Payment levels and amounts
A contract under this section with an MA organization shall require the organization to provide, in any written agreement described in section 1395w–23(a)(4) of this title between the organization and a federally qualified health center, for a level and amount of payment to the federally qualified health center for services provided by such health center that is not less than the level and amount of payment that the plan would make for such services if the services had been furnished by a entity providing similar services that was not a federally qualified health center.

(B) Cost-sharing
Under the written agreement referred to in subparagraph (A), a federally qualified health center must accept the payment amount referred to in such subparagraph plus the Federal payment provided for in section 1395w–112(b)(4) of this title as payment for services covered by the agreement, except that such a health center may collect any amount of cost-sharing permitted under the contract under this section, so long as the amounts of any deductible, coinsurance, or copayment comply with the requirements under section 1395w–24(e) of this title.

(4) Requirement for minimum medical loss ratio
If the Secretary determines for a contract year (beginning with 2014) that an MA plan has failed to have a medical loss ratio of at least .85—

(A) the MA plan shall remit to the Secretary an amount equal to the product of—
(i) the total revenue of the MA plan under this part for the contract year; and
(ii) the difference between .85 and the medical loss ratio;

(B) for 3 consecutive contract years, the Secretary shall not permit the enrollment of new enrollees under the plan for coverage during the second succeeding contract year; and

(C) the Secretary shall terminate the plan contract if the plan fails to have such a medical loss ratio for 5 consecutive contract years.

(5) Prompt payment by Medicare+Choice organization

(1) Requirement
A contract under this part shall require a Medicare+Choice 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 enrollees pursuant to the contract, if the services or supplies are not furnished under a contract between the organization and the provider or supplier (or in the case of a Medicare+Choice private fee-for-service plan, if a claim is submitted to such organization by an enrollee).

(2) Secretary's option to bypass noncomplying organization
In the case of a Medicare+Choice eligible organization which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with paragraph (1), the Secretary may provide for direct payment of the amounts owed to providers and suppliers (or, in the case of a Medicare+Choice private fee-for-service plan, amounts owed to the enrollees) for covered services and supplies furnished to individuals enrolled under this part under the contract. If the Secretary provides for the direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this part to reflect the amount of the Secretary's payments (and the Secretary's costs in making the payments).

(3) Incorporation of certain prescription drug plan contract requirements
The following provisions shall apply to contracts with a Medicare Advantage organization offering an MA–PD plan in the same manner as they apply to contracts with a PDP sponsor offering a prescription drug plan under part D:

(A) Prompt payment
Section 1395w–112(b)(4) of this title.

(B) Submission of claims by pharmacies located in or contracting with long-term care facilities
Section 1395w–112(b)(5) of this title.

(C) Regular update of prescription drug pricing standard
Section 1395w–112(b)(6) of this title.

(g) Intermediate sanctions

(1) In general
If the Secretary determines that a Medicare+Choice organization with a contract under this section—

(A) 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;

(B) imposes premiums on individuals enrolled under this part in excess of the
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paragraphs (A) through (K) of this paragraph.

(2) Remedies

supplier who contracts with such organization, agent of such organization, or any provider or

the Secretary may provide, in addition to any

Secretary determines that any employee or

the remedies described in paragraph (2), if the

Secretary may provide, in addition to any

the remedies described in paragraph (2). The

an individual in violation of the provisions

of this title; enrolls an individual in any plan under

is furnished—

(i) to the Secretary under this part, or

(ii) to an individual or to any other entity

under this part;

(F) fails to comply with the applicable re-

quirements of section 1395w–22(j)(3) or

1395w–22(k)(2)(A)(ii) of this title;

(G) employs or contracts with any individual

or entity that is excluded from partici-

pation under this subchapter under section

1320a–7 or 1320a–7a of this title for the provi-

sion of health care, utilization review, medi-

cal social work, or administrative services

or employs or contracts with any entity for

the provision (directly or indirectly) through such an excluded individual or en-

tity of such services;

(H) except as provided under subparagraph

(C) or (D) of section 1395w–101(b)(1) of this

title, enrolls an individual in any plan under

this part without the prior consent of the in-

dividual or the designee of the individual;

(I) transfers an individual enrolled under

this part from one plan to another without

the prior consent of the individual or the

designee of the individual or solely for the

purpose of earning a commission;

(J) fails to comply with marketing restric-

tions described in subsections (h) and (j) of

section 1395w–21 of this title or applicable

implementing regulations or guidance; or

(K) employs or contracts with any individ-

ual or entity who engages in the conduct de-

scribed in subparagraphs (A) through (J) of

this paragraph;

the Secretary may provide, in addition to any

other remedies authorized by law, for any of

the remedies described in paragraph (2). The

Secretary may provide, in addition to any

other remedies authorized by law, for any of

the remedies described in paragraph (2), if the

Secretary determines that any employee or

agent of such organization, or any provider or

supplier who contracts with such organization,

has engaged in any practice that would rea-

sonably be expected to have the effect of de-

nying or discouraging enrollment (except as

permitted by this part) by eligible individ-

uals with the organization whose medical

condition or history indicates a need for sub-

stantial future medical services;

(E) misrepresents or falsifies information

that is furnished—

such determination, except with respect to a
determination under subparagraph (E), an
assessment of not more than the amount
claimed by such plan or plan sponsor based

upon the misrepresentation or falsified in-
formation involved, plus, with respect to a
determination under paragraph (1)(B), double
the excess amount charged in violation of
such paragraph (and the excess amount
charged shall be deducted from the penalty
claimed by such plan or plan sponsor based

upon the misrepresentation or falsified in-
formation involved, plus, with respect to a
determination under paragraph (1)(D), $15,000 for each indi-

vidual not enrolled as a result of the prac-
tice involved.

(B) suspension of enrollment of individuals

under this part after the date the Secretary

notifies the organization of a determination

under paragraph (1) and the Secretary is satis-

fied that the basis for such determina-

tion has been corrected and is not likely to recur, or

(C) suspension of payment to the organi-

zation under this part for individuals enrolled

after the date the Secretary notifies the or-

ganization of a determination under para-

graph (1) and until the Secretary is satis-

fied that the basis for such determination has

been corrected and is not likely to recur.

(3) Other intermediate sanctions

In the case of a Medicare+Choice organiza-

tion for which the Secretary makes a deter-

mination under subsection (c)(2) of this sec-

tion the basis of which is not described in

paragraph (1), the Secretary may apply the

following intermediate sanctions:

(A) Civil money penalties of not more than

$25,000 for each determination under sub-

section (c)(2) of this section if the deficiency

that is the basis of the determination has di-

rectly adversely affected (or has the sub-

stantial likelihood of adversely affecting) an

individual covered under the organization’s

contract.

(B) Civil money penalties of not more than

$10,000 for each week beginning after the ini-

tiation of civil money penalty procedures by

the Secretary during which the deficiency

that is the basis of a determination under

subsection (c)(2) of this section exists.

(C) Suspension of enrollment of individuals

under this part after the date the Secretary

notifies the organization of a determination

under subsection (c)(2) of this section and

until the Secretary is satisfied that the defi-

ciency that is the basis for the determina-

tion has been corrected and is not likely to recur.

(D) Civil monetary penalties of not more than

$100,000, or such higher amount as the

Secretary may establish by regulation,

where the finding under subsection (c)(2)(A)
of this section is based on the organization’s

termination of its contract under this sec-

tion other than at a time and in a manner

provided for under subsection (a) of this sec-

1 So in original. Probably means subpar. (E) of par. (1).
(4) Civil money penalties

The provisions of section 1320a–7a (other than subsections (a) and (b)) of this title shall apply to a civil money penalty under paragraph (2) or (3) in the same manner as they apply to a civil money penalty or proceeding under section 1320a–7a(a) of this title.

(h) Procedures for termination

(1) In general

The Secretary may terminate a contract with a Medicare+Choice organization under this section in accordance with formal investigation and compliance procedures established by the Secretary under which—

(A) the Secretary 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 subsection (c)(2) of this section; and

(B) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before terminating the contract.

(2) Exception for imminent and serious risk to health

Paragraph (1) shall not apply if the Secretary determines that a delay in termination, resulting from compliance with the procedures specified in such paragraph prior to termination, would pose an imminent and serious risk to the health of individuals enrolled under this part with the organization.

(i) Medicare+Choice program compatibility with employer or union group health plans

(1) Contracts with MA organizations

To facilitate the offering of Medicare+Choice plans under contracts between Medicare+Choice organizations and employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity’s employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of the offering of, or the enrollment in such Medicare+Choice plans.

(2) Employer sponsored MA plans

To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity’s employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such MA plans. Notwithstanding section 1395w–21(f)(r) of this title, an MA plan described in the previous sentence may restrict the enrollment of individuals under this part to individuals who are beneficiaries and participants in such plan.


1999—Subsec. (c)(4). Pub. L. 106–113, § 1000(a)(6) (title V, § 513(a)), substituted “2-year period” for “5-year period” and “except as provided in subparagraph (B)” for “except in such other circumstances”.

Subsec. (e)(2)(B). Pub. L. 106–113, § 1000(a)(6) (title V, § 522(a)(1)), substituted “Any amounts collected shall be available without further appropriation to the Secretary for” for “Any amounts collected are authorized to be appropriated only for”.

Subsec. (e)(2)(C). Pub. L. 106–113, § 1000(a)(6) (title V, § 522(a)(2)), amended heading and text of subpar. (C) generally. Prior to amendment, text read as follows: “For any fiscal year, the fees authorized under subparagraph (B) are contingent upon enactment in an appropriations act of a provision specifying the aggregate amount of fees the Secretary is directed to collect in a fiscal year. Fees collected during any fiscal year under this paragraph shall be deposited and credited as offsetting collections.”


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


EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–275, title I, § 164(e), July 15, 2008, 122 Stat. 2575, provided that: “The amendments made by subsections (c)(1), (d), and (e)(1) amending this section and section 1395w–28 of this title shall apply to plan years beginning on or after January 1, 2010.”

Pub. L. 110–275, title I, § 172(b), July 15, 2008, 122 Stat. 2581, provided that: “The amendments made by this section amending this section and section 1395w–12 of this title shall apply to plan years beginning on or after January 1, 2010.”

Pub. L. 110–275, title I, § 173(c), July 15, 2008, 122 Stat. 2581, provided that: “The amendments made by this section amending this section and section 1395w–12 of this title shall apply to plan years beginning on or after January 1, 2009.”

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 237(c) of Pub. L. 108–173 applicable with respect to plan years beginning on or after Jan. 1, 2006, see section 233(a) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

Amendment by section 237(c) of Pub. L. 108–173 applicable to services provided on or after Jan. 1, 2006, and contract years beginning on or after such date, see section 237(e) of Pub. L. 108–173, set out as a note under section 1320a–7b of this title.

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–554, § 114(a)(6) (title VI, § 617(b)), Dec. 21, 2000, 114 Stat. 2763, 2763A–562, provided that: “The amendment made by subsection (a) amending this section shall apply with respect to years beginning with 2001.”

Pub. L. 106–554, § 114(a)(6) (title VI, § 623(b)), Dec. 21, 2000, 114 Stat. 2763, 2763A–566, provided that: “The amendment made by subsection (a) amending this section shall apply to terminations occurring after the date of the enactment of this Act [Dec. 21, 2000].”

EFFECTIVE DATE OF 1999 AMENDMENT

Pub. L. 106–113, div. B, § 1000(a)(6) (title V, § 513(c)), Nov. 29, 1999, 113 Stat. 1358, 1501A–383, provided that: “Nothing in the amendment made by paragraph (1)(C) [amending this section] shall be construed to affect the authority of the Secretary of Health and Human Services to provide for exceptions in addition to the exceptions provided in such amendment, including exceptions provided under Operational Policy Letter #103 (OPL99.103).”

TECHNICAL CORRECTION TO MA PRIVATE FEED-FOR-SERVICE PLANS

Pub. L. 111–148, title III, § 3207, Mar. 23, 2010, 124 Stat. 459, provided that: “For plan year 2011 and subsequent plan years, to the extent that the Secretary of Health and Human Services is applying the 2009 Service Area Extension Waiver policy (as modified in the April 11, 2008, Centers for Medicare & Medicaid Services’ memorandum with the subject ‘2009 Employer Group Waiver Granted to Certain MA Local Coordinated Care Plans’) to Medicare Advantage coordinated care plans, the Sec-
retary shall extend the application of such waiver policy to employers who contract directly with the Secretary as a Medicare Advantage private fee-for-service plan under section 1857(v)(2) of the Social Security Act (42 U.S.C. 1395w–27(i)(2)) and that had enrollment as of October 1, 2009.”

STUDY OF MULTI-YEAR CONTRACTS
Pub. L. 108–173, title I, §107(d), Dec. 8, 2003, 117 Stat. 2171, directed the Secretary of Health and Human Services to provide for a study on the feasibility and advisability of providing for contracting with PDP sponsors and MA organizations under this part and part D of this subchapter on a multi-year basis, and to submit to Congress a report on such study not later than Jan. 1, 2007.

IMMEDIATE EFFECTIVE DATE FOR CERTAIN REQUIREMENTS FOR DEMONSTRATIONS
Section 4002(g) of Pub. L. 105–33 provided that: “Section 1395w–27a of this title [section 1395w–21 of this title] applies to demonstrations with respect to which such Act [section 1395w–21 of this title].”

§ 1395w–27a. Special rules for MA regional plans
(a) Regional service area; establishment of MA regions
(1) Coverage of entire MA region
The service area for an MA regional plan shall consist of an entire MA region established under paragraph (2) and the provisions of section 1395w–24(h) of this title shall not apply to such a plan.

(2) Establishment of MA regions
(A) MA region
For purposes of this subchapter, the term “MA region” means such a region within the 50 States and the District of Columbia as established by the Secretary under this paragraph.

(B) Establishment
(i) Initial establishment
Not later than January 1, 2005, the Secretary shall first establish and publish MA regions.

(ii) Periodic review and revision of service areas
The Secretary may periodically review MA regions under this paragraph and, based on such review, may revise such regions if the Secretary determines such revision to be appropriate.

(C) Requirements for MA regions
The Secretary shall establish, and may revise, MA regions under this paragraph in a manner consistent with the following:

(i) Number of regions
There shall be no fewer than 10 regions, and no more than 50 regions.

(ii) Maximizing availability of plans
The regions shall maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, especially those residing in rural areas.

(D) Market survey and analysis
Before establishing MA regions, the Secretary shall conduct a market survey and analysis, including an examination of current insurance markets, to determine how the regions should be established.

(3) National plan
Nothing in this subsection shall be construed as preventing an MA regional plan from being offered in more than one MA region (including all regions).

(b) Application of single deductible and catastrophic limit on out-of-pocket expenses
An MA regional plan shall include the following:

(1) Single deductible
Any deductible for benefits under the original medicare fee-for-service program option shall be a single deductible (instead of a separate inpatient hospital deductible and a part B deductible) and may be applied differentially for in-network services and may be waived for preventive or other items and services.

(2) Catastrophic limit
(A) In-network
A catastrophic limit on out-of-pocket expenditures for in-network benefits under the original medicare fee-for-service program option.

(B) Total
A catastrophic limit on out-of-pocket expenditures for all benefits under the original medicare fee-for-service program option.

(c) Portion of total payments to an organization subject to risk for 2006 and 2007
(1) Application of risk corridors
(A) In general
This subsection shall only apply to MA regional plans offered during 2006 or 2007.

(B) Notification of allowable costs under the plan
In the case of an MA organization that offers an MA regional plan in an MA region in 2006 or 2007, the organization shall notify the Secretary, before such date in the succeeding year as the Secretary specifies, of—

(i) its total amount of costs that the organization incurred in providing rebatable integrated benefits (as defined in subparagraph (D)) and with respect to such benefits the portion of such costs that is attributable to administrative expenses described in subparagraph (C); and

(ii) its total amount of costs that the organization incurred in providing rebatable integrated benefits (as defined in subparagraph (D)) and with respect to such benefits the portion of such costs that is attributable to administrative expenses described in subparagraph (C); and not described in clause (i) of this subparagraph.

(C) Allowable costs defined
For purposes of this subsection, the term “allowable costs” means, with respect to an MA regional plan for a year, the total amount of costs described in subparagraph (B) for the plan and year, reduced by the por-
(2) Adjustment of payment

(A) No adjustment if allowable costs within 3 percent of target amount

If the allowable costs for the plan for the year are at least 97 percent, but do not exceed 103 percent, of the target amount for the plan and year, there shall be no payment adjustment under this subsection for the plan and year.

(B) Increase in payment if allowable costs above 103 percent of target amount

(i) Costs between 103 and 108 percent of target amount

If the allowable costs for the plan for the year are greater than 103 percent, but not greater than 108 percent, of the target amount for the plan and year, the Secretary shall increase the total of the monthly payments made to the organization offering the plan for the year under section 1395w–23(a) of this title by an amount equal to 50 percent of the difference between such allowable costs and 103 percent of such target amount.

(ii) Costs above 108 percent of target amount

If the allowable costs for the plan for the year are greater than 108 percent of the target amount for the plan and year, the Secretary shall increase the total of the monthly payments made to the organization offering the plan for the year under section 1395w–23(a) of this title by an amount (or otherwise recover from the plan an amount) equal to the sum of—

(I) 2.5 percent of such target amount; and

(II) 80 percent of the difference between 92 percent of such target amount and such allowable costs.

(D) Target amount described

For purposes of this paragraph, the term “target amount” means, with respect to an MA regional plan offered by an organization in a year, an amount equal to—

(i) the sum of—

(I) the total monthly payments made to the organization for enrollees in the plan for the year that are attributable to benefits under the original Medicare fee-for-service program option (as defined in section 1395w–22(a)(1)(B) of this title); and

(II) the total of the MA monthly basic beneficiary premium collectable for such enrollees for the year; and

(III) the total amount of the rebates under section 1395w–24(b)(1)(C)(i) of this title that are attributable to rebatable integrated benefits; reduced by

(ii) the amount of administrative expenses assumed in the bid insofar as the bid is attributable to benefits described in clause (i)(I) or (i)(III).

(3) Disclosure of information

(A) In general

Each contract under this part shall provide—

(i) that an MA organization offering an MA regional plan shall provide the Secretary with such information as the Secretary determines is necessary to carry out this subsection; and

(ii) that, pursuant to section 1395w–27(d)(2)(B) of this title, the Secretary has the right to inspect and audit any books and records of the organization that pertain to the information regarding costs provided to the Secretary under paragraph (1)(B).

(B) Restriction on use of information

Information disclosed or obtained pursuant to the provisions of this subsection may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this subsection.

(d) Organizational and financial requirements

(1) In general

In the case of an MA organization that is offering an MA regional plan in an MA region and—
(A) meets the requirements of section 1395w–25(a)(1) of this title with respect to at least one such State in such region; and

(B) with respect to each other State in such region in which it does not meet requirements, it demonstrates to the satisfaction of the Secretary that it has filed the necessary application to meet such requirements,

the Secretary may waive such requirement with respect to each State described in subparagraph (B) for such period of time as the Secretary determines appropriate for the timely processing of such an application by the State (and, if such application is denied, through the end of such plan year as the Secretary determines appropriate to provide for a transition).

(2) Selection of appropriate State

In applying paragraph (1) in the case of an MA organization that meets the requirements of section 1395w–25(a)(1) of this title with respect to more than one State in a region, the organization shall select, in a manner specified by the Secretary among such States, one State the rules of which shall apply in the case of the States described in paragraph (1)(B).


(f) Computation of applicable MA region-specific non-drug monthly benchmark amounts

(1) Computation for regions

For purposes of section 1395w–23(j)(2) of this title and this section, subject to subsection (e) of this section, the term “MA region-specific non-drug monthly benchmark amount” means, with respect to an MA region for a month in a year, the sum of the 2 components described in paragraph (2) for the region and year. The Secretary shall compute such benchmark amount for each MA region before the beginning of each annual, coordinated election period under section 1395w–21(e)(3)(B) of this title for each year (beginning with 2006).

(2) 2 components

For purposes of paragraph (1), the 2 components described in this paragraph for an MA region and a year are the following:

(A) Statutory component

The product of the following:

(i) Statutory region-specific non-drug amount

The statutory region-specific non-drug amount (as defined in paragraph (3)) for the region and year.

(ii) Statutory national market share

The statutory national market share percentage, determined under paragraph (4) for the year.

(B) Plan-bid component

The product of the following:

(i) Weighted average of MA plan bids in region

The weighted average of the plan bids for the region and year (as determined under paragraph (5)(A)).

(ii) Non-statutory market share

1 minus the statutory national market share percentage, determined under paragraph (4) for the year.

(3) Statutory region-specific non-drug amount

For purposes of paragraph (2)(A)(i), the term “statutory region-specific non-drug amount” means, for an MA region and year, an amount equal the sum (for each MA local area within the region) of the product of—

(A) MA area-specific non-drug monthly benchmark amount under section 1395w–23(j)(1)(A) of this title for that area and year; and

(B) the number of MA eligible individuals residing in the local area, divided by the total number of MA eligible individuals residing in the region.

(4) Computation of statutory market share percentage

(A) In general

The Secretary shall determine for each year a statutory national market share percentage that is equal to the proportion of MA eligible individuals nationally who were not enrolled in an MA plan during the reference month.

(B) Reference month defined

For purposes of this part, the term “reference month” means, with respect to a year, the most recent month during the previous year for which the Secretary determines that data are available to compute the percentage specified in subparagraph (A) and other relevant percentages under this part.

(5) Determination of weighted average MA bids for a region

(A) In general

For purposes of paragraph (2)(B)(i), the weighted average of plan bids for an MA region and a year is the sum, for MA regional plans described in subparagraph (D) in the region and year, of the products (for each plan) of the following:

(i) Monthly MA statutory non-drug bid amount

The unadjusted MA statutory non-drug monthly bid amount for the plan.

(ii) Plan’s share of MA enrollment in region

The factor described in subparagraph (B) for the plan.

(B) Plan’s share of MA enrollment in region

(i) In general

Subject to the succeeding provisions of this subparagraph, the factor described in this subparagraph for a plan is equal to the number of individuals described in subparagraph (C) for such plan, divided by the total number of such individuals for all MA regional plans described in subparagraph (D) for that region and year.

(ii) Single plan rule

In the case of an MA region in which only a single MA regional plan is being of-
ferred, the factor described in this subparagraph shall be equal to 1.

(iii) Equal division among multiple plans in year in which plans are first available

In the case of an MA region in the first year in which any MA regional plan is offered, if more than one MA regional plan is offered in such year, the factor described in this subparagraph for a plan shall (as specified by the Secretary) be equal to—

(I) 1 divided by the number of such plans offered in such year; or

(II) a factor for such plan that is based upon the organization’s estimate of projected enrollment, as reviewed and adjusted by the Secretary to ensure reasonableness and as is certified by the Chief Actuary of the Centers for Medicare & Medicaid Services.

(C) Counting of individuals

For purposes of subparagraph (B)(i), the Secretary shall count for each MA regional plan described in subparagraph (D) for an MA region and year, the number of individuals who reside in the region and who were enrolled under such plan under this part during the reference month.

(D) Plans covered

For an MA region and year, an MA regional plan described in this subparagraph is an MA regional plan that is offered in the region and year and was offered in the region in the reference month.

(g) Election of uniform coverage determination

Instead of applying section 1395w–22(a)(2)(C) of this title with respect to an MA regional plan, the organization offering the plan may elect to have a local coverage determination for the entire MA region be the local coverage determination applied for any part of such region (as selected by the organization).

(h) Assuring network adequacy

(1) In general

For purposes of enabling MA organizations that offer MA regional plans to meet applicable provider access requirements under section 1395w–22 of this title with respect to such plans, the Secretary may provide for payment under this section to an essential hospital that offers inpatient hospital services to enrollees in such a plan under which the MA organization offering the plan certifies to the Secretary that the organization was unable to reach an agreement between the hospital and the organization regarding provision of such services under the plan. Such payment may be available only if—

(A) the organization provides assurances satisfactory to the Secretary that the organization will make payment to the hospital for inpatient hospital services of an amount that is not less than the amount that would be payable to the hospital under section 1395ww of this title with respect to such services; and

(B) with respect to specific inpatient hospital services provided to an enrollee, the hospital demonstrates to the satisfaction of the Secretary that the hospital’s costs of such services exceed the payment amount described in subparagraph (A).

(2) Payment amounts

The payment amount under this subsection for inpatient hospital services provided by a subsection (d) hospital to an enrollee in an MA regional plan shall be, subject to the limitation of funds under paragraph (3), the amount (if any) by which—

(A) the amount of payment that would have been paid for such services under this subchapter if the enrollees were covered under the original medicare fee-for-service program option and the hospital were a critical access hospital; exceeds

(B) the amount of payment made for such services under paragraph (1)(A).

(3) Available amounts

There shall be available for payments under this subsection—

(A) in 2006, $25,000,000; and

(B) in each succeeding year the amount specified in this paragraph for the preceding year increased by the market basket percentage increase (as defined in section 1395ww(b)(3)(B)(iii) of this title) for the fiscal year ending in such succeeding year.

Payments under this subsection shall be made from the Federal Hospital Insurance Trust Fund.

(4) Essential hospital

In this subsection, the term “essential hospital” means, with respect to an MA regional plan offered by an MA organization, a subsection (d) hospital (as defined in section 1395ww(d) of this title) that the Secretary determines, based upon an application filed by the organization with the Secretary, is necessary to meet the requirements referred to in paragraph (1) for such plan.


Amendments


Subsec. (f)(1). Pub. L. 111–148, § 3201(a)(2)(C)(i), which directed substitution of “1395w–23(j)(1)(A)’’ for “1395w–23(j)(2)’’ and “subsections (e) and (i)’’ for “subsection (e)’’, respectively, was repealed by Pub. L. 111–152, § 1102(a). See Effective Date of 2010 Amendment note below.

Subsec. (i). Pub. L. 111–148, §3201(f)(2)(B), which directed addition of subsec. (i), was repealed by Pub. L. 111–152, §1102(a). As enacted, text read as follows: “For years beginning with 2014, the Secretary shall apply the performance bonuses under section 1395w–23(n) of this title (relating to bonuses for care coordination and management, quality performance, and new and low enrollment MA plans) to MA regional plans in a similar manner as such performance bonuses apply to MA plans under such subsection.” See Effective Date of 2010 Amendment note below.

2009—Subsec. (e)(7). Pub. L. 111–8 struck out par. (7) which related to biennial GAO reports to be submitted by the Comptroller General to the Secretary and Congress.


2007—Subsec. (e)(2)(A)(i). Pub. L. 110–173, which directed substitution of “the Fund during 2013, $1,790,000,000.” for “the Fund” and all that follows, was executed by making the substitution for “the Fund—

“(I) during 2012, $1,600,000,000; and

“(II) during 2013, $1,790,000,000.”
to reflect the probable intent of Congress.

Pub. L. 110–48 substituted “the Fund—

“(I) during 2012, $1,600,000,000; and

“(II) during 2013, $1,790,000,000.”

for “the Fund during the period beginning on January 1, 2012, and ending on December 31, 2013, a total of $3,500,000,000.”

2006—Subsec. (e)(2)(A)(i). Pub. L. 109–432 substituted “2014” for “2013” and “$1” for “$1,790,000,000”.

EFFECTIVE DATE OF 2010 AMENDMENT

Repeal of sections 3201 and 3203 of Pub. L. 111–148 and the amendments made by such sections, 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.

EFFECTIVE DATE

Section applicable with respect to plan years beginning on or after Jan. 1, 2006, see section 223(a) of Pub. L. 110–173, set out as an Effective Date of 2003 Amendment note under section 1395w–21 of this title.

ELIMINATION OF MA REGIONAL PLAN STABILIZATION FUND; TRANSITION


§1395w–28. Definitions; miscellaneous provisions

(a) Definitions relating to Medicare+Choice organizations

In this part—

(1) Medicare+Choice organization

The term ‘‘Medicare+Choice organization’’ means a public or private entity that is certified under section 1395w–26 of this title as meeting the requirements and standards of this part for such an organization.

(2) Provider-sponsored organization

The term ‘‘provider-sponsored organization’’ is defined in section 1395w–25(d)(1) of this title.

(b) Definitions relating to Medicare+Choice plans

(1) Medicare+Choice plan

The term ‘‘Medicare+Choice plan’’ means health benefits coverage offered under a policy, contract, or plan by a Medicare+Choice organization pursuant to and in accordance with a contract under section 1395w–27 of this title.

(2) Medicare+Choice private fee-for-service plan

The term ‘‘Medicare+Choice private fee-for-service plan’’ means a Medicare+Choice plan that—

(A) reimburses hospitals, physicians, and other providers at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

(B) does not vary such rates for such a provider based on utilization relating to such provider; and

(C) does not restrict the selection of providers among those who are lawfully authorized to provide the covered services and agree to accept the terms and conditions of payment established by the plan.

Nothing in subparagraph (B) shall be construed to preclude a plan from varying rates for such a provider based on the specialty of the provider, the location of the provider, or other factors related to such provider that are not related to utilization, or to preclude a plan from increasing rates for such a provider based on increased utilization of specified preventive or screening services.

(3) MSA plan

(A) In general

The term ‘‘MSA plan’’ means a Medicare+Choice plan that—

(i) provides reimbursement for at least the items and services described in section 1395w–22(a)(1) of this title in a year but only after the enrollee incurs countable expenses (as specified under the plan) equal to the amount of an annual deductible (described in subparagraph (B));

(ii) counts as such expenses (for purposes of such deductible) at least all amounts that would have been payable under parts A and B of this subchapter with respect to such expenses, (spect to such expenses, any deductibles or coinsurance) under parts A and B of this subchapter, and that would have been payable by the enrollee as deductibles, coinsurance, or copayments, if the enrollee had elected to receive benefits through the provisions of such parts; and

(iii) provides, after such deductible is met for a year and for all subsequent expenses for items and services referred to in clause (i) in the year, for a level of reimbursement that is not less than—

(I) 100 percent of such expenses, or

(II) 100 percent of the amounts that would have been paid (without regard to any deductibles or coinsurance) under parts A and B of this subchapter with respect to such expenses, whichever is less.

(B) Deductible

The amount of annual deductible under an MSA plan—

(i) for contract year 1999 shall be not more than $6,000; and

(ii) for a subsequent contract year shall be not more than the maximum amount of
such deductible for the previous contract year under this subparagraph increased by the national per capita Medicare+Choice growth percentage under section 1395w–23(c)(6) of this title for the year.

If the amount of the deductible under clause (ii) is not a multiple of $50, the amount shall be rounded to the nearest multiple of $50.

(4) MA regional plan
The term “MA regional plan” means an MA plan described in section 1395w–21(a)(2)(A)(i) of this title—
(A) that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;
(B) that provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and
(C) the service area of which is one or more entire MA regions.

(5) MA local plan
The term “MA local plan” means an MA plan that is not an MA regional plan.

(6) Specialized MA plans for special needs individuals

(A) In general
The term “specialized MA plan for special needs individuals” means an MA plan that exclusively serves special needs individuals (as defined in subparagraph (B)) and that, as of January 1, 2010, meets the applicable requirements of paragraph (2), (3), or (4) of subsection (f), as the case may be.

(B) Special needs individual
The term “special needs individual” means an MA eligible individual who—
(i) is institutionalized (as defined by the Secretary);
(ii) is entitled to medical assistance under a State plan under subchapter XIX of this chapter with those provided under a Medicare+Choice plan in a manner that assures continuity of a full-range of acute care and long-term care services to poor elderly or disabled individuals eligible for benefits under this subchapter and under such plan.

(c) Other references to other terms

(1) Medicare+Choice eligible individual
The term “Medicare+Choice eligible individual” is defined in section 1395w–21(a)(3) of this title.

(2) Medicare+Choice payment area
The term “Medicare+Choice payment area” is defined in section 1395w–23(d) of this title.

(3) National per capita Medicare+Choice growth percentage
The “national per capita Medicare+Choice growth percentage” is defined in section 1395w–23(c)(6) of this title.

(4) Medicare+Choice monthly basic beneficiary premium; Medicare+Choice monthly supplemental beneficiary premium
The terms “Medicare+Choice monthly basic beneficiary premium” and “Medicare+Choice monthly supplemental beneficiary premium” are defined in section 1395w–24(a)(2) of this title.

(5) MA local area
The term “MA local area” is defined in section 1395w–23(d)(2) of this title.

(d) Coordinated acute and long-term care benefits under Medicare+Choice plan
Nothing in this part shall be construed as preventing a State from coordinating benefits under a Medicaid plan under subchapter XIX of this chapter with those provided under a Medicare+Choice plan in a manner that assures continuity of a full-range of acute care and long-term care services to poor elderly or disabled individuals eligible for benefits under this subchapter and under such plan.

(e) Restriction on enrollment for certain Medicare+Choice plans

(1) In general
In the case of a Medicare+Choice religious fraternal benefit society plan described in paragraph (2), notwithstanding any other provision of this part to the contrary and in accordance with regulations of the Secretary, the society offering the plan may restrict the enrollment of individuals under this part to individuals who are members of the church, convention, or group described in paragraph (3)(B) with which the society is affiliated.

(2) Medicare+Choice religious fraternal benefit society plan described
For purposes of this subsection, a Medicare+Choice religious fraternal benefit society plan described in this paragraph is a Medicare+Choice plan described in section 1395w–21(a)(2) of this title that—
(A) is offered by a religious fraternal benefit society described in paragraph (3) only to members of the church, convention, or group described in paragraph (3)(B); and
(B) permits all such members to enroll under the plan without regard to health status-related factors.

Nothing in this subsection shall be construed as waiving any plan requirements relating to financial solvency.

(3) “Religious fraternal benefit society” defined
For purposes of paragraph (2)(A), a “religious fraternal benefit society” described in this section is an organization that—
(A) is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt
from taxation under section 501(a) of such Act;
(B) is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches;
(C) offers, in addition to a Medicare+Choice religious fraternal benefit society plan, health coverage to individuals not entitled to benefits under this subchapter who are members of such church, convention, or group; and
(D) does not impose any limitation on membership in the society based on any health status-related factor.

(4) Payment adjustment
Under regulations of the Secretary, in the case of individuals enrolled under this part under a Medicare+Choice religious fraternal benefit society plan described in paragraph (2), the Secretary shall provide for such adjustment to the payment amounts otherwise established under section 1395w–24 of this title as may be appropriate to assure an appropriate payment level, taking into account the actuarial characteristics and experience of such individuals.

(f) Requirements regarding enrollment in specialized MA plans for special needs individuals

(1) Requirements for enrollment
In the case of a specialized MA plan for special needs individuals (as defined in subsection (b)(6) of this section), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2014, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs individuals.

(2) Additional requirements for institutional SNPS
In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(i), the applicable requirements described in this paragraph are as follows:
(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individual described in subsection (b)(6)(B)(i). In the case of an individual who is living in the community but requires an institutional level of care, such individual shall not be considered a special needs individual described in subsection (b)(6)(B)(i) unless the determination that the individual requires an institutional level of care was made—
(i) using a State assessment tool of the State in which the individual resides; and
(ii) by an entity other than the organization offering the plan.
(B) The plan meets the requirements described in paragraph (5).
(C) If applicable, the plan meets the requirement described in paragraph (7).

(3) Additional requirements for dual SNPS
In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii), the applicable requirements described in this paragraph are as follows:
(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individual described in subsection (b)(6)(B)(ii).
(B) The plan meets the requirements described in paragraph (5).
(C) The plan provides each prospective enrollee, prior to enrollment, with a comprehensive written statement (using standardized content and format established by the Secretary) that describes—
(i) the benefits and cost-sharing protections that the individual is entitled to under the State Medicaid program under subchapter XIX; and
(ii) which of such benefits and cost-sharing protections are covered under the plan.
Such statement shall be included with any description of benefits offered by the plan.
(D) The plan has a contract with the State Medicaid agency to provide benefits, or arrange for benefits to be provided, for which such individual is entitled to receive as medical assistance under subchapter XIX. Such benefits may include long-term care services consistent with State policy.
(E) If applicable, the plan meets the requirement described in paragraph (7).

(4) Additional requirements for severe or disabling chronic condition SNPS
In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii), the applicable requirements described in this paragraph are as follows:
(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individual described in subsection (b)(6)(B)(ii).
(B) The plan meets the requirements described in paragraph (5).
(C) If applicable, the plan meets the requirement described in paragraph (7).

(5) Care management requirements for all SNPS
The requirements described in this paragraph are that the organization offering a specialized MA plan for special needs individuals—
(A) have in place an evidenced-based model of care with appropriate networks of providers and specialists; and
(B) with respect to each individual enrolled in the plan—
(1) conduct an initial assessment and an annual reassessment of the individual’s physical, psychosocial, and functional needs;
(ii) develop a plan, in consultation with the individual as feasible, that identifies goals and objectives, including measurable outcomes as well as specific services and benefits to be provided; and
(iii) use an interdisciplinary team in the management of care.

1So in original. Probably should be “individual”.
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(6) Transition and exception regarding restriction on enrollment

(A) In general

Subject to subparagraph (C), the Secretary shall establish procedures for the transition of applicable individuals to—

(1) a Medicare Advantage plan that is not a specialized MA plan for special needs individuals (as defined in subsection (b)(6)); or

(2) the original Medicare fee-for-service program under parts A and B.

(B) Applicable individuals

For purposes of clause (1), the term ‘applicable individual’ means an individual who—

(1) is enrolled under a specialized MA plan for special needs individuals (as defined in subsection (b)(6)); and

(2) is not within the 1 or more of the classes of special needs individuals to which enrollment under the plan is restricted to.

(C) Exception

The Secretary shall provide for an exception to the transition described in subparagraph (A) for a limited period of time for individuals enrolled under a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii) who are no longer eligible for medical assistance under subchapter XIX.

(D) Timeline for initial transition

The Secretary shall ensure that applicable individuals enrolled in a specialized MA plan for special needs individuals (as defined in subsection (b)(6)) prior to January 1, 2010, are transitioned to a plan or the program described in subparagraph (A) by not later than January 1, 2013.

(7) Authority to require special needs plans be NCQA approved

For 2012 and subsequent years, the Secretary shall require that applicable individuals enrolled in a specialized MA plan for special needs individuals be approved by the National Committee for Quality Assurance (based on standards established by the Secretary).

(g) Special rules for senior housing facility plans

(1) In general

In the case of a Medicare Advantage senior housing facility plan described in paragraph (2), notwithstanding any other provision of this part to the contrary and in accordance with regulations of the Secretary, the service area of such plan may be limited to a senior housing facility in a geographic area.

(2) Medicare advantage senior housing facility plan described

For purposes of this subsection, a Medicare Advantage senior housing facility plan is a Medicare Advantage plan that—

(A) restricts enrollment of individuals under this part to individuals who reside in a continuing care retirement community (as defined in section 1395w–22(1)(4)(B) of this title); and

(B) provides primary care services onsite and has a ratio of accessible physicians to beneficiaries that the Secretary determines is adequate;

(C) provides transportation services for beneficiaries to specialty providers outside of the facility; and

(D) has participated (as of December 31, 2009) in a demonstration project established by the Secretary under which such a plan was offered for not less than 1 year.


REFERENCES IN TEXT

Parts A and B of this subchapter, referred to in subsec. (b)(3)(A), are classified generally to Title 26, Internal Revenue Code.

Amendments


Subsec. (f)(6), (7). Pub. L. 111–148, § 3205(c), (e)(4), added pars. (6) and (7).

Subsec. (g). Pub. L. 111–148, § 3208(a), added subsec. (g).


Subsec. (b)(6)(A). Pub. L. 110–275, § 164(c)(1)(A), inserted “and that, as of January 1, 2010, meets the applicable requirements of paragraph (2), (3), or (4) of subsection (f), as the case may be” before period at end.

Subsec. (b)(6)(B)(iii). Pub. L. 110–275, § 164(e)(1), inserted “who have one or more comorbid and medically complex chronic conditions that are substantially disabling or life threatening, have a high risk of hospitalization or other significant adverse health outcomes, and require specialized delivery systems across domains of care” before period at end.


Pub. L. 110–275, § 164(c)(1)(B)(ii), amended heading generally. Prior to amendment, heading read “Restriction on enrollment for specialized MA plans for special needs individuals”.

Pub. L. 110–275, § 164(a), substituted “2011” for “2010”.


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

Pub. L. 111–148, title III, §3206(b), Mar. 23, 2010, 124 Stat. 460, provided that: “The amendment made by this section [amending this section] shall take effect on January 1, 2010, and shall apply to plan years beginning on or after such date.”

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 164(c)(1), (d)(1), (e)(1) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2010, and applicable to all special Medicare Advantage plans for special needs individuals regardless of when the plan first entered the Medicare Advantage program under this part, see section 164(g) of Pub. L. 110–275, set out as a note under section 1395w–27 of this title.

EFFECTIVE DATE OF 2003 AMENDMENT


REGULATIONS

Pub. L. 108–173, title II, §231(f)(2), Dec. 8, 2003, 117 Stat. 2208, provided that: “No later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Secretary of Health and Human Services shall issue final regulations to establish requirements for special needs individuals under section 1859(b)(6)(B)(iii) of the Social Security Act [subsec. (b)(6)(B)(iii) of this section], as added by subsection (b).”

AUTHORITY TO OPERATE; RESOURCES FOR STATE MEDICAID AGENCIES; CONTRACTING REQUIREMENTS


AUTHORITY TO DESIGNATE OTHER PLANS AS SPECIALIZED MA PLANS

Secretary of Health and Human Services, in promulgating regulations to carry out subsection (b)(6) of this section, to provide, notwithstanding subsection (b)(6)(A) of this section, for the offering of specialized MA plans for special needs individuals by MA plans that disproportionately serve special needs individuals, see section 231(d) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.


PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

PRERIOR PROVISIONS

A prior part D of this subchapter, consisting of section 1395x et seq., was redesignated part E of this subchapter.

SUBPART I—PART D ELIGIBLE INDIVIDUALS AND PRESCRIPTION DRUG BENEFITS

§1395w–101. Eligibility, enrollment, and information

(a) Provision of qualified prescription drug coverage through enrollment in plans

(1) In general

Subject to the succeeding provisions of this part, each part D eligible individual (as defined in paragraph (3)(A)) is entitled to obtain
qualified prescription drug coverage (described in section 1395w–102(a) of this title) as follows:

(A) Fee-for-service enrollees may receive coverage through a prescription drug plan
   A part D eligible individual who is not enrolled in an MA plan may obtain qualified prescription drug coverage through enrollment in a prescription drug plan (as defined in section 1395w–28(b)(2) of this title).

(B) Medicare Advantage enrollees
   (i) Enrollees in a plan providing qualified prescription drug coverage receive coverage through the plan
      A part D eligible individual who is enrolled in an MA–PD plan obtains such coverage through such plan.
   (ii) Limitation on enrollment of MA plan enrollees in prescription drug plans
      Except as provided in clauses (iii) and (iv), a part D eligible individual who is enrolled in an MA plan may not enroll in a prescription drug plan under this part.
   (iii) Private fee-for-service enrollees in MA plans not providing qualified prescription drug coverage permitted to enroll in a prescription drug plan
      A part D eligible individual who is enrolled in an MA private fee-for-service plan (as defined in section 1395w–28(b)(2) of this title) that does not provide qualified prescription drug coverage may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.
   (iv) Enrollees in MSA plans permitted to enroll in a prescription drug plan
      A part D eligible individual who is enrolled in an MSA plan (as defined in section 1395w–28(b)(3) of this title) may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

(2) Coverage first effective January 1, 2006
   Coverage under prescription drug plans and MA–PD plans shall first be effective on January 1, 2006.

(3) Definitions
   For purposes of this part:
   (A) Part D eligible individual
      The term “part D eligible individual” means an individual who is entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter.
   (B) MA plan
      The term “MA plan” has the meaning given such term in section 1395w–28(b)(1) of this title.
   (C) MA–PD plan
      The term “MA–PD plan” means an MA plan that provides qualified prescription drug coverage.

(b) Enrollment process for prescription drug plans
   (1) Establishment of process
      (A) In general
         The Secretary shall establish a process for the enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in prescription drug plans consistent with this subsection.
   (B) Application of MA rules
      In establishing such process, the Secretary shall use rules similar to (and coordinated with) the rules for enrollment, disenrollment, termination, and change of enrollment with an MA–PD plan under the following provisions of section 1396w–21 of this title:
      (i) Residence requirements
         Section 1395w–21(b)(1)(A) of this title, relating to residence requirements.
      (ii) Exercise of choice
         Section 1395w–21(c) of this title (other than paragraph (3)(A) of such section), relating to exercise of choice.
      (iii) Coverage election periods
         Subject to paragraphs (2) and (3) of this subsection, section 1395w–21(e) of this title (other than subparagraphs (B), (C), and (E) of paragraph (2) and the second sentence of paragraph (4) of such section), relating to coverage election periods, including initial periods, annual coordinated election periods, special election periods, and election periods for exceptional circumstances.
      (iv) Coverage periods
         Section 1395w–21(f) of this title, relating to effectiveness of elections and changes of elections.
      (v) Guaranteed issue and renewal
         Section 1395w–21(g) of this title (other than paragraph (2) of such section and clause (i) and the second sentence of clause (ii) of paragraph (3)(A) of such section), relating to guaranteed issue and renewal.
      (vi) Marketing material and application forms
         Section 1395w–21(h) of this title, relating to approval of marketing material and application forms.

In applying clauses (ii), (iv), and (v) of this subparagraph, any reference to section 1395w–21(e) of this title shall be treated as a reference to such section as applied pursuant to clause (iii) of this subparagraph.

(C) Special rule
   The process established under subparagraph (A) shall include, except as provided in subparagraph (D), in the case of a part D eligible individual who is a full-benefit dual eligible individual (as defined in section 1396u–5(c)(6) of this title) who has failed to enroll in a prescription drug plan or an MA–PD plan, for the enrollment in a prescription drug plan that has a monthly beneficiary premium that does not exceed the premium assistance available under section 1395w–114(a)(1)(A) of this title.1 If there is more than one such plan available, the Sec-
(2) Initial enrollment period

(A) Program initiation

In the case of an individual who is a part D eligible individual as of November 15, 2005, there shall be an initial enrollment period that shall be the same as the annual, coordinated open election period described in section 1395w–21(e)(3)(B)(iii) of this title, as applied under paragraph (1)(B)(iii).

(B) Continuing periods

In the case of an individual who becomes a part D eligible individual after November 15, 2005, there shall be an initial enrollment period which is the period under section 1395w–21(e)(1) of this title, as applied under paragraph (1)(B)(iii) of this section, as if “entitled to benefits under part A of this subchapter” were substituted for “entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter”, but in no case shall such period end before the period described in subparagraph (A).

(3) Additional special enrollment periods

The Secretary shall establish special enrollment periods, including the following:

(A) Involuntary loss of creditable prescription drug coverage

(i) In general

In the case of a part D eligible individual who involuntarily loses creditable prescription drug coverage (as defined in section 1395w–113(b)(4) of this title). Notwithstanding any other provision of law but subject to subparagraph (B), the Secretary may provide to each PDP sponsor and MA organization such identifying information about part D eligible individuals as the Secretary determines to be necessary to facilitate efficient marketing of prescription drug plans and MA–PD plans to such individuals and enrollment of such individuals in such plans.

(ii) Use of information

In establishing special enrollment periods under clause (i), the Secretary shall take into account when the part D eligible individuals are provided notice of the loss of creditable prescription drug coverage.

(iii) Failure to pay premium

For purposes of clause (i), a loss of coverage shall be treated as voluntary if the coverage is terminated because of failure to pay a required beneficiary premium.

(iv) Reduction in coverage

For purposes of clause (i), a reduction in coverage so that the coverage no longer meets the requirements under section 1395w–113(b)(5) of this title (relating to actuarial equivalence) shall be treated as an involuntary loss of coverage.

(B) Errors in enrollment

In the case described in section 1395p(h) of this title (relating to errors in enrollment), in the same manner as such section applies to part B of this subchapter.

(C) Exceptional circumstances

In the case of part D eligible individuals who meet such exceptional conditions (in addition to those conditions applied under paragraph (1)(B)(iii)) as the Secretary may provide.

(D) Medicaid coverage

In the case of an individual (as determined by the Secretary) who is a full-benefit dual eligible individual (as defined in section 1396u–5(c)(6) of this title).

(E) Discontinuance of MA–PD election during first year of eligibility

In the case of a part D eligible individual who discontinues enrollment in an MA–PD plan under the second sentence of section 1395w–21(e)(4) of this title at the time of the election of coverage under such sentence under the original medicare fee-for-service program.

(4) Information to facilitate enrollment

(A) In general

Notwithstanding any other provision of law but subject to subparagraph (B), the Secretary may provide to each PDP sponsor and MA organization such identifying information about part D eligible individuals as the Secretary determines to be necessary to facilitate efficient marketing of prescription drug plans and MA–PD plans to such individuals and enrollment of such individuals in such plans.

(B) Limitation

(i) Provision of information

The Secretary may provide the information under subparagraph (A) only to the extent necessary to carry out such subparagraph.

(ii) Use of information

Such information provided by the Secretary to a PDP sponsor or an MA organization may be used by such sponsor or organization only to facilitate marketing of, and enrollment of part D eligible individuals in, prescription drug plans and MA–PD plans.

(5) Reference to enrollment procedures for MA–PD plans

For rules applicable to enrollment, disenrollment, termination, and change of enroll-
(b) Reference to penalties for late enrollment

Section 1395w–113(b) of this title imposes a late enrollment penalty for part D eligible individuals who—

(A) enroll in a prescription drug plan or an MA–PD plan after the initial enrollment period described in paragraph (2); and

(B) fail to maintain continuous creditable prescription drug coverage during the period of non-enrollment.

(c) Providing information to beneficiaries

(1) Activities

The Secretary shall conduct activities that are designed to broadly disseminate information to part D eligible individuals (and prospective part D eligible individuals) regarding the coverage provided under this part. Such activities shall ensure that such information is first made available at least 30 days prior to the initial enrollment period described in subsection (b)(2)(A) of this section.

(2) Requirements

The activities described in paragraph (1) shall—

(A) be similar to the activities performed by the Secretary under section 1395w–21 of this title, including dissemination (including through the toll-free telephone number 1–800–MEDICARE) of comparative information for prescription drug plans and MA–PD plans; and

(B) be coordinated with the activities performed by the Secretary under such section and under section 1395b–2 of this title.

(3) Comparative information

(A) In general

Subject to subparagraph (B), the comparative information referred to in paragraph (2) shall include a comparison of the following with respect to qualified prescription drug coverage:

(i) Benefits

The benefits provided under the plan.

(ii) Monthly beneficiary premium

The monthly beneficiary premium under the plan.

(iii) Quality and performance

The quality and performance under the plan.

(iv) Beneficiary cost-sharing

The cost-sharing required of part D eligible individuals under the plan.

(v) Consumer satisfaction surveys

The results of consumer satisfaction surveys regarding the plan conducted pursuant to section 1395w–104(d) of this title.

(B) Exception for unavailability of information

The Secretary is not required to provide comparative information under clauses (iii) and (v) of subparagraph (A) with respect to a plan—

(i) for the first plan year in which it is offered; and

(ii) for the next plan year if it is impracticable or the information is otherwise unavailable.

(4) Information on late enrollment penalty

The information disseminated under paragraph (1) shall include information concerning the methodology for determining the late enrollment penalty under section 1395w–113(b) of this title.


References in Text

Part A of this subchapter, referred to in subsecs. (a)(3)(A) and (b)(2)(B), is classified to section 1396c et seq. of this title.

Part B of this subchapter, referred to in subsecs. (a)(3)(A) and (b)(2)(B), (3)(B), is classified to section 1395j et seq. of this title.

Amendments

2010—Subsec. (b)(1)(C). Pub. L. 111–148, § 3303(b)(1), inserted “except as provided in subparagraph (D),” after “shall include.”


2006—Subsec. (b)(1)(B)(iii). Pub. L. 109–432 substituted “subparagraphs (B), (C), and (E)” for “subparagraphs (B) and (C).”

Effective Date of 2010 Amendment

Pub. L. 111–148, title III, § 3313, Mar. 23, 2010, 124 Stat. 477, provided that: “The amendments made by this subsection probably should be “this section”, amending this section and section 1395w–114 of this title shall apply to premiums for months, and enrollments for plan years, beginning on or after January 1, 2011.”

Office of the Inspector General Studies and Reports


“(a) Study and Annual Report on Part D Formularies’ Inclusion of Drugs Commonly Used by Dual Eligibles.—

“(1) Study.—The Inspector General of the Department of Health and Human Services shall conduct a study of the extent to which formularies used by prescription drug plans and MA–PD plans under part D [this part] include drugs commonly used by full-benefit dual eligible individuals (as defined in section 1935(c)(6) of the Social Security Act [42 U.S.C. 1395u–5(c)(6)]).

“(2) Annual reports.—Not later than July 1 of each year (beginning with 2011), 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.

“(b) Study and Report on Prescription Drug Prices Under Medicare Part D and Medicare.—

“(1) Study.—

“(A) In general.—The Inspector General of the Department of Health and Human Services shall conduct a study on prices for covered part D drugs under the Medicare prescription drug program under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.] and for covered out-
patient drugs under title XIX (42 U.S.C. 1396 et seq.). Such study shall include the following:

"(i) A comparison, with respect to the 200 most frequently dispensed covered part D drugs under such program and covered outpatient drugs under such title (as determined by the Inspector General based on volume and expenditures), of—

"(I) the prices paid for covered part D drugs by PDP sponsors of prescription drug plans and Medicare Advantage organizations offering MA–PD plans; and

"(II) the prices paid for covered outpatient drugs by a State plan under title XIX.

"(ii) An assessment of—

"(I) the financial impact of any discrepancies in such prices on the Federal Government; and

"(II) the financial impact of any such discrepancies on enrollees under part D or individuals eligible for medical assistance under a State plan under title XIX.

"(B) Price.—For purposes of subparagraph (A), the price of a covered part D drug or a covered outpatient drug shall include any rebate or discount under such program or such title, respectively, including any negotiated price concession described in section 1860D–2(d)(1)(A) of the Social Security Act (42 U.S.C. 1395w–102(d)(1)(A)) or rebate under an agreement under section 1927 of the Social Security Act (42 U.S.C. 1396–8).

"(C) Authority to collect any necessary information.—Notwithstanding any other provision of law, the Inspector General of the Department of Health and Human Services shall be able to collect any information related to the prices of covered part D drugs under such program and covered outpatient drugs under such title XIX necessary to carry out the comparison under subparagraph (A).

"(2) Report.—

"(A) In general.—Not later than October 1, 2011, subject to subparagraph (B), the Inspector General shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Inspector General determines appropriate.

"(B) Limitation on information contained in report.—The report submitted under subparagraph (A) shall not include any information that the Inspector General determines is proprietary or is likely to negatively impact the ability of a PDP sponsor or a State plan under title XIX (42 U.S.C. 1396 et seq.) to negotiate prices for covered part D drugs or covered outpatient drugs, respectively.

"(C) Definitions.—In this section:

"(i) Covered part D drug.—The term ‘covered part D drug’ has the meaning given such term in section 1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e)).

"(ii) Covered outpatient drug.—The term ‘covered outpatient drug’ has the meaning given such term in section 1859(a)(1) of such Act (42 U.S.C. 1395w–28(a)(1)).

"(iii) Medicare Advantage organization.—The term ‘Medicare Advantage organization’ has the meaning given such term in section 1859(a)(1) of such Act (42 U.S.C. 1395w–28(a)(1)).

"(iv) Pharmacists.—The term ‘pharmacists’ includes —

"(I) pharmacy benefit managers;

"(II) providers of pharmaceutical assistance programs, and

"(III) providers of pharmacy services.

"(v) Prescription drug plan.—The term ‘prescription drug plan’ has the meaning given such term in section 1860D–4(a) of such Act (42 U.S.C. 1395w–151(a)(14)).

"(vi) State.—The term ‘State’ means —

"(I) a State (as determined by the Inspector General); or

"(II) the Commonwealth of Puerto Rico.

"(D) R

"(E) Federal Definition.—The term ‘prescription drug plan’ has the meaning given such term in section 1860D–4(a) of such Act (42 U.S.C. 1395w–151(a)(14)).

"§ 1395w–101

SUBMISSION OF LEGISLATIVE PROPOSAL

Pub. L. 108–173, title I, §101(b), Dec. 8, 2003, 117 Stat. 2150, 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 title and title II [see Tables for classification].’’

STUDY ON TRANSITIONING PART B PRESCRIPTION DRUG COVERAGE

Pub. L. 108–173, title I, §101(c), Dec. 8, 2003, 117 Stat. 2150, provided that: ‘‘Not later than January 1, 2005, the Secretary [of Health and Human Services] shall submit a report to Congress that makes recommendations regarding methods for providing benefits under subpart 1 of part D of title XVIII of the Social Security Act [this subpart] for outpatient prescription drugs for which benefits are provided under part B of such title [part B of this subchapter].’’

REPORT ON PROGRESS IN IMPLEMENTATION OF PRESCRIPTION DRUG BENEFIT

Pub. L. 108–173, title I, §101(d), Dec. 8, 2003, 117 Stat. 2150, provided that: ‘‘Not later than March 1, 2005, the Secretary [of Health and Human Services] shall submit to Congress a report to Congress on the progress that has been made in implementing the prescription drug benefit under this title [see Tables for classification]. The Secretary shall include in the report specific steps that have been taken, and that need to be taken, to ensure a timely start of the program on January 1, 2006. The report shall include recommendations regarding an appropriate transition from the program under section 1860D–31 of the Social Security Act [section 1395w–141 of this title] to prescription drug benefits under subpart 1 of part D of title XVIII of such Act [this subpart].’’

STATE PHARMACEUTICAL ASSISTANCE TRANSITION COMMISSION


‘‘(A) Establishment.—

‘‘(1) In general.—There is established, as of the first day of the third month beginning after the date of the enactment of this Act [Dec. 8, 2003], a State Pharmaceutical Assistance Transition Commission (in this section referred to as the ‘Commission’) to develop a proposal for addressing the unique transitional issues facing State pharmaceutical assistance programs, and program participants, due to the implementation of the voluntary prescription drug benefit program under part D of title XVIII of the Social Security Act [this part], as added by this title, and to ensure a timely start of the program on January 1, 2006.

‘‘(2) Definitions.—For purposes of this section:

‘‘(A) State pharmaceutical assistance program defined.—The term ‘State pharmaceutical assistance program’ means a program other than the Medicaid program operated by a State (or under contract with a State) that provides as of the date of the enactment of this Act [Dec. 8, 2003] financial assistance to Medicare beneficiaries for the purchase of prescription drugs.

‘‘(B) Program participant.—The term ‘program participant’ means a low-income Medicare beneficiary who is a participant in a State pharmaceutical assistance program.

‘‘(C) Composition.—The Commission shall include the following:

‘‘(i) A representative of each Governor of each State that the Secretary [of Health and Human Services] identifies as operating on a statewide basis a State pharmaceutical assistance program that provides for eligibility and benefits that are comparable or more generous than the low-income assistance eligibility and benefits offered under section 1860D–14 of the Social Security Act [section 1395w–114 of this title].

‘‘(2) Representatives from other States that the Secretary identifies have in operation other State
pharmaceutical assistance programs, as appointed by the Secretary.

(3) Representatives of organizations that have an inherent interest in program participants or the program itself, as appointed by the Secretary but not to exceed the number of representatives under paragraphs (1) and (2).

(4) Representatives of Medicare Advantage organizations, pharmaceutical benefit managers, and other private health insurance plans, as appointed by the Secretary.

(5) The Secretary (or the Secretary’s designee) and such other members as the Secretary may specify.

The Secretary shall designate a member to serve as Chair of the Commission and the Commission shall meet at the call of the Chair.

(c) Development of Proposal.—The Commission shall develop the proposal described in subsection (a) in a manner consistent with the following principles:

(1) Protection of the interests of program participants in a manner that is the least disruptive to such participants and that includes a single point of contact for enrollment and processing of benefits.

(2) Protection of the financial and flexibility interests of States so that States are not financially worse off as a result of the enactment of this title (see Tables for classification).

(3) Principles of Medicare modernization under this Act (see Tables for classification).

(d) Report.—By not later than January 1, 2005, the Commission shall submit to the President and Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate.

(e) Support.—The Secretary shall provide the Commission with the administrative support services necessary for the Commission to carry out its responsibilities under this section.

(f) Termination.—The Commission shall terminate 30 days after the date of submission of the report under subsection (d).

§ 1395w–102. Prescription drug benefits

(a) Requirements

(1) In general

For purposes of this part and part C of this subchapter, the term “qualified prescription drug coverage” means either of the following:

(A) Standard prescription drug coverage with access to negotiated prices

Standard prescription drug coverage (as defined in subsection (b) of this section) and access to negotiated prices under subsection (d) of this section.

(B) Alternative prescription drug coverage with at least actuarially equivalent benefits and access to negotiated prices

Coverage of covered part D drugs which meets the alternative prescription drug coverage requirements of subsection (c) of this section and access to negotiated prices under subsection (d) of this section, but only if the benefit design of such coverage is approved by the Secretary, as provided under subsection (c) of this section.

(2) Permitting supplemental prescription drug coverage

(A) In general

Subject to subparagraph (B), qualified prescription drug coverage may include supplemental prescription drug coverage consisting of either or both of the following:

(i) Certain reductions in cost-sharing

(I) In general

A reduction in the annual deductible, a reduction in the coinsurance percentage, or an increase in the initial coverage limit with respect to covered part D drugs, or any combination thereof, so as to achieve cost-sharing arrangements that are actuarially equivalent to those provided by a prescription drug plan that provides supplemental prescription drug coverage.

(ii) Optional drugs

Coverage of any product that would be a covered part D drug but for the application of subsection (e)(2)(A) of this section.

(B) Requirement

A PDP sponsor may not offer a prescription drug plan that provides supplemental prescription drug coverage pursuant to subparagraph (A) in an area unless the sponsor also offers a prescription drug plan in the area that only provides basic prescription drug coverage.

(2) Basic prescription drug coverage

For purposes of this part and part C of this subchapter, the term “basic prescription drug coverage” means either of the following:

(A) Coverage that meets the requirements of paragraph (1)(A).

(B) Coverage that meets the requirements of paragraph (1)(B) but does not have any supplemental prescription drug coverage described in paragraph (2)(A).

(4) Application of secondary payor provisions

The provisions of section 1395w–22(a)(4) of this title shall apply under this part in the same manner as they apply under part C of this subchapter.
(5) Construction

Nothing in this subsection shall be construed as changing the computation of incurred costs under subsection (b)(4) of this section.

(b) Standard prescription drug coverage

For purposes of this part and part C of this subchapter, the term “standard prescription drug coverage” means coverage of covered part D drugs that meets the following requirements:

(1) Deductible

(A) In general

The coverage has an annual deductible—

(i) for 2006, that is equal to $250; or

(ii) for a subsequent year, that is equal to the amount specified under this paragraph for the previous year increased by the percentage specified in paragraph (6) for the year involved.

(B) Rounding

Any amount determined under subparagraph (A)(ii) that is not a multiple of $5 shall be rounded to the nearest multiple of $5.

(2) Benefit structure

(A) 25 percent coinsurance

Subject to subparagraphs (C) and (D), the coverage has coinsurance (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3)) that is—

(i) equal to 25 percent; or

(ii) actuarially equivalent (using processes and methods established under section 1395w–111(c) of this title) to an average expected payment of 25 percent of such costs.

(B) Use of tiers

Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization from applying tiered copayments under a plan, so long as such tiered copayments are consistent with subparagraphs (A)(ii), (C), and (D).

(C) Coverage for generic drugs in coverage gap

(i) In general

Except as provided in paragraph (4), the coverage for an applicable beneficiary (as defined in section 1395w–114a(g)(1) of this title) has coinsurance (for costs above the initial coverage limit under paragraph (3) and below the out-of-pocket threshold) for covered part D drugs that are applicable drugs under section 1395w–114a(g)(2) of this title that is—

(I) equal to the difference between the applicable gap percentage (specified in clause (ii) for the year) and the discount percentage specified in section 1395w–114a(g)(4)(A) of this title for such applicable drugs; or

(II) actuarially equivalent (using processes and methods established under section 1395w–111(c) of this title) to an average expected payment of such percentage of such costs, for covered part D drugs that are applicable drugs under section 1395w–114a(g)(2) of this title.

(ii) Applicable gap percentage

The applicable gap percentage specified in this clause for—

(I) 2013 and 2014 is 97.5 percent;

(II) 2015 and 2016 is 95 percent;

(III) 2017 is 90 percent;

(IV) 2018 is 85 percent;

(V) 2019 is 80 percent; and

(VI) 2020 and each subsequent year is 75 percent.

(3) Initial coverage limit

(A) In general

Except as provided in paragraphs (2)(C), (2)(D), and (4), the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes (including the annual deductible)—

(i) for 2006, that is equal to $2,250; or

(ii) for a subsequent year, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

(B) Rounding

Any amount determined under subparagraph (A)(ii) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(ii) Generic-gap coinsurance percentage

The generic-gap coinsurance percentage specified in this clause for—

(I) 2011 is 93 percent;

(II) 2012 and each succeeding year before 2020 is the generic-gap coinsurance percentage under this clause for the previous year decreased by 7 percentage points; and

(III) 2020 and each subsequent year is 25 percent.
(4) Protection against high out-of-pocket expenditures

(A) In general

(i) In general

The coverage provides benefits, after the part D eligible individual has incurred costs (as described in subparagraph (C)) for covered part D drugs in a year equal to the annual out-of-pocket threshold specified in subparagraph (B), with cost-sharing that is equal to the greater of—

(I) a copayment of $2 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1396r–8(k)(7)(A)(1) of this title) and $5 for any other drug; or

(II) coinsurance that is equal to 5 percent.

(ii) Adjustment of amount

For a year after 2006, the dollar amounts specified in clause (i)(I) shall be equal to the dollar amounts specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved. Any amount established under this clause that is not a multiple of 5 cents shall be rounded to the nearest multiple of 5 cents.

(B) Annual out-of-pocket threshold

(i) In general

For purposes of this part, the “annual out-of-pocket threshold” specified in this subparagraph—

(I) for 2006, is equal to $3,600;

(II) for each of years 2007 through 2013, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved;

(III) for 2014 and 2015, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved, minus 0.25 percentage point;

(IV) for each of years 2016 through 2019, is equal to the amount specified in this subparagraph for the previous year, increased by the lesser of—

(aa) the annual percentage increase described in paragraph (7) for the year involved, plus 2 percentage points; or

(bb) the annual percentage increase described in paragraph (6) for the year;

(V) for 2020, is equal to the amount that would have been applied under this subparagraph for 2020 if the amendments made by section 1101(d)(1) of the Health Care and Education Reconciliation Act of 2010 had not been enacted; or

(VI) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

(ii) Rounding

Any amount determined under clause (i)(II) that is not a multiple of $50 shall be rounded to the nearest multiple of $50.

(C) Application

Except as provided in subparagraph (E), in applying subparagraph (A)—

(i) incurred costs shall only include costs incurred with respect to covered part D drugs for the annual deductible described in paragraph (1), for cost-sharing described in paragraph (2), and for amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3), but does not include any costs incurred for covered part D drugs which are not included (or treated as being included) in the plan’s formulary;

(ii) subject to clause (iii), such costs shall be treated as incurred only if they are paid by the part D eligible individual (or by another person, such as a family member, on behalf of the individual) and the part D eligible individual (or other person) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement (other than under such section or such a Program) for such costs; and

(iii) such costs shall be treated as incurred and shall not be considered to be reimbursed under clause (ii) if such costs are borne or paid—

(I) under section 1395w–114 of this title;

(II) under a State Pharmaceutical Assistance Program;

(III) by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 1603 of title 25); or

(IV) under an AIDS Drug Assistance Program under part B of title XXVI of the Public Health Service Act [42 U.S.C. 300ff–21 et seq.].

(D) Information regarding third-party reimbursement

(i) Procedures for exchanging information

In order to accurately apply the requirements of subparagraph (C)(ii), the Secretary is authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor—

(I) for determining whether costs for part D eligible individuals are being reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement; and

(II) for alerting the PDP sponsors and MA organizations that offer the prescription drug plans and MA–PD plans in which such individuals are enrolled about such reimbursement arrangements.

(ii) Authority to request information from enrollees

A PDP sponsor or an MA organization may periodically ask part D eligible indi-
individuals enrolled in a prescription drug plan or an MA–PD plan offered by the sponsor or organization whether such individuals have or expect to receive such third-party reimbursement. A material misrepresentation of the information described in the preceding sentence by an individual (as defined in standards set by the Secretary and determined through a process established by the Secretary) shall constitute grounds for termination of enrollment in any plan under section 1395w–21(g)(3)(B) of this title and as applied under this part under section 1395w–101(b)(1)(B)(v) of this title for a period specified by the Secretary.

(E) Inclusion of costs of applicable drugs under medicare coverage gap discount program

In applying subparagraph (A), incurred costs shall include the negotiated price (as defined in paragraph (6) of section 1395w–114a(g) of this title) of an applicable drug (as defined in paragraph (2) of such section) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1395w–114a of this title, regardless of whether part of such costs were paid by a manufacturer under such program, except that incurred costs shall not include the portion of the negotiated price that represents the reduction in coinsurance resulting from the application of paragraph (2)(D).

(5) Construction

Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization offering an MA–PD plan from reducing to zero the cost-sharing otherwise applicable to preferred or generic drugs.

(6) Annual percentage increase

The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered part D drugs in the United States for part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify.

(7) Additional annual percentage increase

The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending in July of the previous year.

c) Alternative prescription drug coverage requirements

A prescription drug plan or an MA–PD plan may provide a different prescription drug benefit design from standard prescription drug coverage so long as the Secretary determines (consistent with section 1395w–111(c) of this title) that the following requirements are met and the plan applies for, and receives, the approval of the Secretary for such benefit design:

(1) Assuring at least actuarially equivalent coverage

(A) Assuring equivalent value of total coverage

The actuarial value of the total coverage is at least equal to the actuarial value of standard prescription drug coverage.

(B) Assuring equivalent unsubsidized value of coverage

The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under section 1395w–115 of this title with respect to such coverage.

(C) Assuring standard payment for costs at initial coverage limit

The coverage is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3) of this section for the year, of an amount equal to at least the product of—

(i) the amount by which the initial coverage limit described in subsection (b)(3) of this section for the year exceeds the deductible described in subsection (b)(1) of this section for the year; and

(ii) 100 percent minus the coinsurance percentage specified in subsection (b)(2)(A)(i) of this section.

(2) Maximum required deductible

The deductible under the coverage shall not exceed the deductible amount specified under subsection (b)(1) of this section for the year.

(3) Same protection against high out-of-pocket expenditures

The coverage provides the coverage required under subsection (b)(4) of this section.

(d) Access to negotiated prices

(1) Access

(A) In general

Under qualified prescription drug coverage offered by a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan, the sponsor or organization shall provide enrollees with access to negotiated prices used for payment for covered part D drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or an initial coverage limit (described in subsection (b)(3) of this section).

(B) Negotiated prices

For purposes of this part, negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs.

(C) Medicaid-related provisions

The prices negotiated by a prescription drug plan, by an MA–PD plan with respect to

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covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1395w–132(a)(2) of this title) with respect to such drugs on behalf of part D eligible individuals, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1396e–8(c)(1)(C) of this title.

(2) Disclosure

A PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall disclose to the Secretary (in a manner specified by the Secretary) the aggregate negotiated price concessions described in paragraph (1)(B) made available to the sponsor or organization by a manufacturer that are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers. The provisions of section 1396r–8(b)(3)(D) of this title apply to information disclosed to the Secretary under this paragraph.

(3) Audits

To protect against fraud and abuse and to ensure proper disclosures and accounting under this part and in accordance with section 1395w–27(d)(2)(B) of this title (as applied under section 1395w–112(b)(3)(C) of this title), the Secretary may conduct periodic audits, directly or through contracts, of the financial statements and records of PDP sponsors with respect to prescription drug plans and MA organizations with respect to MA–PD plans.

(e) Covered part D drug defined

(1) In general

Except as provided in this subsection, for purposes of this part, the term “covered part D drug” means—

(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1396r–8(k)(2) of this title; or

(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary), and such term includes a vaccine licensed under section 262 of this title (and, for vaccines administered on or after January 1, 2008, its administration) and any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4)).

(2) Exclusions

(A) In general

Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1396r–8(d)(2) of this title, other than subparagraph (E) of such section (relating to smoking cessation agents), other than subparagraph (I) of such section (relating to barbiturates) if the barbiturate is used in the treatment of epilepsy, cancer, or a chronic mental health disorder, and other than subparagraph (J) of such section (relating to benzodiazepines), or under section 1396r–8(d)(3) of this title, as such sections were in effect on December 8, 2003. Such term also does not include a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration.

(B) Medicare covered drugs

A drug prescribed for a part D eligible individual that would otherwise be a covered part D drug under this part shall not be so considered if payment for such drug as so prescribed and dispensed or administered with respect to that individual is available (or would be available but for the application of a deductible) under part A or B of this subchapter for that individual.

(3) Application of general exclusion provisions

A prescription drug plan or an MA–PD plan may exclude from qualified prescription drug coverage any covered part D drug—

(A) for which payment would not be made if section 1395y(a) of this title applied to this part; or

(B) which is not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to subsections (g) and (h), respectively, of section 1395w–104 of this title.

(4) Medically accepted indication defined

(A) In general

For purposes of paragraph (1), the term “medically accepted indication” has the meaning given that term—

(i) in the case of a covered part D drug used in an anticancer chemotherapeutic regimen, in section 1395x(t)(2)(B) of this title, except that in applying such section—

(1) “prescription drug plan or MA–PD plan” shall be substituted for “carrier” each place it appears; and

(2) subject to subparagraph (B), the compendia described in section 1396r–8(g)(1)(B)(i)(III) of this title shall be included in the list of compendia described in clause (i)(I) section 1395x(t)(2)(B) of this title; and

(ii) in the case of any other covered part D drug, in section 1396r–8(k)(6) of this title.

(B) Conflict of interest

On and after January 1, 2010, subparagraph (A)(i)(II) shall not apply unless the compendia described in section 1396r–8(g)(1)(B)(i)(III) of this title meets the requirement in the third sentence of section 1395x(t)(2)(B) of this title.

(C) Update

For purposes of applying subparagraph (A)(ii), the Secretary shall revise the list of

1So in original. Probably should be “meet”. 
compendia described in section 1396r–8(g)(1)(B)(i) of this title as is appropriate for identifying medically accepted indications for drugs. Any such revision shall be done in a manner consistent with the process for revising compendia under section 1395x(a)(2)(B) of this title.


REFERENCES IN TEXT

Part C of this subchapter, referred to in subsecs. (a)(1), (3), (4) and (b), is classified to section 1395w–21 et seq. of this title.


The Public Health Service Act, referred to in subsec. (b)(4)(C)(ii)(IV), is act July 1, 1944, ch. 68, 58 Stat. 682. Part B of title XXVI of the Act is classified generally to part B (§300ff–21 et seq.) of subchapter XXIV of chapter 6A of this title. For complete classification of this Act to the Code, see Short Title note set out under section 203 of this title and Table.

Parts A and B of this subchapter, referred to in subsec. (e)(2)(B), are classified to sections 1396c et seq. and 1395b et seq., respectively, of this title.

AMENDMENTS

2010—Subsec. (b)(2)(A). Pub. L. 111–152, §110(b)(3)(A), substituted “Subject to subparagraphs (C) and (D), the coverage” for “The coverage.”

Subsec. (b)(2)(B). Pub. L. 111–152, §110(b)(3)(B), substituted “(as defined in paragraph (4))” for “(as defined in paragraph (4))” in introductory provisions.

Subsec. (b)(3)(A). Pub. L. 111–152, §110(b)(3)(D), substituted “Subject to subparagraphs (A)(ii), (C), and (D)” for “as subparagraph (A)(ii)”.

Subsec. (b)(3)(C). Pub. L. 111–152, §110(b)(3)(C), added subparagraph (C) and (D).

Subsec. (b)(4)(A). Pub. L. 111–152, §110(b)(3)(D), substituted “Subject to subparagraphs (2)(C), (2)(D), and (4)” for “paragraph (4)”.

Pub. L. 111–148, §3315(1), which directed substitution of “paragraphs (4) and (7)” for “paragraph (4)” in introductory provisions, was repealed by Pub. L. 111–152, §110(a)(2). See Construction of 2010 Amendment note below.

Subsec. (b)(4)(B)(i) to (VI). Pub. L. 111–152, §110(d)(1), added subcls. (II) to (V) and redesignated former subcl. (II) as (V).

Subsec. (b)(4)(C). Pub. L. 111–148, §3314(a), in cl. (ii), substituted “subject to clause (ii), such costs shall be treated as incurred only if” for “such costs shall be treated as incurred only if” and stricken out “, under section 1395w–114 of this title, or under a State Pharmaceutical Assistance Program” after “on behalf of the individual),” and added cl. (iii).

Pub. L. 111–148, §3301(c)(1)(A), substituted “Except as provided in subparagraph (E), in applying” for “In applying” in introductory provisions.

Subsec. (b)(4)(E). Pub. L. 111–152, §110(b)(3)(E), inserted before period at end “, except that incurred costs shall not include the portion of the negotiated price that represents the reduction in coinsurance resulting from the application of paragraph (2)(D)”.


Pub. L. 111–148, §3315(2), which directed addition of par. (7), was repealed by Pub. L. 111–152, §110(a)(3). As enacted, text read as follows:

“(A) IN GENERAL.—For the plan year beginning on January 1, 2010, the initial coverage limit described in paragraph (5)(B) otherwise applicable shall be increased by $500.

“(B) APPLICATION.—In applying subparagraph (A)—

“(i) except as otherwise provided in this subparagraph, there shall be no change in the premiums, bids, or any other parameters under this part or part C;

“(ii) costs that would be treated as incurred costs for purposes of applying paragraph (4) but for the application of subparagraph (A) shall continue to be treated as incurred costs;

“(iii) the Secretary shall establish procedures, which may include a reconciliation process, to fully reimburse PDP sponsors with respect to prescription drug plans and MA organizations with respect to MA–PD plans for the reduction in beneficiary cost sharing associated with the application of subparagraph (A);

“(iv) the Secretary shall develop an estimate of the additional increased costs attributable to the application of this paragraph for increased drug utilization and financing and administrative costs and shall use such estimate to adjust payments to PDP sponsors with respect to prescription drug plans under this part and MA organizations with respect to MA–PD plans under part C; and

“(v) the Secretary shall establish procedures for retroactive reimbursement of part D eligible individuals who are covered under such a plan made by which are incurred before the date of initial implementation of subparagraph (A) and which would be reimbursed under such a plan if such implementation occurred as of January 1, 2010.

“(C) NO EFFECT ON SUBSEQUENT YEARS.—The increase under subparagraph (A) only apply with respect to the plan year beginning on January 1, 2010, and the initial coverage limit for plan years beginning on or after January 1, 2011, shall be determined as if subparagraph (A) had never applied.”

See Construction of 2010 Amendment note below.

2008—Subsec. (e)(1). Pub. L. 110–275, §182(a)(1)(A), substituted “(as defined in paragraph (4))” for “(as defined in section 1396r–8(k)(6) of this title)” in concluding provisions.

Subsec. (e)(2)(A). Pub. L. 110–275, §175(a), inserted “other than subparagraph (J) of such section (relating to barbiturates) if the barbiturate is used in the treatment of epilepsy, cancer, or a chronic mental health disorder, and other than subparagraph (J) of such section (relating to benzodiazepines),” after “agents),”.

Subsec. (e)(4). Pub. L. 110–275, §182(a)(1)(B), which directed amendment of subsec. (e)(1) in the matter following subpar. (B) by adding par. (4) at the end, was executed by adding par. (4) at end of subsec. (e), to reflect the probable intent of Congress.


2005—Subsec. (e)(2)(A). Pub. L. 109–91, §109(a)(2), inserted at end “Such term also does not include a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration.”

Pub. L. 109–91, §109(a)(1), inserted before period at end “, as such sections were in effect on December 8, 2003”.

EFFECTIVE DATE OF 2010 AMENDMENT


§ 1395w–103. Access to a choice of qualified prescription drug coverage

(a) Assuring access to a choice of coverage

(1) Choice of at least two plans in each area

The Secretary shall ensure that each part D eligible individual has available, consistent with paragraph (2), a choice of enrollment in at least 2 qualifying plans (as defined in paragraph (3)) in the area in which the individual resides, at least one of which is a prescription drug plan. In any such case in which such plans are not available, the part D eligible individual shall be given the opportunity to enroll in a fallback prescription drug plan.

(2) Requirement for different plan sponsors

The requirement in paragraph (1) is not satisfied with respect to an area if only one entity offers all the qualifying plans in the area.

(b) Flexibility in risk assumed and application of fallback plan

In order to ensure access pursuant to subsection (a) of this section in an area—

(1) the Secretary may approve limited risk plans under section 1395w–111(f) of this title for the area; and

(2) only if such access is still not provided in the area after applying paragraph (1), the Secretary shall provide for the offering of a fallback prescription drug plan for that area under section 1395w–111(g) of this title.

§ 1395w–104. Beneficiary protections for qualified prescription drug coverage

(a) Dissemination of information

(1) General information

(A) Application of MA information

A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1395w–22(c)(1) of this title relating to such plan, insofar as the Secretary determines appropriate with respect to benefits provided under this part, and including the information described in subparagraph (B).

(B) Drug specific information

The information described in this subparagraph is information concerning the following:

(i) Access to specific covered part D drugs, including access through pharmacy networks.

(ii) How any formulary (including any tiered formulary structure) used by the sponsor functions, including a description of how a part D eligible individual may obtain information on the formulary consistent with paragraph (3).

(iii) Beneficiary cost-sharing requirements and how a part D eligible individual may obtain information on such requirements, including tiered or other copayment level applicable to each drug (or class of drugs), consistent with paragraph (3).

(3) Qualifying plan defined

For purposes of this section, the term “qualifying plan” means—

(A) a prescription drug plan; or

(B) an MA–PD plan described in section 1395w–21(a)(2)(A)(i) of this title that provides—

(i) basic prescription drug coverage; or

(ii) qualified prescription drug coverage that provides supplemental prescription drug coverage so long as there is no MA monthly supplemental beneficiary premium applied under the plan, due to the application of a credit against such premium of a rebate under section 1395w–24(b)(1)(C) of this title.

Payment for administration of part D vaccines in 2007

Pub. L. 109–432, div. B, title II, §202(a), Dec. 20, 2006, 120 Stat. 2986, provided that: “Notwithstanding any other provision of law, in the case of a vaccine that is a covered part D drug under section 1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e)) that is administered during 2007, the administration of such vaccine shall be paid under part B of title XVIII of such Act (part B of this subchapter) as if it were the administration of a vaccine described in section 1861(s)(10)(B) of such Act (42 U.S.C. 1395w(s)(10)(B) [probably should be 1395x(s)(10)(B)].)”
(iv) The medication therapy management program required under subsection (c) of this section.

(2) Disclosure upon request of general coverage, utilization, and grievance information

Upon request of a part D eligible individual who is eligible to enroll in a prescription drug plan, the PDP sponsor offering such plan shall provide information similar (as determined by the Secretary) to the information described in subparagraphs (A), (B), and (C) of section 1395w–22(c)(2) of this title to such individual.

(3) Provision of specific information

(A) Response to beneficiary questions

Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information on a timely basis to enrollees upon request. Such mechanism shall include access to information through the use of a toll-free telephone number and, upon request, the provision of such information in writing.

(B) Availability of information on changes in formulary through the Internet

A PDP sponsor offering a prescription drug plan shall make available on a timely basis through an Internet website information on specific changes in the formulary under the plan (including changes to tiered or preferred status of covered part D drugs).

(4) Claims information

A PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees—

(A) an explanation of benefits (in accordance with section 1385b–7(a) of this title or in a comparable manner); and

(B) when prescription drug benefits are provided under this part, a notice of the benefits in relation to—

(i) the initial coverage limit for the current year; and

(ii) the annual out-of-pocket threshold for the current year.

Notices under subparagraph (B) need not be provided more often than as specified by the Secretary and notices under subparagraph (B)(ii) shall take into account the application of section 1395w–102(b)(4)(C) of this title to the extent practicable, as specified by the Secretary.

(b) Access to covered part D drugs

(1) Assuring pharmacy access

(A) Participation of any willing pharmacy

A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.

(B) Discounts allowed for network pharmacies

For covered part D drugs dispensed through in-network pharmacies, a prescription drug plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required. In no case shall such a reduction result in an increase in payments made by the Secretary under section 1395w–115 of this title to a plan.

(C) Convenient access for network pharmacies

(i) In general

The PDP sponsor of the prescription drug plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules established by the Secretary).

(ii) Application of TRICARE standards

The Secretary shall establish rules for convenient access to in-network pharmacies under this subparagraph that are no less favorable to enrollees than the rules for convenient access to pharmacies included in the statement of work of solicitation (#MDA906-03-R-0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

(iii) Adequate emergency access

Such rules shall include adequate emergency access for enrollees.

(iv) Convenient access in long-term care facilities

Such rules may include standards with respect to access for enrollees who are residing in long-term care facilities and for pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 1603 of title 25).

(D) Level playing field

Such a sponsor shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a pharmacy (other than a mail order pharmacy), with any differential in charge paid by such enrollee.

(E) Not required to accept insurance risk

The terms and conditions under subparagraph (A) may not require participating pharmacies to accept insurance risk as a condition of participation.

(2) Use of standardized technology

(A) In general

The PDP sponsor of a prescription drug plan shall issue (and reissue, as appropriate) such a card (or other technology) that may be used by an enrollee to assure access to negotiated prices under section 1395w–102(d) of this title.

(B) Standards

(i) In general

The Secretary shall provide for the development, adoption, or recognition of standards relating to a standardized format for the card or other technology required under subparagraph (A). Such standards shall be compatible with part C of subchapter XI of this chapter and may
be based on standards developed by an appropriate standard setting organization.

(ii) Consultation
In developing the standards under clause (i), the Secretary shall consult with the National Council for Prescription Drug Programs and other standard setting organizations determined appropriate by the Secretary.

(iii) Implementation
The Secretary shall develop, adopt, or recognize the standards under clause (i) by such date as the Secretary determines shall be sufficient to ensure that PDP sponsors utilize such standards beginning January 1, 2006.

(3) Requirements on development and application of formularies
If a PDP sponsor of a prescription drug plan uses a formulary (including the use of tiered cost-sharing), the following requirements must be met:

(A) Development and revision by a pharmacy and therapeutic (P&T) committee
(i) In general
The formulary must be developed and reviewed by a pharmacy and therapeutic committee. A majority of the members of such committee shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

(ii) Inclusion of independent experts
Such committee shall include at least one practicing physician and at least one practicing pharmacist, each of whom—
(I) is independent and free of conflict with respect to the sponsor and plan; and
(II) has expertise in the care of elderly or disabled persons.

(B) Formulary development
In developing and reviewing the formulary, the committee shall—
(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and on such other information as the committee determines to be appropriate; and
(ii) take into account whether including in the formulary (or in a tier in such formulary) particular covered part D drugs has therapeutic advantages in terms of safety and efficacy.

(C) Inclusion of drugs in all therapeutic categories and classes
(i) In general
Subject to subparagraph (G), the formulary must include drugs within each therapeutic category and class of covered part D drugs, although not necessarily all drugs within such categories and classes.

(ii) Model guidelines
The Secretary shall request the United States Pharmacopoeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.

(iii) Limitation on changes in therapeutic classification
The PDP sponsor of a prescription drug plan may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as the Secretary may permit to take into account new therapeutic uses and newly approved covered part D drugs.

(D) Provider and patient education
The PDP sponsor shall establish policies and procedures to educate and inform health care providers and enrollees concerning the formulary.

(E) Notice before removing drug from formulary or changing preferred or tier status of drug
Any removal of a covered part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available (such as under subsection (a)(3) of this section) to the Secretary, affected enrollees, physicians, pharmacists, and pharmacists.

(F) Periodic evaluation of protocols
In connection with the formulary, the sponsor of a prescription drug plan shall provide for the periodic evaluation and analysis of treatment protocols and procedures.

(G) Required inclusion of drugs in certain categories and classes
(i) Formulary requirements
(I) In general
Subject to subclause (II), a PDP sponsor offering a prescription drug plan shall be required to include all covered part D drugs in the categories and classes identified by the Secretary under clause (ii)(I).

(II) Exceptions
The Secretary may establish exceptions that permit a PDP sponsor offering a prescription drug plan to exclude from its formulary a particular covered part D drug in a category or class that is otherwise required to be included in the formulary under subclause (I) (or to otherwise limit access to such a drug, including through prior authorization or utilization management).

(ii) Identification of drugs in certain categories and classes
(I) In general
Subject to clause (iv), the Secretary shall identify, as appropriate, categories
and classes of drugs for which the Secretary determines are of clinical concern.

(II) Criteria

The Secretary shall use criteria established by the Secretary in making any determination under subclause (I).

(iii) Implementation

The Secretary shall establish the criteria under clause (ii)(II) and any exceptions under clause (i)(II) through the promulgation of a regulation which includes a public notice and comment period.

(iv) Requirement for certain categories and classes until criteria established

Until such time as the Secretary establishes the criteria under clause (ii)(II) the following categories and classes of drugs shall be identified under clause (ii)(I):

(I) Anticonvulsants.
(II) Antidepressants.
(III) Antineoplastics.
(IV) Antipsychotics.
(V) Antiretrovirals.
(VI) Immunosuppressants for the treatment of transplant rejection.

(II) Use of single, uniform exceptions and appeals process

Notwithstanding any other provision of this part, each PDP sponsor of a prescription drug plan shall—

(i) use a single, uniform exceptions and appeals process (including, to the extent the Secretary determines feasible, a single, uniform model form for use under such process) with respect to the determination of prescription drug coverage for an enrollee under the plan; and

(ii) provide instant access to such process by enrollees through a toll-free telephone number and an Internet website.

(c) Cost and utilization management; quality assurance; medication therapy management program

(1) In general

The PDP sponsor shall have in place, directly or through appropriate arrangements, with respect to covered part D drugs, the following:

(A) A cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs (as defined in section 1396w–2(k)(7)(A)(i) of this title).

(B) Quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

(C) A medication therapy management program described in paragraph (2).

(D) A program to control fraud, abuse, and waste.

Nothing in this section shall be construed as impairing a PDP sponsor from utilizing cost management tools (including differential payments) under all methods of operation.

(2) Medication therapy management program

(A) Description

(i) In general

A medication therapy management program described in this paragraph is a program of drug therapy management that may be furnished by a pharmacist and that is designed to assure, with respect to targeted beneficiaries described in clause (ii), that covered part D drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Such a program may distinguish between services in ambulatory and institutional settings.

(ii) Targeted beneficiaries described

Targeted beneficiaries described in this clause are part D eligible individuals who—

(I) have multiple chronic diseases (such as diabetes, asthma, hypertension, hyperlipidemia, and congestive heart failure);

(II) are taking multiple covered part D drugs; and

(III) are identified as likely to incur annual costs for covered part D drugs that exceed a level specified by the Secretary.

(B) Elements

Such program may include elements that promote—

(i) enhanced enrollee understanding to promote the appropriate use of medications by enrollees and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, and other appropriate means;

(ii) increased enrollee adherence with prescription medication regimens through medication refill reminders, special packaging, and other compliance programs and other appropriate means; and

(iii) detection of adverse drug events and patterns of overuse and underuse of prescription drugs.

(C) Required interventions

For plan years beginning on or after the date that is 2 years after March 23, 2010, prescription drug plan sponsors shall offer medication therapy management services to targeted beneficiaries described in subparagraph (A)(ii) that include, at a minimum, the following to increase adherence to prescription medications or other goals deemed necessary by the Secretary:

(i) An annual comprehensive medication review furnished person-to-person or using telehealth technologies (as defined by the Secretary) by a licensed pharmacist or other qualified provider. The comprehensive medication review—

(I) shall include a review of the individual’s medications and may result in the creation of a recommended medica-
ion action plan or other actions in consultation with the individual and with input from the prescriber to the extent necessary and practicable; and

(II) shall include providing the individual with a written or printed summary of the results of the review.

The Secretary, in consultation with relevant stakeholders, shall develop a standardized format for the action plan under subclause (I) and the summary under subclause (II).

(ii) Follow-up interventions as warranted based on the findings of the annual medication review or the targeted medication enrollment and which may be provided person-to-person or using telehealth technologies (as defined by the Secretary).

(D) Assessment

The prescription drug plan sponsor shall have in place a process to assess, at least on a quarterly basis, the medication use of individuals who are at risk but not enrolled in the medication therapy management program, including individuals who have experienced a transition in care, if the prescription drug plan sponsor has access to that information.

(E)\(^1\) Automatic enrollment with ability to opt-out

The prescription drug plan sponsor shall have in place a process to—

(i) subject to clause (ii), automatically enroll targeted beneficiaries described in subparagraph (A)(ii), including beneficiaries identified under subparagraph (D), in the medication therapy management program required under this subsection; and

(ii) permit such beneficiaries to opt-out of enrollment in such program.

(E)\(^1\) Development of program in cooperation with licensed pharmacists

Such program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

(F) Coordination with care management plans

The Secretary shall establish guidelines for the coordination of any medication therapy management program under this paragraph with respect to a targeted beneficiary with any care management plan established with respect to such beneficiary under a chronic care improvement program under section 1395b–8 of this title.

(G) Considerations in pharmacy fees

The PDP sponsor of a prescription drug plan shall take into account, in establishing fees for pharmacists and others providing services under such plan, the resources used, and time required to, implement the medication therapy management program under this paragraph. Each such sponsor shall disclose to the Secretary upon request the amount of any such management or dispensing fees. The provisions of section 1396r–8(b)(3)(D) of this title apply to information disclosed under this subparagraph.

(3) Reducing wasteful dispensing of outpatient prescription drugs in long-term care facilities

The Secretary shall require PDP sponsors of prescription drug plans to utilize specific, uniform dispensing techniques, as determined by the Secretary, in consultation with relevant stakeholders (including representatives of nursing facilities, residents of nursing facilities, pharmacists, the pharmacy industry (including retail and long-term care pharmacy), prescription drug plans, MA–PD plans, and any other stakeholders the Secretary determines appropriate), such as weekly, daily, or automated dose dispensing, when dispensing covered part D drugs to enrollees who reside in a long-term care facility in order to reduce waste associated with 30-day fills.

(d) Consumer satisfaction surveys

In order to provide for comparative information under section 1395w–101(c)(3)(A)(v) of this title, the Secretary shall conduct consumer satisfaction surveys with respect to PDP sponsors and prescription drug plans in a manner similar to the manner such surveys are conducted for MA organizations and MA plans under part C of this subchapter.

(e) Electronic prescription program

1. Application of standards

As of such date as the Secretary may specify, but not later than 1 year after the date of promulgation of final standards under paragraph (4)(D), prescriptions and other information described in paragraph (2)(A) for covered part D drugs prescribed for part D eligible individuals that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2).

2. Program requirements

Consistent with uniform standards established under paragraph (3)—

(A) Provision of information to prescribing health care professional and dispensing pharmacies and pharmacists

An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered part D drug:

(i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.

\(^1\)So in original. Two subpars. (E) have been enacted.
(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

(B) Application to medical history information

Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to carry out this subparagraph, the program shall provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) of information that relates to the medical history concerning the individual and related to a covered part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

(C) Limitations

Information shall only be disclosed under subparagraph (A) or (B) if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

(D) Timing

To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis.

(3) Standards

(A) In general

The Secretary shall provide consistent with this subsection for the promulgation of uniform standards relating to the requirements for electronic prescription drug programs under paragraph (2).

(B) Objectives

Such standards shall be consistent with the objectives of improving—

(i) patient safety;

(ii) the quality of care provided to patients; and

(iii) efficiencies, including cost savings, in the delivery of care.

(C) Design criteria

Such standards shall—

(i) be designed so that, to the extent practicable, the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists;

(ii) be compatible with standards established under part C of subchapter XI of this chapter, standards established under subsection (b)(2)(B)(i) of this section, and with general health information technology standards; and

(iii) be designed so that they permit electronic exchange of drug labeling and drug listing information maintained by the Food and Drug Administration and the National Library of Medicine.

(D) Permitting use of appropriate messaging

Such standards shall allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems referred to in subsection (c)(1)(B) of this section.

(E) Permitting patient designation of dispensing pharmacy

(i) In general

Consistent with clause (ii), such standards shall permit a part D eligible individual to designate a particular pharmacy to dispense a prescribed drug.

(ii) No change in benefits

Clause (i) shall not be construed as affecting—

(I) the access required to be provided to pharmacies by a prescription drug plan; or

(II) the application of any differences in benefits or payments under such a plan based on the pharmacy dispensing a covered part D drug.

(4) Development, promulgation, and modification of standards

(A) Initial standards

Not later than September 1, 2005, the Secretary shall develop, adopt, recognize, or modify initial uniform standards relating to the requirements for electronic prescription drug programs described in paragraph (2) taking into consideration the recommendations (if any) from the National Committee on Vital and Health Statistics (as established under section 242k(k) of this title) under subparagraph (B).

(B) Role of NCVHS

The National Committee on Vital and Health Statistics shall develop recommendations for uniform standards relating to such requirements in consultation with the following:

(i) Standard setting organizations (as defined in section 1320d(8) of this title)

(ii) Practicing physicians.

(iii) Hospitals.

(iv) Pharmacies.

(v) Practicing pharmacists.

(vi) Pharmacy benefit managers.

(vii) State boards of pharmacy.

(viii) State boards of medicine.

(ix) Experts on electronic prescribing.

(x) Other appropriate Federal agencies.

(C) Pilot project to test initial standards

(i) In general

During the 1-year period that begins on January 1, 2006, the Secretary shall conduct a pilot project to test the initial standards developed under subparagraph (A) prior to the promulgation of the final uniform standards under subparagraph (D) in order to provide for the efficient implementation of the requirements described in paragraph (2).

(ii) Exception

Pilot testing of standards is not required under clause (i) where there already is ade-
quate industry experience with such standards, as determined by the Secretary after consultation with affected standard setting organizations and industry users.

(iii) Voluntary participation of physicians and pharmacies

In order to conduct the pilot project under clause (i), the Secretary shall enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards.

(iv) Evaluation and report

(1) Evaluation

The Secretary shall conduct an evaluation of the pilot project conducted under clause (i).

(2) Report to Congress

Not later than April 1, 2007, the Secretary shall submit to Congress a report on the evaluation conducted under subclause (I).

(D) Final standards

Based upon the evaluation of the pilot project under subparagraph (C)(iv)(I) and not later than April 1, 2008, the Secretary shall promulgate uniform standards relating to the requirements described in paragraph (2).

(5) Relation to State laws

The standards promulgated under this subsection shall supersede any State law or regulation that—

(A) is contrary to the standards or restricts the ability to carry out this part; and

(B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

(6) Establishment of safe harbor

The Secretary, in consultation with the Attorney General, shall promulgate regulations that provide for a safe harbor from sanctions under paragraphs (1) and (2) of section 1320a–7b(b) of this title and an exception to the prohibition under subsection (a)(1) of section 1395nn of this title with respect to the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under this subsection—

(A) in the case of a hospital, by the hospital to members of its medical staff;

(B) in the case of a group practice (as defined in section 1395nn(h)(4) of this title), by the practice to prescribing health care professionals who are members of such practice; and

(C) in the case of a PDP sponsor or MA organization, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization, and to prescribing health care professionals.

(f) Grievance mechanism

Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1395w–22(f) of this title.

(g) Coverage determinations and reconsiderations

(1) Application of coverage determination and reconsideration provisions

A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1395w–22(g) of this title with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to an MA organization with respect to benefits it offers under an MA plan under part C of this subchapter.

(2) Request for a determination for the treatment of tiered formulary drugs

In the case of a prescription drug plan offered by a PDP sponsor that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, a part D eligible individual who is enrolled in the plan may request an exception to the tiered cost-sharing structure. Under such an exception, a nonpreferred drug could be covered under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both. A PDP sponsor shall have an exceptions process under this paragraph consistent with guidelines established by the Secretary for making a determination with respect to such a request. Denial of such an exception shall be treated as a coverage denial for purposes of applying subsection (h) of this section.

(h) Appeals

(1) In general

Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1395w–22(g) of this title with respect to benefits (including a determination related to the application of tiered cost-sharing described in subsection (g)(2) of this section) in a manner similar (as determined by the Secretary) to the manner such requirements apply to an MA organization with respect to benefits under the original medicare fee-for-service program option it offers under an MA plan under part C of this subchapter. In applying this paragraph only the part D eligible individual shall be entitled to bring such an appeal.

(2) Limitation in cases on nonformulary determinations

A part D eligible individual who is enrolled in a prescription drug plan offered by a PDP

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A PDP sponsor offering a prescription drug plan shall provide that each pharmacy that dispenses a covered part D drug shall inform the enrollee of the lowest priced generic covered part D drug under the plan that is therapeutically equivalent and bioequivalent and available at such pharmacy.

(2) Timing of notice

(A) In general

Subject to subparagraph (B), the information under paragraph (1) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

(B) Waiver

The Secretary may waive subparagraph (A) in such circumstances as the Secretary may specify.

(l) Requirements with respect to sales and marketing activities

The following provisions shall apply to a PDP sponsor (and the agents, brokers, and other third parties representing such sponsor) in the same manner as such provisions apply to a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization):

(1) The prohibition under section 1395w–21(h)(4)(C) of this title on conducting activities described in section 1395w–21(j)(1) of this title.

(2) The requirement under section 1395w–21(h)(4)(D) of this title to conduct activities described in section 1395w–21(j)(2) of this title in accordance with the limitations established under such subsection.

(3) The inclusion of the plan type in the plan name under section 1395w–21(h)(6) of this title.

(4) The requirements regarding the appointment of agents and brokers and compliance with State information requests under subparagraphs (A) and (B), respectively, of section 1395w–21(h)(7) of this title.


REFERENCES IN TEXT

Part C of subchapter XI of this chapter, referred to in subsecs. (b)(2)(B)(i) and (e)(3)(C)(ii), is classified to section 1320d et seq. of this title.

Part C of this subchapter, referred to in subsecs. (d), (g)(v), and (h)(1), is classified to section 1395w–21 et seq. of this title.

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (e)(2)(C), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

AMENDMENTS


Pub. L. 111–148, §10328(a), added subpars. (C) to (E) and redesignated former subpars. (C) to (E), respectively, as (D) to (G), respectively. Pub. L. 111–148, §3310(a), added par. (3).

2008—Subsec. (b)(3)(C)(i). Pub. L. 110–275, §176(1), substituted “Subject to subparagraph (G), the formula” for “‘The formulary’.


EFFECTIVE DATE OF 2010 AMENDMENT


GRANTS TO PHYSICIANS TO IMPLEMENT ELECTRONIC PRESCRIPTION DRUG PROGRAMS


RULE OF CONSTRUCTION


§ 1395w–111. PDP regions; submission of bids; plan approval

(a) Establishment of PDP regions; service areas

(1) Coverage of entire PDP region

The service area for a prescription drug plan shall consist of an entire PDP region established under paragraph (2).

(2) Establishment of PDP regions

(A) In general

The Secretary shall establish, and may revise, PDP regions in a manner that is consistent with the requirements for the establishment and revision of MA regions under subparagraphs (B) and (C) of section 1395w–27a(a)(2) of this title.

(B) Relation to MA regions

To the extent practicable, PDP regions shall be the same as MA regions under section 1395w–27a(a)(2) of this title. The Secretary may establish PDP regions which are not the same as MA regions if the Secretary determines that the establishment of different regions under this part would improve access to benefits under this part.

(C) Authority for territories

The Secretary shall establish, and may revise, PDP regions for areas in States that are not within the 50 States or the District of Columbia.

(3) National plan

Nothing in this subsection shall be construed as preventing a prescription drug plan from being offered in more than one PDP region (including all PDP regions).

(b) Submission of bids, premiums, and related information

(1) In general

A PDP sponsor shall submit to the Secretary information described in paragraph (2) with respect to each prescription drug plan it offers. Such information shall be submitted at the same time and in a similar manner to the manner in which information described in paragraph (6) of section 1395w–24(a) of this title.
title is submitted by an MA organization under paragraph (1) of such section.

(2) Information described

The information described in this paragraph is information on the following:

(A) Coverage provided

The prescription drug coverage provided under the plan, including the deductible and other cost-sharing.

(B) Actuarial value

The actuarial value of the qualified prescription drug coverage in the region for a part D eligible individual with a national average risk profile for the factors described in section 1395w–115(e)(1)(A) of this title (as specified by the Secretary).

(C) Bid

Information on the bid, including an actuarial certification of—

(i) the basis for the actuarial value described in subparagraph (B) assumed in such bid;

(ii) the portion of such bid attributable to basic prescription drug coverage and, if applicable, the portion of such bid attributable to supplemental benefits;

(iii) assumptions regarding the reinsurance subsidy payments provided under section 1395w–115(b) of this title subtracted from the actuarial value to produce such bid; and

(iv) administrative expenses assumed in the bid.

(D) Service area

The service area for the plan.

(E) Level of risk assumed

(i) In general

Whether the PDP sponsor requires a modification of risk level under clause (ii) and, if so, the extent of such modification. Any such modification shall apply with respect to all prescription drug plans offered by a PDP sponsor in a PDP region. This subparagraph shall not apply to an MA–PD plan.

(ii) Risk levels described

A modification of risk level under this clause may consist of one or more of the following:

(I) Increase in Federal percentage assumed in initial risk corridor

An equal percentage point increase in the percents applied under subparagraphs (B)(i), (B)(i)(I), (C)(i), and (C)(ii)(I) of section 1395w–115(e)(2) of this title. In no case shall the application of previous sentence prevent the application of a higher percentage under section 1395w–115(e)(2)(B)(iii) of this title.

(II) Increase in Federal percentage assumed in second risk corridor

An equal percentage point increase in the percents applied under subpara-

graphs (B)(i)(I) and (C)(i)(I) of section 1395w–115(e)(2) of this title.

(III) Decrease in size of risk corridors

A decrease in the threshold risk percentages specified in section 1395w–115(e)(3)(C) of this title.

(F) Additional information

Such other information as the Secretary may require to carry out this part.

(3) Paperwork reduction for offering of prescription drug plans nationally or in multi-region areas

The Secretary shall establish requirements for information submission under this subsection in a manner that promotes the offering of such plans in more than one PDP region (including all regions) through the filing of consolidated information.

(c) Actuarial valuation

(1) Processes

For purposes of this part, the Secretary shall establish processes and methods for determining the actuarial valuation of prescription drug coverage, including—

(A) an actuarial valuation of standard prescription drug coverage under section 1395w–102(b) of this title;

(B) actuarial valuations relating to alternative prescription drug coverage under section 1395w–102(c)(1) of this title;

(C) an actuarial valuation of the reinsurance subsidy payments under section 1395w–115(b) of this title;

(D) the use of generally accepted actuarial principles and methodologies; and

(E) applying the same methodology for determinations of actuarial valuations under subparagraphs (A) and (B).

(2) Accounting for drug utilization

Such processes and methods for determining actuarial valuation shall take into account the effect that providing alternative prescription drug coverage (rather than standard prescription drug coverage) has on drug utilization.

(3) Responsibilities

(A) Plan responsibilities

PDP sponsors and MA organizations are responsible for the preparation and submission of actuarial valuations required under this part for prescription drug plans and MA–PD plans they offer.

(B) Use of outside actuaries

Under the processes and methods established under paragraph (1), PDP sponsors offering prescription drug plans and MA organizations offering MA–PD plans may use actuarial opinions certified by independent, qualified actuaries to establish actuarial values.

(d) Review of information and negotiation

(1) Review of information

The Secretary shall review the information filed under subsection (b) of this section for the purpose of conducting negotiations under paragraph (2).
(2) Negotiation regarding terms and conditions

Subject to subsection (i) of this section, in exercising the authority under paragraph (1), the Secretary—

(A) has the authority to negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan; and

(B) has authority similar to the authority of the Director of the Office of Personnel Management with respect to health benefits plans under chapter 89 of title 5.

(3) Rejection of bids

Paragraph (5)(C) of section 1395w–24(a) of this title shall apply with respect to bids submitted by an MA organization under such section 1395w–24(a) of this title.

(e) Approval of proposed plans

(1) In general

After review and negotiation under subsection (d) of this section, the Secretary shall approve or disapprove the prescription drug plan.

(2) Requirements for approval

The Secretary may approve a prescription drug plan only if the following requirements are met:

(A) Compliance with requirements

The plan and the PDP sponsor offering the plan comply with the requirements under this part, including the provision of qualified prescription drug coverage.

(B) Actuarial determinations

The Secretary determines that the plan and PDP sponsor meet the requirements under this part relating to actuarial determinations, including such requirements under section 1395w–102(c) of this title.

(C) Application of FEHBP standard

(i) In general

The Secretary determines that the portion of the bid submitted under subsection (b) of this section that is attributable to basic prescription drug coverage is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 300e–1(8)(C) of this title) for such coverage under the plan.

(D) Plan design

(i) In general

The Secretary determines that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan.

(ii) Use of categories and classes in formularies

The Secretary may not find that the design of categories and classes within a formulary violates clause (i) if such categories and classes are consistent with guidelines (if any) for such categories and classes established by the United States Pharmacopeia.

(f) Application of limited risk plans

(1) Conditions for approval of limited risk plans

The Secretary may only approve a limited risk plan (as defined in paragraph (4)(A)) for a PDP region if the access requirements under section 1395w–103(a) of this title would not be met for the region but for the approval of such a plan (or a fallback prescription drug plan under subsection (g) of this section).

(2) Rules

The following rules shall apply with respect to the approval of a limited risk plan in a PDP region:

(A) Limited exercise of authority

Only the minimum number of such plans may be approved in order to meet the access requirements under section 1395w–103(a) of this title.

(B) Maximizing assumption of risk

The Secretary shall provide priority in approval for those plans bearing the highest level of risk (as computed by the Secretary), but the Secretary may take into account the level of the bids submitted by such plans.

(C) No full underwriting for limited risk plans

In no case may the Secretary approve a limited risk plan under which the modification of risk level provides for no (or a de minimis) level of financial risk.

(3) Acceptance of all full risk contracts

There shall be no limit on the number of full risk plans that are approved under subsection (e) of this section.

(4) Risk-plans defined

For purposes of this subsection:

(A) Limited risk plan

The term “limited risk plan” means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in subparagraph (E) of subsection (b)(2) of this section in its bid sub-
transmitted for the plan under such subsection. Such term does not include a fallback prescription drug plan.

(B) Full risk plan

The term “full risk plan” means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

(g) Guaranteeing access to coverage

(1) Solicitation of bids

(A) In general

Separate from the bidding process under subsection (b) of this section, the Secretary shall provide for a process for the solicitation of bids from eligible fallback entities (as defined in paragraph (2)) for the offering in all fallback service areas (as defined in paragraph (3)) in one or more PDP regions of a fallback prescription drug plan (as defined in paragraph (4)) during the contract period specified in paragraph (5).

(B) Acceptance of bids

(i) In general

Except as provided in this subparagraph, the provisions of subsection (e) of this section shall apply with respect to the approval or disapproval of fallback prescription drug plans. The Secretary shall enter into contracts with eligible fallback entities for the offering of fallback prescription drug plans so approved in fallback service areas.

(ii) Limitation of 1 plan for all fallback service areas in a PDP region

With respect to all fallback service areas in any PDP region for a contract period, the Secretary shall approve the offering of only 1 fallback prescription drug plan.

(iii) Competitive procedures

Competitive procedures (as defined in section 132 of title 41) shall be used to enter into a contract under this subsection. The provisions of subsection (d) of section 1395kk–1 of this title shall apply to a contract under this section in the same manner as they apply to a contract under such section.

(iv) Timing

The Secretary shall approve a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the fallback prescription drug plan is offered at the same time as prescription drug plans would otherwise be offered.

(V) No national fallback plan

The Secretary shall not enter into a contract with a single fallback entity for the offering of fallback plans throughout the United States.

(2) Eligible fallback entity

For purposes of this section, the term “eligible fallback entity” means, with respect to all fallback service areas in a PDP region for a contract period, an entity that—

(A) meets the requirements to be a PDP sponsor (or would meet such requirements but for the fact that the entity is not a risk-bearing entity); and

(B) does not submit a bid under subsection (b) of this section for any prescription drug plan for any PDP region for the first year of such contract period.

For purposes of subparagraph (B), an entity shall be treated as submitting a bid with respect to a prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

(3) Fallback service area

For purposes of this subsection, the term “fallback service area” means, for a PDP region with respect to a year, any area within such region for which the Secretary determines before the beginning of the year that the access requirements of the first sentence of section 1395w–103(a) of this title will not be met for part D eligible individuals residing in the area for the year.

(4) Fallback prescription drug plan

For purposes of this part, the term “fallback prescription drug plan” means a prescription drug plan that—

(A) only offers the standard prescription drug coverage and access to negotiated prices described in section 1395w–102(a)(1)(A) of this title and does not include any supplemental prescription drug coverage; and

(B) meets such other requirements as the Secretary may specify.

(5) Payments under the contract

(A) In general

A contract entered into under this subsection shall provide for—

(i) payment for the actual costs (taking into account negotiated price concessions described in section 1395w–102(d)(1)(B) of this title) of covered part D drugs provided to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

(ii) payment of management fees that are tied to performance measures established by the Secretary for the management, administration, and delivery of the benefits under the contract.

(B) Performance measures

The performance measures established by the Secretary pursuant to subparagraph (A)(ii) shall include at least measures for each of the following:

(i) Costs

The entity contains costs to the Medicare Prescription Drug Account and to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

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2So in original. Probably should be “(v)”. 

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(ii) Quality programs

The entity provides such enrollees with quality programs that avoid adverse drug reactions and overutilization and reduce medical errors.

(iii) Customer service

The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

(iv) Benefit administration and claims adjudication

The entity provides efficient and effective benefit administration and claims adjudication.

(6) Monthly beneficiary premium

Except as provided in section 1395w–113(b) of this title (relating to late enrollment penalty) and subject to section 1395w–114 of this title (relating to low-income assistance), the monthly beneficiary premium to be charged under a fallback prescription drug plan offered in all fallback service areas in a PDP region shall be uniform and shall be equal to 25.5 percent of an amount equal to the Secretary’s estimate of the average monthly per capita actuarial cost, including administrative expenses, under the fallback prescription drug plan of providing coverage in the region, as calculated by the Chief Actuary of the Centers for Medicare & Medicaid Services. In calculating such administrative expenses, the Chief Actuary shall use a factor that is based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

(7) General contract terms and conditions

(A) In general

Except as may be appropriate to carry out this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans under this subsection shall be the same as the terms and conditions of contracts under this part for prescription drug plans.

(B) Period of contract

(i) In general

Subject to clause (ii), a contract approved for a fallback prescription drug plan for fallback service areas for a PDP region under this section shall be for a period of 3 years (except as may be renewed after a subsequent bidding process).

(ii) Limitation

A fallback prescription drug plan may be offered under a contract in an area for a year only if that area is a fallback service area for that year.

(C) Entity not permitted to market or brand fallback prescription drug plans

An eligible fallback entity with a contract under this subsection may not engage in any marketing or branding of a fallback prescription drug plan.

(h) Annual report on use of limited risk plans and fallback plans

The Secretary shall submit to Congress an annual report that describes instances in which limited risk plans and fallback prescription drug plans were offered under subsections (f) and (g) of this section. The Secretary shall include in such report such recommendations as may be appropriate to limit the need for the provision of such plans and to maximize the assumption of financial risk under section subsection (f) of this section.

(i) Noninterference

In order to promote competition under this part and in carrying out this part, the Secretary—

(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and

(2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.

(j) Coordination of benefits

A PDP sponsor offering a prescription drug plan shall permit State Pharmaceutical Assistance Programs and Rx plans under sections 1395w–153 and 1395w–134 of this title to coordinate benefits with the plan and, in connection with such coordination with such a Program, not to impose fees that are unrelated to the cost of coordination.


REFERENCES IN TEXT


CODIFICATION


AMENDMENTS


EFFECTIVE DATE OF 2010 AMENDMENT

Amendment by Pub. L. 111–148 applicable to bids submitted for contract years beginning on or after Jan. 1, 2011, see section 3209(c) of Pub. L. 111–148, set out as a note under section 1395w–24 of this title.

STUDY REGARDING REGIONAL VARIATIONS IN PRESCRIPTION DRUG SPENDING


‘‘(1) IN GENERAL.—The Secretary [of Health and Human Services] shall conduct a study that examines variations in per capita spending for covered part D drugs under part D of title XVIII of the Social Security Act [this part] among PDP regions and, with respect to such spending, the amount of such variation that is attributable to—

(A) price variations (described in section 1860D–15(c)(2) of such Act [section 1395w–115(c)(2) of this title]); and
“(B) differences in per capita utilization that is not taken into account in the health status risk adjustment provided under section 1860D–15(c)(1) of such Act [section 1395w–115(c)(1) of this title].
“(2) REPORT AND RECOMMENDATIONS.—Not later than January 1, 2009, the Secretary shall submit to Congress a report on the study conducted under paragraph (1). Such report shall include:

“(A) information regarding the extent of geographic variation described in paragraph (1)(B);
“(B) an analysis of the impact on direct subsidies under section 1860D–15(a)(1) of the Social Security Act [section 1395w–115(a)(1) of this title] in different PDP regions if such subsidies were adjusted to take into account the variation described in subparagraph (A); and
“(C) recommendations regarding the appropriate-ness of applying an additional geographic adjustment factor under section 1860D–15(c)(2) [section 1395w–115(c)(2) of this title] that reflects some or all of the variation described in subparagraph (A).”

§ 1395w–112. Requirements for and contracts with prescription drug plan (PDP) sponsors
(a) General requirements
Each PDP sponsor of a prescription drug plan shall meet the following requirements:

(1) Licensure
Subject to subsection (c) of this section, the sponsor is organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan.

(2) Assumption of financial risk for unsubsi-
dized coverage

(A) In general
Subject to subparagraph (B), to the extent that the entity is at risk the entity assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1395w–115(b) of this title.

(B) Reinsurance permitted
The plan sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the ex-
tent that the sponsor is at risk for providing such coverage.

(3) Solvency for unlicensed sponsors
In the case of a PDP sponsor that is not de-
scribed in paragraph (1) and for which a waiver has been approved under subsection (c) of this section, such sponsor shall meet solvency standards established by the Secretary under subsection (d) of this section.

(b) Contract requirements

(1) In general
The Secretary shall not permit the enrol-
ment under section 1395w–101 of this title in a prescription drug plan offered by a PDP spon-
or under this part, and the sponsor shall not be eligible for payments under section 1395w–114 or 1395w–115 of this title, unless the Secretary has entered into a contract under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover more than one pre-
scription drug plan. Such contract shall pro-
vide that the sponsor agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(2) Limitation on entities offering fallback pre-
scription drug plans
The Secretary shall not enter into a con-
tract with a PDP sponsor for the offering of a prescription drug plan (other than a fallback prescription drug plan) in a PDP region for a year if the sponsor—

(A) submitted a bid under section 1395w–111(g) of this title for such year (as the first year of a contract period under such section) to offer a fallback prescription drug plan in any PDP region;

(B) offers a fallback prescription drug plan in any PDP region during the year; or

(C) offered a fallback prescription drug plan in that PDP region during the previous year.

For purposes of this paragraph, an entity shall be treated as submitting a bid with respect to a prescription drug plan or offering a fallback prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offer-
ing such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

(3) Incorporation of certain medicare advan-
tage contract requirements
Except as otherwise provided, the following provisions of section 1395w–27 of this title shall apply to contracts under this section in the same manner as they apply to contracts under section 1395w–27(a) of this title:

(A) Minimum enrollment
Paragraphs (1) and (3) of section 1395w–27(b) of this title, except that—

(i) the Secretary may increase the mini-
mum number of enrollees required under such paragraph (1) as the Secretary deter-
mines appropriate; and

(ii) the requirement of such paragraph (1) shall be waived during the first con-
tract year with respect to an organization in a region.

(B) Contract period and effectiveness
Section 1395w–27(c) of this title, except that in applying paragraph (4)(B) of such section any reference to payment amounts under section 1395w–23 of this title shall be deemed payment amounts under section 1395w–115 of this title.

(C) Protections against fraud and beneficiary

protections
Section 1395w–27(d) of this title.

(D) Additional contract terms
Section 1395w–27(e) of this title; except that section 1395w–27(e)(2) of this title shall apply as specified to PDP sponsors and payments under this part to an MA-PD plan shall be treated as expenditures made under part D. Notwithstanding any other provision of law, information provided to the Sec-
§ 1395w–112

(4) Prompt payment of clean claims

(A) Prompt payment

(i) In general

Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to all clean claims submitted by pharmacies (other than pharmacies that dispense drugs by mail order only or are located in, or contract with, a long-term care facility) under this part within the applicable number of calendar days after the date on which the claim is received.

(ii) Clean claim defined

In this paragraph, the term “clean claim” means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.

(iii) Date of receipt of claim

In this paragraph, a claim is considered to have been received—

(I) with respect to claims submitted electronically, on the date on which the claim is transferred; and

(II) with respect to claims submitted otherwise, on the 5th day after the post-mark date of the claim or the date specified in the time stamp of the transmission.

(B) Applicable number of calendar days defined

In this paragraph, the term “applicable number of calendar days” means—

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(C) Interest payment

(i) In general

Subject to clause (ii), if payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in subparagraph (B)) after a clean claim is received, the PDP sponsor shall pay interest to the pharmacy that submitted the claim at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which payment is made (as determined under subparagraph (D)(iv)). Interest amounts paid under this subparagraph shall not be counted against the administrative costs of a prescription drug plan or treated as allowable risk corridor costs under section 1395w–115(e) of this title.

(ii) Authority not to charge interest

The Secretary may provide that a PDP sponsor is not charged interest under clause (i) in the case where there are exigent circumstances, including natural disasters and other unique and unexpected events, that prevent the timely processing of claims.

(D) Procedures involving claims

(i) Claim deemed to be clean

A claim is deemed to be a clean claim if the PDP sponsor involved does not provide notice to the claimant of any deficiency in the claim—

(I) with respect to claims submitted electronically, within 10 days after the date on which the claim is received; and

(II) with respect to claims submitted otherwise, within 15 days after the date on which the claim is received.

(ii) Claim determined to not be a clean claim

(I) In general

If a PDP sponsor determines that a submitted claim is not a clean claim, the PDP sponsor shall, not later than the end of the period described in clause (i), notify the claimant of such determination. Such notification shall specify all defects or improprieties in the claim and shall list all additional information or documents necessary for the proper processing and payment of the claim.

(II) Determination after submission of additional information

A claim is deemed to be a clean claim under this paragraph if the PDP sponsor involved does not provide notice to the claimant of any defect or impropriety in the claim within 10 days of the date on which additional information is received under subclause (I).
(iii) Obligation to pay

A claim submitted to a PDP sponsor that is not paid or contested by the sponsor within the applicable number of days (as defined in subparagraph (B)) after the date on which the claim is received shall be deemed to be a clean claim and shall be paid by the PDP sponsor in accordance with subparagraph (A).

(iv) Date of payment of claim

Payment of a clean claim under such subparagraph is considered to have been made on the date on which—

(I) with respect to claims paid electronically, the payment is transferred; and

(II) with respect to claims paid otherwise, the payment is submitted to the United States Postal Service or common carrier for delivery.

(E) Electronic transfer of funds

A PDP sponsor shall pay all clean claims submitted electronically by electronic transfer of funds if the pharmacy so requests or has so requested previously. In the case where such payment is made electronically, remittance may be made by the PDP sponsor electronically as well.

(F) Protecting the rights of claimants

(i) In general

Nothing in this paragraph shall be construed to prohibit or limit a claim or action not covered by the subject matter of this section that any individual or organization has against a provider or a PDP sponsor.

(ii) Anti-retaliation

Consistent with applicable Federal or State law, a PDP sponsor shall not retaliate against an individual or provider for exercising a right of action under this subparagraph.

(G) Rule of construction

A determination under this paragraph that a claim submitted by a pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under this subchapter, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination shall not relieve any party of civil or criminal liability with respect to the claim, nor does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

(5) Submission of claims by pharmacies located in or contracting with long-term care facilities

Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that a pharmacy located in, or having a contract with, a long-term care facility shall have not less than 30 days (but not more than 90 days) to submit claims to the sponsor for reimbursement under the plan.

(6) Regular update of prescription drug pricing standard

If the PDP sponsor of a prescription drug plan uses a standard for reimbursement of pharmacies based on the cost of a drug, each contract entered into with such sponsor under this part with respect to the plan shall provide that the sponsor shall update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.

(c) Waiver of certain requirements to expand choice

(1) Authorizing waiver

(A) In general

In the case of an entity that seeks to offer a prescription drug plan in a State, the Secretary shall waive the requirement of subsection (a)(1) of this section that the entity be licensed in that State if the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for approval of the application described in paragraph (2) have been met.

(B) Application of regional plan waiver rule

In addition to the waiver available under subparagraph (A), the provisions of section 1395w–27a(d) of this title shall apply to PDP sponsors under this part in a manner similar to the manner in which such provisions apply to MA organizations under part C of this subchapter, except that no application shall be required under paragraph (1)(B) of such section in the case of a State that does not provide a licensing process for such a sponsor.

(2) Grounds for approval

(A) In general

The grounds for approval under this paragraph are—

(i) subject to subparagraph (B), the grounds for approval described in subparagraphs (B), (C), and (D) of section 1395w–25(a)(2) of this title; and

(ii) the application by a State of any grounds other than those required under Federal law.

(B) Special rules

In applying subparagraph (A)(i)—

(i) the ground of approval described in section 1395w–25(a)(2)(B) of this title is deemed to have been met if the State does not have a licensing process in effect with respect to the PDP sponsor; and

(ii) for plan years beginning before January 1, 2008, if the State does have such a licensing process in effect, such ground for approval described in such section is deemed to have been met upon submission of an application described in such section.

(3) Application of waiver procedures

With respect to an application for a waiver (or a waiver granted) under paragraph (1)(A) of this subsection, the provisions of subpara-
graphs (E), (F), and (G) of section 1395w–25(a)(2) of this title shall apply, except that clauses (i) and (ii) of such subparagraph (E) shall not apply in the case of a State that does not have a licensing process described in paragraph (2)(B)(i) in effect.

(4) References to certain provisions

In applying provisions of section 1395w–25(a)(2) of this title under paragraphs (2) and (3) of this subsection to prescription drug plans and PDP sponsors—

(A) any reference to a waiver application under section 1395w–25 of this title shall be treated as a reference to a waiver application under paragraph (1)(A) of this subsection; and

(B) any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d) of this section.

d) Solvency standards for non-licensed entities

(1) Establishment and publication

The Secretary, in consultation with the National Association of Insurance Commissioners, shall establish and publish, by not later than January 1, 2005, financial solvency and capital adequacy standards for entities described in paragraph (2).

(2) Compliance with standards

A PDP sponsor that is not licensed by a State under subsection (a)(1) of this section and for which a waiver application has been approved under subsection (c) of this section shall meet solvency and capital adequacy standards established under paragraph (1). The Secretary shall establish certification procedures for such sponsors with respect to such solvency standards in the manner described in section 1395w–25(c)(2) of this title.

e) Licensure does not substitute for or constitute certification

The fact that a PDP sponsor is licensed in accordance with subsection (a)(1) of this section and has a waiver application approved under subsection (c) of this section does not deem the sponsor to meet other requirements imposed under this part for a sponsor.

(f) Periodic review and revision of standards

(1) In general

Subject to paragraph (2), the Secretary may periodically review the standards established under this section and, based on such review, may revise such standards if the Secretary determines such revision to be appropriate.

(2) Prohibition of midyear implementation of significant new regulatory requirements

The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

(g) Prohibition of State imposition of premium taxes; relation to State laws

The provisions of sections 1395w–24(g) and 1395w–26(b)(3) of this title shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C of this subchapter.


REFERENCES IN TEXT

Part D, referred to in subsec. (b)(3)(D), is classified to section 1395w–191 et seq. of this title.

Part C of this subchapter, referred to in subsecs. (c)(1)(B) and (g), is classified to section 1395w–21 et seq. of this title.

AMENDMENTS

2008—Subsec. (b)(3)(D). Pub. L. 110–275, §181, inserted at end “Notwithstanding any other provision of law, information provided to the Secretary under the application of section 1395w–27(e)(1) of this title to contracts under this section under the preceding sentence—” and added cls. (i) and (ii).


EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 171(a) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2010, see section 171(c) of Pub. L. 110–275, set out as a note under section 1395w–27 of this title.

Amendment by section 172(a)(1) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2010, see section 172(b) of Pub. L. 110–275, set out as a note under section 1395w–27 of this title.

Amendment by section 173(a) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2009, see section 173(c) of Pub. L. 110–275, set out as a note under section 1395w–27 of this title.

§ 1395w–113. Premiums; late enrollment penalty

(a) Monthly beneficiary premium

(1) Computation

(A) In general

The monthly beneficiary premium for a prescription drug plan is the base beneficiary premium computed under paragraph (2) as adjusted under this paragraph.

(B) Adjustment to reflect difference between bid and national average bid

(i) Above average bid

If for a month the amount of the standardized bid amount (as defined in paragraph (5)) exceeds the amount of the adjusted national average monthly bid amount (as defined in clause (iii)), the base beneficiary premium for the month shall be increased by the amount of such excess.

(ii) Below average bid

If for a month the amount of the adjusted national average monthly bid amount for the month exceeds the standardized bid amount, the base beneficiary premium for the month shall be decreased by the amount of such excess.

(iii) Adjusted national average monthly bid amount defined

For purposes of this subparagraph, the term “adjusted national average monthly
bid amount’ means the national average monthly bid amount computed under paragraph (4), as adjusted under section 1395w–115(c)(2) of this title.

(C) Increase for supplemental prescription drug benefits

The base beneficiary premium shall be increased by the portion of the PDP approved bid that is attributable to supplemental prescription drug benefits.

(D) Increase for late enrollment penalty

The base beneficiary premium shall be increased by the amount of any late enrollment penalty under subsection (b) of this section.

(E) Decrease for low-income assistance

The monthly beneficiary premium is subject to decrease in the case of a subsidy eligible individual under section 1395w–114 of this title.

(F) Increase based on income

The monthly beneficiary premium shall be increased pursuant to paragraph (7).

(G) Uniform premium

Except as provided in subparagraphs (D), (E), and (F), the monthly beneficiary premium for a prescription drug plan in a PDP region is the same for all part D eligible individuals enrolled in the plan.

(2) Base beneficiary premium

The base beneficiary premium under this paragraph for a prescription drug plan for a month is equal to the product

(A) the beneficiary premium percentage (as specified in paragraph (3)); and

(B) the national average monthly bid amount (computed under paragraph (4)) for the month.

(3) Beneficiary premium percentage

For purposes of this subsection, the beneficiary premium percentage for any year is the percentage equal to a fraction—

(A) the numerator of which is 25.5 percent; and

(B) the denominator of which is 100 percent minus a percentage equal to—

(i) the total reinsurance payments which the Secretary estimates are payable under section 1395w–115(b) of this title with respect to the coverage year; divided by

(ii) the sum of—

(I) the amount estimated under clause (i) for the year; and

(II) the total payments which the Secretary estimates will be paid to prescription drug plans and MA–PD plans that are attributable to the standardized bid amount during the year, taking into account amounts paid by the Secretary and enrollees.

(4) Computation of national average monthly bid amount

(A) In general

For each year (beginning with 2006) the Secretary shall compute a national average monthly bid amount equal to the average of the standardized bid amounts (as defined in paragraph (5)) for each prescription drug plan and for each MA–PD plan described in section 1395w–21(a)(2)(A)(i) of this title. Such average does not take into account the bids submitted for MSA plans, MA private fee-for-service plan, and specialized MA plans for special needs individuals, PACE programs under section 1395see of this title (pursuant to section 1395w–131(f) of this title), and under reasonable cost reimbursement contracts under section 1395mm(h) of this title (pursuant to section 1395w–131(e) of this title).

(B) Weighted average

(i) In general

The monthly national average monthly bid amount computed under subparagraph (A) for a year shall be a weighted average, with the weight for each plan being equal to the average number of part D eligible individuals enrolled in such plan in the reference month (as defined in section 1395w–27a(f)(4) of this title).

(ii) Special rule for 2006

For purposes of applying this paragraph for 2006, the Secretary shall establish procedures for determining the weighted average under clause (i) for 2005.

(5) Standardized bid amount defined

For purposes of this subsection, the term “standardized bid amount” means the following:

(A) Prescription drug plans

(i) Basic coverage

In the case of a prescription drug plan that provides basic prescription drug coverage, the PDP approved bid (as defined in paragraph (6)).

(ii) Supplemental coverage

In the case of a prescription drug plan that provides supplemental prescription drug coverage, the portion of the PDP approved bid that is attributable to basic prescription drug coverage.

(B) MA–PD plans

In the case of an MA–PD plan, the portion of the accepted bid amount that is attributable to basic prescription drug coverage.

(6) PDP approved bid defined

For purposes of this part, the term “PDP approved bid” means, with respect to a prescription drug plan, the bid amount approved for the plan under this part.

(7) Increase in base beneficiary premium based on income

(A) In general

In the case of an individual whose modified adjusted gross income exceeds the threshold amount applicable under paragraph (2) of section 1395r(i) of this title (including application of paragraph (5) of such section) for the calendar year, the monthly amount of the beneficiary premium applicable under
this section for a month after December 2010 shall be increased by the monthly adjustment amount specified in subparagraph (B).

(B) Monthly adjustment amount

The monthly adjustment amount specified in this subparagraph for an individual for a month in a year is equal to the product of—

(i) the quotient obtained by dividing—

(I) the applicable percentage determined under paragraph (3)(C) of section 1395r(1) of this title (including application of paragraph (5) of such section) for the individual for the calendar year reduced by 25.5 percent; by

(II) 25.5 percent; and

(ii) the base beneficiary premium (as computed under paragraph (2)).

(C) Modified adjusted gross income

For purposes of this paragraph, the term “modified adjusted gross income” has the meaning given such term in subparagraph (B) and (C) of such section.

(D) Determination by Commissioner of Social Security

The Commissioner of Social Security shall make any determination necessary to carry out the income-related increase in the base beneficiary premium under this paragraph.

(E) Procedures to assure correct income-related increase in base beneficiary premium

(i) Disclosure of base beneficiary premium

Not later than September 15 of each year beginning with 2010, the Secretary shall disclose to the Commissioner of Social Security the amount of the base beneficiary premium (as computed under paragraph (2)) for the purpose of carrying out the income-related increase in the base beneficiary premium under this paragraph with respect to the following year.

(ii) Additional disclosure

Not later than October 15 of each year beginning with 2010, the Secretary shall disclose to the Commissioner of Social Security the following information for the purpose of carrying out the income-related increase in the base beneficiary premium under this paragraph with respect to the following year:

(I) The modified adjusted gross income threshold applicable under paragraph (2) of section 1395r(1) of this title (including application of paragraph (5) of such section).

(II) The applicable percentage determined under paragraph (3)(C) of section 1395r(1) of this title (including application of paragraph (5) of such section).

(III) The monthly adjustment amount specified in subparagraph (B).

(IV) Any other information the Commissioner of Social Security determines necessary to carry out the income-related increase in the base beneficiary premium under this paragraph.

(F) Rule of construction

The formula used to determine the monthly adjustment amount specified under subparagraph (B) shall only be used for the purpose of determining such monthly adjustment amount under such subparagraph.

(b) Late enrollment penalty

(1) In general

Subject to the succeeding provisions of this subsection, in the case of a part D eligible individual described in paragraph (2) with respect to a continuous period of eligibility, there shall be an increase in the monthly beneficiary premium established under subsection (a) of this section in an amount determined under paragraph (3).

(2) Individuals subject to penalty

A part D eligible individual described in this paragraph is, with respect to a continuous period of eligibility, an individual for whom there is a continuous period of 63 days or longer (all of which in such continuous period of eligibility) beginning on the day after the last date of the individual’s initial enrollment period under section 1395w–101(b)(2) of this title and ending on the date of enrollment under a prescription drug plan or MA–PD plan during all of which the individual was not covered under any creditable prescription drug coverage.

(3) Amount of penalty

(A) In general

The amount determined under this paragraph for a part D eligible individual for a continuous period of eligibility is the greater of—

(i) an amount that the Secretary determines is actuarially sound for each uncovered month (as defined in subparagraph (B)) in the same continuous period of eligibility; or

(ii) 1 percent of the base beneficiary premium (computed under subsection (a)(2) of this section) for each such uncovered month in such period.

(B) Uncovered month defined

For purposes of this subsection, the term “uncovered month” means, with respect to a part D eligible individual, any month beginning after the end of the initial enrollment period under section 1395w–101(b)(2) of this title unless the individual can demonstrate that the individual had creditable prescription drug coverage (as defined in paragraph (4)) for any portion of such month.

(4) Creditable prescription drug coverage defined

For purposes of this part, the term “creditable prescription drug coverage” means any of the following coverage, but only if the coverage meets the requirement of paragraph (5):

(A) Coverage under prescription drug plan or MA–PD plan

Coverage under a prescription drug plan or under an MA–PD plan.
(B) Medicaid
Coverage under a medicaid plan under sub-
chapter XIX of this chapter or under a waiv-
er under section 1315 of this title.

(C) Group health plan
Coverage under a group health plan, in-
cluding a health benefits plan under chapter
89 of title 5 (commonly known as the Federal
employees health benefits program), and a
qualified retiree prescription drug plan (as
defined in section 1395w–122(a)(2) of this title).

(D) State pharmaceutical assistance program
Coverage under a State pharmaceutical as-
istance program described in section
1395w–133(b)(1) of this title.

(E) Veterans’ coverage of prescription drugs
Coverage for veterans, and survivors and
dependents of veterans, under chapter 17 of
title 38.

(F) Prescription drug coverage under medi-
gap policies
Coverage under a medicare supplemental
policy under section 1395ss of this title that
provides benefits for prescription drugs
(whether or not such coverage conforms to
the standards for packages of benefits under
section 1395w–113(b)(1) of this title).

(G) Military coverage (including TRICARE)
Coverage under chapter 55 of title 10.

(H) Other coverage
Such other coverage as the Secretary de-
termines appropriate.

(5) Actuarial equivalence requirement
Coverage meets the requirement of this
paragraph only if the coverage is determined
(in a manner specified by the Secretary) to
provide coverage of the cost of prescription
drugs the actuarial value of which (as defined
by the Secretary) to the individual equals or
exceeds the actuarial value of standard pre-
scription drug coverage (as determined under
section 1395w–111(c) of this title).

(6) Procedures to document creditable pre-
scription drug coverage
(A) In general
The Secretary shall establish procedures
(including the form, manner, and time) for
the documentation of creditable prescription
drug coverage, including procedures to assist in
determining whether coverage meets the
requirement of paragraph (5).

(B) Disclosure by entities offering creditable
prescription drug coverage
(i) In general
Each entity that offers prescription drug
coverage of the type described in subpara-
graphs (B) through (H) of paragraph (4) shall
provide for disclosure, in a form, manner, and time consistent with stand-
ard s established by the Secretary, to the
Secretary and part D eligible individuals of
whether the coverage meets the require-
ment of paragraph (5) or whether such cov-

erage is changed so it no longer meets such
requirement.

(ii) Disclosure of non-creditable coverage
In the case of such coverage that does
not meet such requirement, the disclosure to
dividuals who was enrolled in prescription drug cov-

erage under a State pharmaceutical as-
istance program described in section
1395w–133(b)(1) of this title.

(E) Veterans’ coverage of prescription drugs
Coverage for veterans, and survivors and
dependents of veterans, under chapter 17 of
title 38.

(F) Prescription drug coverage under medi-
gap policies
Coverage under a medicare supplemental
policy under section 1395ss of this title that
provides benefits for prescription drugs
(whether or not such coverage conforms to
the standards for packages of benefits under
section 1395w–113(b)(1) of this title).

(G) Military coverage (including TRICARE)
Coverage under chapter 55 of title 10.

(H) Other coverage
Such other coverage as the Secretary de-
termines appropriate.

(5) Actuarial equivalence requirement
Coverage meets the requirement of this
paragraph only if the coverage is determined
(in a manner specified by the Secretary) to
provide coverage of the cost of prescription
drugs the actuarial value of which (as defined
by the Secretary) to the individual equals or
exceeds the actuarial value of standard pre-
scription drug coverage (as determined under
section 1395w–111(c) of this title).

(6) Procedures to document creditable pre-
scription drug coverage
(A) In general
The Secretary shall establish procedures
(including the form, manner, and time) for
the documentation of creditable prescription
drug coverage, including procedures to assist in
determining whether coverage meets the
requirement of paragraph (5).

(B) Disclosure by entities offering creditable
prescription drug coverage
(i) In general
Each entity that offers prescription drug
coverage of the type described in subpara-
graphs (B) through (H) of paragraph (4) shall
provide for disclosure, in a form, manner, and time consistent with stand-
ard s established by the Secretary, to the
Secretary and part D eligible individuals of
whether the coverage meets the require-
ment of paragraph (5) or whether such cov-
(c) Collection of monthly beneficiary premiums

(1) In general

Subject to paragraphs (2), (3), and (4), the provisions of section 1395w–24(d) of this title shall apply to PDP sponsors and premiums (and any late enrollment penalty) under this part in the same manner as they apply to MA organizations and beneficiary premiums under part C of this subchapter, except that any reference to a Trust Fund is deemed for this purpose a reference to the Medicare Prescription Drug Account.

(2) Crediting of late enrollment penalty

(A) Portion attributable to increased actuarial costs

With respect to late enrollment penalties imposed under subsection (b) of this section, the Secretary shall specify the portion of such a penalty that the Secretary estimates is attributable to increased actuarial costs assumed by the PDP sponsor or MA organization (and not taken into account through risk adjustment provided under section 1395w–115(c)(1) of this title or through reinsurance payments under section 1395w–115(b) of this title) as a result of such late enrollment.

(B) Collection through withholding

In the case of a late enrollment penalty that is collected from a part D eligible individual in the manner described in section 1395w–24(d)(2)(A) of this title, the Secretary shall provide that only the portion of such penalty estimated under subparagraph (A) shall be paid to the PDP sponsor or MA organization offering the part D plan in which the individual is enrolled.

(C) Collection by plan

In the case of a late enrollment penalty that is collected from a part D eligible individual in a manner other than the manner described in section 1395w–24(d)(2)(A) of this title, the Secretary shall establish procedures for reducing payments otherwise made to the PDP sponsor or MA organization by an amount equal to the amount of such penalty less the portion of such penalty estimated under subparagraph (A).

(3) Fallback plans

In applying this subsection in the case of a fallback prescription drug plan, paragraph (2) shall not apply and the monthly beneficiary premium shall be collected in the manner specified in section 1395w–24(d)(2)(A) of this title (or such other manner as may be provided under section 1395s of this title in the case of monthly premiums under section 1395r of this title).

(4) Collection of monthly adjustment amount

(A) In general

Notwithstanding any provision of this subsection or section 1395w–24(d)(2) of this title, subject to subparagraph (B), the amount of the income-related increase in the base beneficiary premium for an individual for a month (as determined under subsection (a)(7)) shall be paid through withholding from benefit payments in the manner provided under section 1395s of this title.

(B) Agreements

In the case where the monthly benefit payments of an individual that are withheld under subparagraph (A) are insufficient to pay the amount described in such subparagraph, the Commissioner of Social Security shall enter into agreements with the Secretary, the Director of the Office of Personnel Management, and the Railroad Retirement Board as necessary in order to allow other agencies to collect the amount described in subparagraph (A) that was not withheld under such subparagraph.

(B) Elimination of deductible

A reduction in the annual deductible applicable under section 1395w–102(b)(1) of this title to $0.

(C) Continuation of coverage above the initial coverage limit

The continuation of coverage from the initial coverage limit (under paragraph (3) of section 1395w–102(b) of this title) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced cost-sharing described in subparagraph (D).

(D) Reduction in cost-sharing below out-of-pocket threshold

(i) Institutionalized individuals

In the case of an individual who is a full-benefit dual eligible individual and who is an institutionalized individual or couple (as defined in section 1396n(a)(1)(B) of this title) or, effective on a date specified by the Secretary (but in no case earlier than January 1, 2012), who would be such an institutionalized individual or couple, if the full-benefit dual eligible individual were not receiving services under a home and community-based waiver authorized for a State under section 1315 of this title or subsection (c) or (d) of section 1396n of this title or under a State plan amendment under subsection (i) of such section or services provided through enrollment in a medicaid managed care organization with a contract under section 1396b(m) of this title or under section 1396u–2 of this title, the elimination of any beneficiary coinsurance described in section 1395w–102(b)(2) of this title (for all amounts through the total amount of expenditures at which benefits are available under section 1395w–102(b)(4) of this title).

(ii) Lowest income dual eligible individuals

In the case of an individual not described in clause (i) who is a full-benefit dual eligible individual and whose income does not exceed 100 percent of the poverty line applicable to a family of the size involved, the substitution for the beneficiary coinsurance described in section 1395w–102(b)(2) of this title (for all amounts through the total amount of expenditures at which benefits are available under section 1395w–102(b)(4) of this title) of a copayment amount that does not exceed $1 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1396c–8(k)(7)(A)(I) of this title) and $3 for any other drug, or, if less, the copayment amount applicable to an individual under clause (iii).

(iii) Other individuals

In the case of an individual not described in clause (i) or (ii), the substitution for the beneficiary coinsurance described in section 1395w–102(b)(2) of this title (for all amounts through the total amount of expenditures at which benefits are available under section 1395w–102(b)(4) of this title) of a copayment amount that does not exceed the copayment amount specified under section 1395w–102(b)(4)(A)(I) of this title for the drug and year involved.

(E) Elimination of cost-sharing above annual out-of-pocket threshold

The elimination of any cost-sharing imposed under section 1395w–102(b)(4)(A) of this title.

(2) Other individuals with income below 150 percent of poverty line

In the case of a subsidy eligible individual who is not described in paragraph (1), the individual is entitled under this section to the following:

(A) Sliding scale premium subsidy

An income-related premium subsidy determined on a linear sliding scale ranging from 100 percent of the amount described in paragraph (1)(A) for individuals with incomes at or below 135 percent of such level to 0 percent of such amount for individuals with incomes at 150 percent of such level.

(B) Reduction of deductible

A reduction in the annual deductible applicable under section 1395w–102(b)(1) of this title to $50.

(C) Continuation of coverage above the initial coverage limit

The continuation of coverage from the initial coverage limit (under paragraph (3) of section 1395w–102(b) of this title) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced coinsurance described in subparagraph (D).

(D) Reduction in cost-sharing below out-of-pocket threshold

The substitution for the beneficiary coinsurance described in section 1395w–102(b)(2) of this title (for all amounts above the deductible under subparagraph (B) through the total amount of expenditures at which benefits are available under section 1395w–102(b)(4) of this title) of coinsurance of “15 percent” instead of coinsurance of “25 percent” in section 1395w–102(b)(2) of this title.

(E) Reduction of cost-sharing above annual out-of-pocket threshold

Subject to subsection (c) of this section, the substitution for the cost-sharing imposed under section 1395w–102(b)(4)(A) of this title of a copayment or coinsurance not to exceed the copayment or coinsurance amount specified under section 1395w–102(b)(4)(A)(I) of this title for the drug and year involved.

(3) Determination of eligibility

(A) Subsidy eligible individual defined

For purposes of this part, subject to subparagraph (F), the term “subsidy eligible individual” means a part D eligible individual who—
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(i) is enrolled in a prescription drug plan or MA–PD plan;
(ii) has income below 150 percent of the poverty line applicable to a family of the size involved; and
(iii) meets the resources requirement described in subparagraph (D) or (E).

(B) Determinations

(i) In general

The determination of whether a part D eligible individual residing in a State is a subsidy eligible individual and whether the individual is described in paragraph (1) shall be determined under the State plan under subchapter XIX of this chapter for the State under section 1396u–5(a) of this title or by the Commissioner of Social Security. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.

(ii) Effective period

Determinations under this subparagraph shall be effective beginning with the month in which the individual applies for medical assistance under such subchapter.

(iii) Redeterminations and appeals through medicaid

Redeterminations and appeals, with respect to eligibility determinations under clause (i) made under a State plan under subchapter XIX of this chapter, shall be made in accordance with the frequency of, and manner in which, redeterminations and appeals of eligibility are made under such plan for purposes of medical assistance under such subchapter.

(iv) Redeterminations and appeals through Commissioner

With respect to eligibility determinations under clause (i) made by the Commissioner of Social Security—

(I) redeterminations shall be made at such time or times as may be provided by the Commissioner;

(II) the Commissioner shall establish procedures for appeals of such determinations that are similar to the procedures described in the third sentence of section 1383(c)(1)(A) of this title; and

(III) judicial review of the final decision of the Commissioner made after a hearing shall be available to the same extent, and with the same limitations, as provided in subsections (g) and (h) of section 405 of this title.

(v) Treatment of medicaid beneficiaries

Subject to subparagraph (F), the Secretary—

(I) shall provide that part D eligible individuals who are full-benefit dual eligible individuals (as defined in section 1396u–5(c)(6) of this title) or who are recipients of supplemental security income benefits under subchapter XVI of this chapter shall be treated as subsidy eligible individuals described in paragraph (1); and

(ii) may provide that part D eligible individuals not described in subclause (I) who are determined for purposes of the State plan under subchapter XIX of this chapter to be eligible for medical assistance under clause (i), (iii), or (iv) of section 1396a(a)(10)(E) of this title are treated as being determined to be subsidy eligible individuals described in paragraph (1).

Insofar as the Secretary determines that the eligibility requirements under the State plan for medical assistance referred to in subclause (II) are substantially the same as the requirements for being treated as a subsidy eligible individual described in paragraph (1), the Secretary shall provide for the treatment described in such subclause.

(vi) Special rule for widows and widowers

Notwithstanding the preceding provisions of this subparagraph, in the case of an individual whose spouse dies during the effective period for a determination or redetermination that has been made under this subparagraph, such effective period shall be extended through the date that is 1 year after the date on which the determination or redetermination would (but for the application of this clause) otherwise cease to be effective.

(C) Income determinations

For purposes of applying this section—

(i) in the case of a part D eligible individual who is not treated as a subsidy eligible individual under subparagraph (B)(v), income shall be determined in the manner described in section 1396d(p)(1)(B) of this title, without regard to the application of section 1396a(r)(2) of this title and except that support and maintenance furnished in kind shall not be counted as income; and

(ii) the term “poverty line” has the meaning given such term in section 9902(2) of this title, including any revision required by such section.

Nothing in clause (i) shall be construed to affect the application of section 1396a(r)(2) of this title for the determination of eligibility for medical assistance under subchapter XIX of this chapter.

(D) Resource standard applied to full low-income subsidy to be based on three times SSI resource standard

The resources requirement of this subparagraph is that an individual’s resources (as determined under section 1382b of this title for purposes of the supplemental security income program subject to the life insurance policy exclusion provided under subparagraph (G)) do not exceed—

(i) for 2006 three times the maximum amount of resources that an individual
may have and obtain benefits under that program; and
(ii) for a subsequent year the resource limitation established under this clause for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any resource limitation established under clause (ii) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(E) Alternative resource standard
(i) In general
The resources requirement of this subparagraph is that an individual’s resources (as determined under section 1382b of this title for purposes of the supplemental security income program subject to the life insurance policy exclusion provided under subparagraph (G)) do not exceed—
(I) for 2006, $10,000 (or $20,000 in the case of the combined value of the individual’s assets or resources and the assets or resources of the individual’s spouse); and
(II) for a subsequent year the dollar amounts specified in this subparagraph (or subclause (I)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any dollar amount established under subclause (II) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(ii) Use of simplified application form and process
The Secretary, jointly with the Commissioner of Social Security, shall—
(I) develop a model, simplified application form and process consistent with clause (iii) for the determination and verification of a part D eligible individual’s assets or resources under this subparagraph; and
(II) provide such form to States.

(iii) Documentation and safeguards
Under such process—
(I) the application form shall consist of an attestation under penalty of perjury regarding the level of assets or resources (or combined assets and resources in the case of a married part D eligible individual) and valuations of general classes of assets or resources;
(II) such form shall be accompanied by copies of recent statements (if any) from financial institutions in support of the application; and
(III) matters attested to in the application shall be subject to appropriate methods of verification.

(iv) Methodology flexibility
The Secretary may permit a State in making eligibility determinations for premium and cost-sharing subsidies under this section to use the same asset or resource methodologies that are used with respect to eligibility for medical assistance for medicare cost-sharing described in section 1396d(p) of this title so long as the Secretary determines that the use of such methodologies will not result in any significant differences in the number of individuals determined to be subsidy eligible individuals.

(F) Treatment of territorial residents
In the case of a part D eligible individual who is not a resident of the 50 States or the District of Columbia, the individual is not eligible to be a subsidy eligible individual under this section but may be eligible for financial assistance with prescription drug expenses under section 1396u-5(e) of this title.

(G) Life insurance policy exclusion
In determining the resources of an individual (and the eligible spouse of the individual, if any) under section 1382b of this title for purposes of subparagraphs (D) and (E) no part of the value of any life insurance policy shall be taken into account.

(4) Indexing dollar amounts
(A) Copayment for lowest income dual eligible individuals
The dollar amounts applied under paragraph (1)(D)(i)—
(i) for 2007 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year; or
(ii) for a subsequent year shall be the dollar amounts specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any amount established under clause (i) or (ii), that is based on an increase of $1 or $3, that is not a multiple of 5 cents or 10 cents, respectively, shall be rounded to the nearest multiple of 5 cents or 10 cents, respectively.

(B) Reduced deductible
The dollar amount applied under paragraph (2)(B)—
(i) for 2007 shall be the dollar amount specified in such paragraph increased by the annual percentage increase described in section 1395w-102(b)(6) of this title for 2007; or
(ii) for a subsequent year shall be the dollar amount specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase described in section 1395w-102(b)(6) of this title for the year involved.

Any amount established under clause (i) or (ii) that is not a multiple of $1 shall be rounded to the nearest multiple of $1.

(5) Waiver of de minimis premiums
The Secretary shall, under procedures established by the Secretary, permit a prescription
drug plan or an MA–PD plan to waive the monthly beneficiary premium for a subsidy eligible individual if the amount of such premium is de minimis. If such premium is waived under the plan, the Secretary shall not reassess subsidy eligible individuals enrolled in the plan to other plans based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark premium amount.

(b) **Premium subsidy amount**

(1) **In general**

The premium subsidy amount described in this subsection for a subsidy eligible individual residing in a PDP region and enrolled in a prescription drug plan or MA–PD plan is the low-income benchmark premium amount (as defined in paragraph (2)) for the PDP region in which the individual resides or, if greater, the amount specified in paragraph (3).

(2) **Low-income benchmark premium amount defined**

(A) **In general**

For purposes of this subsection, the term “low-income benchmark premium amount” means, with respect to a PDP region in which—

(i) all prescription drug plans are offered by the same PDP sponsor, the weighted average of the amounts described in subparagraph (B)(i) for such plans; or

(ii) there are prescription drug plans offered by more than one PDP sponsor, the weighted average of amounts described in subparagraph (B) for prescription drug plans and MA–PD plans described in section 1395w–21(a)(2)(A)(i) of this title offered in such region.

(B) **Premium amounts described**

The premium amounts described in this subparagraph are, in the case of—

(i) a prescription drug plan that is a basic prescription drug plan, the monthly beneficiary premium for such plan;

(ii) a prescription drug plan that provides alternative prescription drug coverage the actuarial value of which is greater than that of standard prescription drug coverage, the portion of the monthly beneficiary premium that is attributable to basic prescription drug coverage; and

(iii) an MA–PD plan, the portion of the MA monthly prescription drug beneficiary premium that is attributable to basic prescription drug benefits (described in section 1395w–22(a)(6)(B)(ii)1 of this title) and determined before the application of the monthly rebate computed under section 1395w–24(b)(1)(C)(i) of this title for that plan and year involved and, in the case of a qualifying plan, before the application of the increase under section 1395w–28(a) of this title for that plan and year involved.

The premium amounts described in this subparagraph do not include any amounts attributable to late enrollment penalties under section 1395w–113(b) of this title.

(3) **Access to 0 premium plan**

In no case shall the premium subsidy amount under this subsection for a PDP region be less than the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the region.

(c) **Administration of subsidy program**

(1) **In general**

The Secretary shall provide a process whereby, in the case of a part D eligible individual who is determined to be a subsidy eligible individual and who is enrolled in a prescription drug plan or is enrolled in an MA–PD plan—

(A) the Secretary provides for a notification of the PDP sponsor or the MA organization offering the plan involved that the individual is eligible for a subsidy and the amount of the subsidy under subsection (a) of this section;

(B) the sponsor or organization involved reduces the premiums or cost-sharing otherwise imposed by the amount of the applicable subsidy and submits to the Secretary information on the amount of such reduction;

(C) the Secretary periodically and on a timely basis reimburses the sponsor or organization for the amount of such reductions; and

(D) the Secretary ensures the confidentiality of individually identifiable information.

In applying subparagraph (C), the Secretary shall compute reductions based upon imposition under subsections (a)(1)(D) and (a)(2)(E) of this section of unreduced copayment amounts applied under such subsections.

(2) **Use of capitated form of payment**

The reimbursement under this section with respect to cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved.

(d) **Facilitation of reassignments**

Beginning not later than January 1, 2011, the Secretary shall, in the case of a subsidy eligible individual who is enrolled in one prescription drug plan and is subsequently reassigned by the Secretary to a new prescription drug plan, provide the individual, within 30 days of such reassignment, with—

(1) information on formulary differences between the individual’s former plan and the plan to which the individual is reassigned with respect to the individual’s drug regimens; and

(2) a description of the individual’s right to request a coverage determination, exception, or reconsideration under section 1395w–104(g) of this title, bring an appeal under section 1395w–104(h) of this title, or resolve a grievance under section 1395w–104(f) of this title.

(e) **Relation to medicaid program**

For special provisions under the medicaid program relating to medicare prescription drug benefits, see section 1396u–5 of this title.

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1So in original. Section 1395w–22(a)(6) of this title does not contain a subpar. (B).

AMENDMENTS

2010—Subsec. (a)(1)(D)(i). Pub. L. 111–148, §3309, inserted “or, effective on a date specified by the Secretary (but in no case earlier than January 1, 2012), who would be such an institutionalized individual or couple, if the full-benefit dual eligible individual were not receiving services under a home and community-based waiver authorized for a State under section 1315 of this title or a subsection (c) or (d) of section 1396n of this title or under a State plan amendment under subsection (i) of such section or services provided through enrollment in a medicare managed care organization with a contract under section 1396m(e) of this title or under section 1396a–2 of this title” after “‘1396a(q)(1)(B) of this title’”.


Subsec. (b)(2)(B)(iii). Pub. L. 111–152 substituted “and determined before the application of the monthly rebate computed under section 1395w–24(b)(1)(C)(ii) of this title for that plan and year involved and, in the case of a qualifying plan, before the application of the increase under section 1395w–23(e) of this title for that plan and year involved” for “, determined without regard to any reduction in such premium as a result of any beneficiary rebate under section 1395w–24(b)(1)(C) of this title or bonus payment under section 1395w–23(n) of this title”.

Pub. L. 111–148, §3302(a), inserted “, determined without regard to any reduction in such premium as a result of any beneficiary rebate under section 1395w–24(b)(1)(C) of this title or bonus payment under section 1395w–23(n) of this title”.

Subsecs. (d), (e). Pub. L. 111–148, §3305, added subsec. (d) and redesignated former subsec. (d) as (e).

2008—Subsec. (a)(1)(A). Pub. L. 110–275, §114(a)(2), substituted “100 percent of the amount described in subsection (b)(1) of this section (but not to exceed the premium amount specified in subsection (b)(2)(B))” for “equal to—

“(i) 100 percent of the amount described in subsection (b)(1) of this section, but not to exceed the premium amount specified in subsection (b)(2)(B) of this section; plus

“(ii) 30 percent of any late enrollment penalties imposed under section 1395w–113(b) of this title for the first 60 months in which such penalties are imposed for that individual, and 100 percent of any such penalties for any subsequent month.”


Subsec. (a)(3)(C)(i). Pub. L. 110–275, §116(a)(1), inserted “and except that support and maintenance furnished in kind shall not be counted as income” after “‘section 1396a(r)(2) of this title’”.


EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, §§3302(b), Mar. 23, 2010, 124 Stat. 468, provided that: “The amendment made by subsection (a) [amending this section] shall apply to premiums for months beginning on or after January 1, 2011.”

Amendment by section 3303(a) of Pub. L. 111–148 applicable to premiums for months, and enrollments for plan years, beginning on or after January 1, 2011, see section 3303(c) of Pub. L. 111–148, set out as a note under section 1395w–101 of this title.


EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 114(a)(2) of Pub. L. 110–275 applicable to subsidies for months beginning with Jan. 2009, see section 114(b) of Pub. L. 110–275, set out as a note under section 1395w–113 of this title.

Pub. L. 110–275, title I, §116(b), July 15, 2008, 122 Stat. 2507, provided that: “The amendments made by this section [amending this section] shall take effect with respect to applications filed on or after January 1, 2010.”


GAO STUDY REGARDING IMPACT OF ASSETS TEST FOR SUBSIDY ELIGIBLE INDIVIDUALS


“(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the extent to which drug utilization and access to covered part D drugs under part D of title XVIII of the Social Security Act [this part] by subsidy eligible individuals differs from such utilization and access for individuals who would qualify as such subsidy eligible individuals but for the application of section 1860D–14(a)(3)(A)(ii) of such Act [subsec. (a)(3)(A)(ii) of this section].

“(2) REPORT.—Not later than September 30, 2007, the Comptroller General shall submit a report to Congress on the study conducted under paragraph (1) that includes such recommendations for legislation as the Comptroller General determines are appropriate.”

$ 1395w–114a. Medicare coverage gap discount program

(a) Establishment

The Secretary shall establish a Medicare coverage gap discount program (in this section referred to as the ‘‘program’’) by not later than January 1, 2011. Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of the duties described in subsection (c)(1). The Secretary shall establish a model agreement for use under the program by not later than 180 days after March 23, 2010, in consultation with manufacturers, and allow for comment on such model agreement.

(b) Terms of agreement

(1) In general

(A) Agreement

An agreement under this section shall require the manufacturer to provide applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer.

(B) Provision of discounted prices at the point-of-sale

Except as provided in subsection (c)(1)(A)(i), such discounted prices shall be provided to the applicable beneficiary at the

point-of-sale.
(C) Timing of agreement
(i) Special rule for 2011
In order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2011, and ending on December 31, 2011, the manufacturer shall enter into such agreement not later than not later than 30 days after the date of the establishment of a model agreement under subsection (a).
(ii) 2012 and subsequent years
In order for an agreement with a manufacturer to be in effect under this section with respect to plan year 2012 or a subsequent plan year, the manufacturer shall enter into such agreement (or such agreement shall be renewed under paragraph (4)(A)) not later than January 30 of the preceding year.
(2) Provision of appropriate data
Each manufacturer with an agreement in effect under this section shall collect and have available appropriate data, as determined by the Secretary, to ensure that it can demonstrate to the Secretary compliance with the requirements under the program.
(3) Compliance with requirements for administration of program
Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under subsection (d)(3), as applicable, for purposes of administering the program, including any determination under clause (i) of subsection (c)(1)(A) or procedures established under such subsection (c)(1)(A).
(4) Length of agreement
(A) In general
An agreement under this section shall be effective for an initial period of not less than 18 months and shall be automatically renewed for a period of not less than 1 year unless terminated under subparagraph (B).
(B) Termination
(i) By the Secretary
The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

(i) By a manufacturer
A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—
(I) if the termination occurs before January 30 of a plan year, as of the day after the end of the plan year; and
(II) if the termination occurs on or after January 30 of a plan year, as of the day after the end of the succeeding plan year.
(iii) Effectiveness of termination
Any termination under this subparagraph shall not affect discounts for applicable drugs of the manufacturer that are due under the agreement before the effective date of its termination.
(iv) Notice to third party
The Secretary shall provide notice of such termination to a third party with a contract under subsection (d)(3) within not less than 30 days before the effective date of such termination.
(c) Duties described and special rule for supplemental benefits
(1) Duties described
The duties described in this subsection are the following:
(A) Administration of program
Administering the program, including—
(i) the determination of the amount of the discounted price of an applicable drug of a manufacturer;
(ii) except as provided in clause (iii), the establishment of procedures under which discounted prices are provided to applicable beneficiaries at pharmacies or by mail order service at the point-of-sale;
(iii) in the case where, during the period beginning on January 1, 2011, and ending on December 31, 2011, it is not practicable to provide such discounted prices at the point-of-sale (as described in clause (ii)), the establishment of procedures to provide such discounted prices as soon as practicable after the point-of-sale;
(iv) the establishment of procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—
(I) the negotiated price of the applicable drug; and
(II) the discounted price of the applicable drug;
(v) the establishment of procedures to ensure that the discounted price for an applicable drug under this section is applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of ap-
applicable beneficiaries as the Secretary may specify;
   (vi) the establishment of procedures to implement the special rule for supplemental benefits under paragraph (2); and
   (vii) providing a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the third party with a contract under subsection (d)(3).

(B) Monitoring compliance

   (i) In general
   The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under this section.

   (ii) Notification
   If a third party with a contract under subsection (d)(3) determines that the manufacturer is not in compliance with such agreement, the third party shall notify the Secretary of such noncompliance for appropriate enforcement under subsection (e).

   (C) Collection of data from prescription drug plans and MA–PD plans
   The Secretary may collect appropriate data from prescription drug plans and MA–PD plans in a timeframe that allows for discounted prices to be provided for applicable drugs under this section.

(2) Special rule for supplemental benefits

   For plan year 2011 and each subsequent plan year, in the case where an applicable beneficiary has supplemental benefits with respect to applicable drugs under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in, the applicable beneficiary shall not be provided a discounted price for applicable drugs under this section until after such supplemental benefits have been applied with respect to the applicable drug.

(d) Administration

   (1) In general
   Subject to paragraph (2), the Secretary shall provide for the implementation of this section, including the performance of the duties described in subsection (c)(1).

   (2) Limitation
   (A) In general
   Subject to subparagraph (B), in providing for such implementation, the Secretary shall not receive or distribute any funds of a manufacturer under the program.

   (B) Exception
   The limitation under subparagraph (A) shall not apply to the Secretary with respect to drugs dispensed during the period beginning on January 1, 2011, and ending on December 31, 2011, but only if the Secretary determines that the exception to such limitation under this subparagraph is necessary in order for the Secretary to begin implementation of this section and provide applicable beneficiaries timely access to discounted prices during such period.

(3) Contract with third parties

   The Secretary shall enter into a contract with 1 or more third parties to administer the requirements established by the Secretary in order to carry out this section. At a minimum, the contract with a third party under the preceding sentence shall require that the third party—
   (A) receive and transmit information between the Secretary, manufacturers, and other individuals or entities the Secretary determines appropriate;
   (B) receive, distribute, or facilitate the distribution of funds of manufacturers to appropriate individuals or entities in order to meet the obligations of manufacturers under agreements under this section;
   (C) provide adequate and timely information to manufacturers, consistent with the agreement with the manufacturer under this section, as necessary for the manufacturer to fulfill its obligations under this section; and
   (D) permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the third party to determine discounts for applicable drugs of the manufacturer under the program.

(4) Performance requirements

   The Secretary shall establish performance requirements for a third party with a contract under paragraph (3) and safeguards to protect the independence and integrity of the activities carried out by the third party under the program under this section.

(5) Implementation

   The Secretary may implement the program under this section by program instruction or otherwise.

(6) Administration

   Chapter 35 of title 44 shall not apply to the program under this section.

(e) Enforcement

   (1) Audits
   Each manufacturer with an agreement in effect under this section shall be subject to periodic audit by the Secretary.

   (2) Civil money penalty
   (A) In general
   The Secretary shall impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with such agreement for each such failure in an amount the Secretary determines is commensurate with the sum of—
   (i) the amount that the manufacturer would have paid with respect to such discounts under the agreement, which will then be used to pay the discounts which the manufacturer had failed to provide; and
   (ii) 25 percent of such amount.

   (B) Application
   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(a) of this title.

(f) Clarification regarding availability of other covered part D drugs

Nothing in this section shall prevent an applicable beneficiary from purchasing a covered part D drug that is not an applicable drug (including a generic drug or a drug that is not on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in).

(g) Definitions

In this section:

(1) Applicable beneficiary

The term “applicable beneficiary” means an individual who, on the date of dispensing a covered part D drug—

(A) is enrolled in a prescription drug plan or an MA–PD plan;

(B) is not enrolled in a qualified retiree prescription drug plan;

(C) is not entitled to an income-related subsidy under section 1395w–114(a) of this title; and

(D) who—

(i) has reached or exceeded the initial coverage limit under section 1395w–102(b)(3) of this title during the year; and

(ii) has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(A) of this title.

(2) Applicable drug

The term “applicable drug” means, with respect to an applicable beneficiary, a covered part D drug—

(A) approved under a new drug application under section 355(b) of title 21 or, in the case of a biologic product, licensed under section 360c(b) of title 21 under such regulation; or

(B)(i) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

(ii) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in.

(3) Applicable number of calendar days

The term “applicable number of calendar days” means—

(A) with respect to claims for reimbursement submitted electronically, 14 days; and

(B) with respect to claims for reimbursement submitted otherwise, 30 days.

(4) Discounted price

(A) In general

The term “discounted price” means 50 percent of the negotiated price of the applicable drug of a manufacturer.

(B) Clarification

Nothing in this section shall be construed as affecting the responsibility of an applicable beneficiary for payment of a dispensing fee for an applicable drug.

(C) Special case for certain claims

In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall at or above the initial coverage limit under section 1395w–102(b)(3) of this title and below the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B) of this title for the year, the manufacturer of the applicable drug shall provide the discounted price under this section on only the portion of the negotiated price of the applicable drug that falls at or above such initial coverage limit and below such annual out-of-pocket threshold.

(5) Manufacturer

The term “manufacturer” means any entity which is engaged in the production, preparation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) Negotiated price

The term “negotiated price” has the meaning given such term in section 423.100 of title 42, Code of Federal Regulations (as in effect on March 23, 2010), except that such negotiated price shall not include any dispensing fee for the applicable drug.

(7) Qualified retiree prescription drug plan

The term “qualified retiree prescription drug plan” means any drug plan which is engaged in the production, preparation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.

(MENDMENTS)


(AMENDMENTS)


Pub. L. 111–152, § 1101(b)(2)(B)(i), substituted “January 1, 2011” for “July 1, 2010” and “not later than 30 days after the date of the establishment of a model agreement under subsection (a)” for “May 1, 2010”, before “(ii) heading to reflect the probable intent of Congress.”

§ 1395w–115. Subsidies for part D eligible individuals for qualified prescription drug coverage

(a) Subsidy payment

In order to reduce premium levels applicable to qualified prescription drug coverage for part D eligible individuals consistent with an overall subsidy level of 74.5 percent for basic prescription drug coverage, to reduce adverse selection among prescription drug plans and MA–PD plans, and to promote the participation of PDP sponsors under this part and MA organizations under part C of this subchapter, the Secretary shall provide for payment to a PDP sponsor that offers a prescription drug plan and an MA organization that offers an MA–PD plan of the following subsidies in accordance with this section:

1. Direct subsidy
   A direct subsidy for each part D eligible individual enrolled in a prescription drug plan or MA–PD plan for a month equal to—
   (A) the amount of the plan’s standardized bid amount (as defined in section 1395w–113(a)(6) of this title), adjusted under subsection (c)(1) of this section, reduced by
   (B) the base beneficiary premium (as computed under paragraph (2) of section 1395w–113(a) of this title and as adjusted under paragraph (1)(B) of such section).

2. Subsidy through reinsurance

The reinsurance payment amount (as defined in subsection (b) of this section).

This section constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this section.

(b) Reinsurance payment amount

(1) In general

The reinsurance payment amount under this subsection for a part D eligible individual enrolled in a prescription drug plan or MA–PD plan for a coverage year is an amount equal to 80 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B) of this title.

(2) Allowable reinsurance costs

For purposes of this section, the term “allowable reinsurance costs” means, with respect to gross covered prescription drug costs under a prescription drug plan offered by a PDP sponsor or an MA–PD plan offered by an MA organization, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization or by (or on behalf of) an enrollee under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were standard prescription drug coverage.

(3) Gross covered prescription drug costs

For purposes of this section, the term “gross covered prescription drug costs” means, with respect to a part D eligible individual enrolled in a prescription drug plan or MA–PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

(4) Coverage year defined

For purposes of this section, the term “coverage year” means a calendar year in which covered part D drugs are dispensed if the claim for such drugs (and payment on such claim) is made not later than such period after the end of such year as the Secretary specifies.

(c) Adjustments relating to bids

(1) Health status risk adjustment

(A) Establishment of risk adjustors

The Secretary shall establish an appropriate methodology for adjusting the standardized bid amount under subsection (a)(1)(A) of this section to take into account variation in costs for basic prescription drug coverage among prescription drug plans and MA–PD plans based on the differences in actuarial risk of different enrollees being served. Any such risk adjustment shall be designed in a manner so as not to result in a change in the aggregate amounts payable to such plans under subsection (a)(1) of this section and through that portion of the monthly beneficiary prescription drug premiums described in subsection (a)(1)(B) of this section and MA monthly prescription drug beneficiary premiums.

(B) Considerations

In establishing the methodology under subparagraph (A), the Secretary may take into account the similar methodologies used under section 1395w–23(a)(3) of this title to adjust payments to MA organizations for benefits under the original Medicare fee-for-service program option.

(C) Data collection

In order to carry out this paragraph, the Secretary shall require—
(i) PDP sponsors to submit data regarding drug claims that can be linked to the individual level to part A and part B data and such other information as the Secretary determines necessary; and
(ii) MA organizations that offer MA–PD plans to submit data regarding drug claims that can be linked to the individual level to other data that such organizations are required to submit to the Secretary and such other information as the Secretary determines necessary.

(D) Publication
At the time of publication of risk adjustment factors under section 1395w–23(b)(1)(B)(i)(II) of this title, the Secretary shall publish the risk adjusters established under this paragraph for the succeeding year.

(2) Geographic adjustment
(A) In general
Subject to subparagraph (B), for purposes of section 1395w–113(a)(1)(B)(iii) of this title, the Secretary shall establish an appropriate methodology for adjusting the national average monthly bid amount (computed under section 1395w–113(a)(4) of this title) to take into account differences in prices for covered part D drugs among PDP regions.

(B) De minimis rule
If the Secretary determines that the price variations described in subparagraph (A) among PDP regions are de minimis, the Secretary shall not provide for adjustment under this paragraph.

(C) Budget neutral adjustment
Any adjustment under this paragraph shall be applied in a manner so as to not result in a change in the aggregate payments made under this part that would have been made if the Secretary had not applied such adjustment.

(d) Payment methods
(1) In general
Payments under this section shall be based on such a method as the Secretary determines. The Secretary may establish a payment method by which interim payments of amounts under this section are made during a year based on the Secretary’s best estimate of amounts that will be payable after obtaining all of the information.

(2) Requirement for provision of information
(A) Requirement
Payments under this section to a PDP sponsor or MA organization are conditioned upon the furnishing to the Secretary, in a form and manner specified by the Secretary, of such information as may be required to carry out this section.

(B) Restriction on use of information
Information disclosed or obtained pursuant to subparagraph (A) may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section.

(3) Source of payments
Payments under this section shall be made from the Medicare Prescription Drug Account.

(4) Application of enrollee adjustment
The provisions of section 1395w–23(a)(2) of this title shall apply to payments to PDP sponsors under this section in the same manner as they apply to payments to MA organizations under section 1395w–23(a) of this title.

(e) Portion of total payments to a sponsor or organization subject to risk
(1) Computation of adjusted allowable risk corridor costs
(A) In general
For purposes of this subsection, the term “adjusted allowable risk corridor costs” means, for a plan for a coverage year (as defined in subsection (b)(4) of this section)—
(i) the allowable risk corridor costs (as defined in subparagraph (B)) for the plan for the year, reduced by
(ii) the sum of
(I) the total reinsurance payments made under subsection (b) of this section to the sponsor of the plan for the year, and
(II) the total subsidy payments made under section 1395w–114 of this title to the sponsor of the plan for the year.

(B) Allowable risk corridor costs
For purposes of this subsection, the term “allowable risk corridor costs” means, with respect to a prescription drug plan offered by a PDP sponsor or an MA–PD plan offered by an MA organization, the part of costs (not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year) incurred by the sponsor or organization under the plan that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were basic prescription drug coverage taking into account the adjustment under section 1395w–111(c)(2) of this title. In computing allowable costs under this paragraph, the Secretary shall compute such costs based upon imposition under paragraphs (1)(D) and (2)(E) of section 1395w–114(a) of this title of the maximum amount of copayments permitted under such paragraphs.

(2) Adjustment of payment
(A) No adjustment if adjusted allowable risk corridor costs within risk corridor
If the adjusted allowable risk corridor costs (as defined in paragraph (1)) for the plan for the year are at least equal to the first threshold lower limit of the risk corridor.
(B) Increase in payment if adjusted allowable risk corridor costs above upper limit of risk corridor

(i) Costs between first and second threshold upper limits

If the adjusted allowable risk corridor costs for the plan for the year are greater than the first threshold upper limit but not greater than the second threshold upper limit, of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between such adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

(ii) Costs above second threshold upper limits

If the adjusted allowable risk corridor costs for the plan for the year are greater than the second threshold upper limit, of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to the sum of—

(I) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between the first threshold upper limit and the second threshold upper limit; and

(II) 80 percent of the difference between such adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) Conditions for application of higher percentage for 2006 and 2007

The conditions described in this clause are met for 2006 or 2007 if the Secretary determines with respect to such year that—

(I) at least 60 percent of prescription drug plans and MA–PD plans to which this subsection applies have adjusted allowable risk corridor costs for the plan for the year that are more than the first threshold upper limit of the risk corridor for the plan for the year; and

(II) such plans represent at least 60 percent of part D eligible individuals enrolled in any prescription drug plan or MA–PD plan.

(C) Reduction in payment if adjusted allowable risk corridor costs below lower limit of risk corridor

(i) Costs between first and second threshold lower limits

If the adjusted allowable risk corridor costs for the plan for the year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization offering the plan for the year an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and such adjusted allowable risk corridor costs.

(ii) Costs below second threshold lower limit

If the adjusted allowable risk corridor costs for the plan for the year are less than the second threshold lower limit of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to the sum of—

(I) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(II) 80 percent of the difference between the second threshold upper limit of the risk corridor and such adjusted allowable risk corridor costs.

(3) Establishment of risk corridors

(A) In general

For each plan year the Secretary shall establish a risk corridor for each prescription drug plan and each MA–PD plan. The risk corridor for a plan for a year shall be equal to a range as follows:

(i) First threshold lower limit

The first threshold lower limit of such corridor shall be equal to—

(I) the target amount described in subparagraph (B) for the plan; minus

(II) an amount equal to the first threshold risk percentage for the plan (as determined under subparagraph (C)(i)) of such target amount.

(ii) Second threshold lower limit

The second threshold lower limit of such corridor shall be equal to—

(I) the target amount described in subparagraph (B) for the plan; minus

(II) an amount equal to the second threshold risk percentage for the plan (as determined under subparagraph (C)(ii)) of such target amount.

(iii) First threshold upper limit

The first threshold upper limit of such corridor shall be equal to the sum of—
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(4) Plans at risk for entire amount of supplemental prescription drug coverage

A PDP sponsor and MA organization that offers a plan that provides supplemental prescription drug benefits shall be at full financial risk for the provision of such supplemental benefits.

(5) No effect on monthly premium

No adjustment in payments made by reason of this subsection shall affect the monthly beneficiary premium or the MA monthly prescription drug beneficiary premium.

(f) Disclosure of information

(1) In general

Each contract under this part and under part C of this subchapter shall provide that—

(A) the PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall provide the Secretary with such information as the Secretary determines is necessary to carry out this section; and

(B) the Secretary shall have the right in accordance with section 1395w–27(d)(2)(B) of this title (as applied under section 1395w–112(b)(3)(C) of this title) to inspect and audit any books and records of a PDP sponsor or MA organization that pertain to the information regarding costs provided to the Secretary under subparagraph (A).

(2) Restriction on use of information

Information disclosed or obtained pursuant to the provisions of this section may be used—

(A) by officers, employees, and contractors of the Department of Health and Human Services for the purposes of, and to the extent necessary in—

(i) carrying out this section; and

(ii) conducting oversight, evaluation, and enforcement under this subchapter; and

(B) by the Attorney General and the Comptroller General of the United States for the purposes of, and to the extent necessary in, carrying out health oversight activities.

(g) Payment for fallback prescription drug plans

In lieu of the amounts otherwise payable under this section to a PDP sponsor offering a fallback prescription drug plan (as defined in section 1395w–111(g)(4) of this title), the amount payable shall be the amounts determined under the contract for such plan pursuant to section 1395w–111(g)(5) of this title.


REFERENCES IN TEXT

Part C of this subchapter, referred to in subsecs. (a) and (f)(1), is classified to section 1395w–21 et seq. of this title.

Section 1395w–111(g)(4) of this title, referred to in subsec. (g), was in the original “section 1860D–3(c)(4)”, and was translated as reading “section 1860D–11(g)(4)”, meaning section 1860D–11(g)(4) 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. (c), and section 1395w–111(g)(4) of this title defines “fallback prescription drug plan” for purposes of this part.

AMENDMENTS

2010—Subsec. (f)(2). Pub. L. 111–148 substituted “may be used—” for “may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent nec-

\(^1\) See in original. The word “and” probably should not appear.

\(^2\) See References in Text note below.
§ 1395w–116. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund

(a) Establishment and operation of Account

(1) Establishment

There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1395t of this title an account to be known as the “Medicare Prescription Drug Account” (in this section referred to as the “Account”).

(2) Funding

The Account shall consist of such gifts and bequests as may be made as provided in section 401(i)(1) of this title, accrued interest on balances in the Account, and such amounts as may be deposited in, or appropriated to, such Account as provided in this part.

(3) Separate from rest of Trust Fund

Funds provided under this part to the Account shall be kept separate from all other funds within the Federal Supplementary Medical Insurance Trust Fund, but shall be invested, and such investments redeemed, in the same manner as all other funds and investments within such Trust Fund.

(b) Payments from Account

(1) In general

The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments to operate the program under this part, including—

(A) payments under section 1395w–114 of this title (relating to low-income subsidy payments);

(B) payments under section 1395w–115 of this title (relating to subsidy payments and payments for fallback plans);

(C) payments to sponsors of qualified retiree prescription drug plans under section 1395w–129(a) of this title; and

(D) payments with respect to administrative expenses under this part in accordance with section 401(g) of this title.

(2) Transfers to Medicaid account for increased administrative costs

The Managing Trustee shall transfer from time to time from the Account to the Grants to States for Medicaid account amounts the Secretary certifies are attributable to increases in payment resulting from the application of section 1396a–5(b) of this title.

(3) Payments of premiums withheld

The Managing Trustee shall make payment to the PDP sponsor or MA organization involved of the premiums (and the portion of late enrollment penalties) that are collected in the manner described in section 1395w–24(d)(2)(A) of this title and that are payable under a prescription drug plan or MA–PD plan offered by such sponsor or organization.

(4) Treatment in relation to part B premium

Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1395r of this title.

(c) Deposits into Account

(1) Low-income transfer

Amounts paid under section 1396u–5(c) of this title (and any amounts collected or offset under paragraph (1)(C) of such section) are deposited into the Account.

(2) Amounts withheld

Pursuant to sections 1395w–113(c) and 1395w–24(d) of this title (as applied under this part), amounts that are withheld (and allocated) to the Account are deposited into the Account.

(3) Appropriations to cover Government contributions

There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Account, an amount equivalent to the amount of payments made from the Account under subsection (b) of this section plus such amounts as the Managing Trustee certifies is necessary to maintain an appropriate contingency margin, reduced by the amounts deposited under paragraph (1) or subsection (a)(2) of this section.

(4) Initial funding and reserve

In order to assure prompt payment of benefits provided under this part and the administrative expenses thereunder during the early months of the program established by this part and to provide an initial contingency reserve, there are authorized to be appropriated to the Account, out of any moneys in the Treasury not otherwise appropriated, such amount as the Secretary certifies are required, but not to exceed 10 percent of the estimated total expenditures from such Account in 2006.

(5) Transfer of any remaining balance from Transitional Assistance Account

Any balance in the Transitional Assistance Account that is transferred under section 1395w–141(k)(5) of this title shall be deposited into the Account.


SUBPART 3—APPLICATION TO MEDICARE ADVANTAGE PROGRAM AND TREATMENT OF EMPLOYER–SPONSORED PROGRAMS AND OTHER PRESCRIPTION DRUG PLANS

§ 1395w–131. Application to Medicare Advantage program and related managed care programs

(a) Special rules relating to offering of qualified prescription drug coverage

(1) In general

An MA organization on and after January 1, 2006—

(A) may not offer an MA plan described in section 1395w–21(a)(2)(A) of this title in an area unless either that plan (or another MA plan offered by the organization in that

...
same service area) includes required prescription drug coverage (as defined in paragraph (2)); and

(B) may not offer prescription drug coverage (other than that required under parts A and B of this subchapter) to an enrollee—

(i) under an MSA plan; or

(ii) under another MA plan unless such drug coverage under such other plan provides qualified prescription drug coverage and unless the requirements of this section with respect to such coverage are met.

(2) Qualifying coverage

For purposes of paragraph (1)(A), the term “required coverage” means with respect to an MA–PD plan—

(A) basic prescription drug coverage; or

(B) qualified prescription drug coverage that provides supplemental prescription drug coverage, so long as there is no MA monthly supplemental beneficiary premium applied under the plan (due to the application of a credit against such premium of a rebate under section 1395w–24(b)(1)(C) of this title).

(b) Application of default enrollment rules

(1) Seamless continuation

In applying section 1395w–21(c)(3)(A)(ii) of this title, an individual who is enrolled in a health benefits plan shall not be considered to have been deemed to make an election into an MA–PD plan unless such health benefits plan provides any prescription drug coverage.

(2) MA continuation

In applying section 1395w–21(c)(3)(B) of this title, an individual who is enrolled in an MA plan shall not be considered to have been deemed to make an election into an MA–PD plan unless—

(A) for purposes of the election as of January 1, 2006, the MA plan provided as of December 31, 2005, any prescription drug coverage; or

(B) for periods after January 1, 2006, such MA plan is an MA–PD plan.

(3) Discontinuance of MA–PD election during first year of eligibility

In applying the second sentence of section 1395w–21(e)(4) of this title in the case of an individual who is electing to discontinue enrollment in an MA–PD plan, the individual shall be permitted to enroll in a prescription drug plan under part D at the time of the election of coverage under the original medicare fee-for-service program.

(4) Rules regarding enrollees in MA plans not providing qualified prescription drug coverage

In the case of an individual who is enrolled in an MA plan (other than an MSA plan) that does not provide qualified prescription drug coverage, if the organization offering such coverage discontinues the offering with respect to the individual of all MA plans that do not provide such coverage—

(i) the individual is deemed to have elected the original medicare fee-for-service program option, unless the individual affirmatively elects to enroll in an MA–PD plan; and

(ii) in the case of such a deemed election, the disenrollment shall be treated as an involuntary termination of the MA plan described in subparagraph (B)(ii) of section 1395ss(s)(3) of this title for purposes of applying such section.

The information disclosed under section 1395w–22(c)(1) of this title for individuals who are enrolled in such an MA plan shall include information regarding such rules.

(c) Application of part D rules for prescription drug coverage

With respect to the offering of qualified prescription drug coverage by an MA organization under this part on and after January 1, 2006—

(1) In general

Except as otherwise provided, the provisions of this part shall apply under part C of this subchapter with respect to prescription drug coverage provided under MA–PD plans in lieu of the other provisions of part C of this subchapter that would apply to such coverage under such plans.

(2) Waiver

The Secretary shall waive the provisions referred to in paragraph (1) to the extent the Secretary determines that such provisions duplicate, or are in conflict with, provisions otherwise applicable to the organization or plan under part C of this subchapter or as may be necessary in order to improve coordination of this part with the benefits under this part.

(3) Treatment of MA owned and operated pharmacies

The Secretary may waive the requirement of section 1395w–104(b)(1)(C) of this title in the case of an MA–PD plan that provides access (other than mail order) to qualified prescription drug coverage through pharmacies owned and operated by the MA organization, if the Secretary determines that the organization’s pharmacy network is sufficient to provide comparable access for enrollees under the plan.

(d) Special rules for private fee-for-service plans that offer prescription drug coverage

With respect to an MA plan described in section 1395w–21(a)(2)(C) of this title that offers qualified prescription drug coverage, on and after January 1, 2006, the following rules apply:

(1) Requirements regarding negotiated prices

Subsections (a)(1) and (d)(1) of section 1395w–102 of this title and section 1395w–104(b)(2)(A) of this title shall not be construed to require the plan to provide negotiated prices (described in subsection (d)(1)(B) of such section), but shall apply to the extent the plan does so.

(2) Modification of pharmacy access standard and disclosure requirement

If the plan provides coverage for drugs purchased from all pharmacies, without charging additional cost-sharing, and without regard to
whether they are participating pharmacies in a network or have entered into contracts or agreements with pharmacies to provide drugs to enrollees covered by the plan, subsections (b)(1)(C) and (k) of section 1395w–104 of this title shall not apply to the plan.

(3) Drug utilization management program and medication therapy management program not required
The requirements of subparagraphs (A) and (C) of section 1395w–104(c)(1) of this title shall not apply to the plan.

(4) Application of reinsurance
The Secretary shall determine the amount of reinsurance payments under section 1395w–115(b) of this title using a methodology that—
(A) bases such amount on the Secretary’s estimate of the amount of such payments that would be payable if the plan were an MA–PD plan described in section 1395w–21(a)(2)(A)(i) of this title and the previous provisions of this subsection did not apply; and
(B) takes into account the average reinsurance payments made under section 1395w–115(b) of this title for populations of similar risk under MA–PD plans described in such section.

(5) Exemption from risk corridor provisions
The provisions of section 1395w–115(e) of this title shall not apply.

(6) Exemption from negotiations
Subsections (d) and (e)(2)(C) of section 1395w–111 of this title shall not apply and the provisions of section 1395w–24(a)(5)(B) of this title shall not apply to the proposed bid and terms and conditions described in section 1395w–111(d) of this title.

(7) Treatment of incurred costs without regard to formulary
The exclusion of costs incurred for covered part D drugs which are not included (or treated as being included) in a plan’s formulary under section 1395w–102(b)(4)(B)(i) of this title shall not apply insofar as the plan does not utilize a formulary.

(e) Application to reasonable cost reimbursement contractors
(1) In general
Subject to paragraphs (2) and (3) and rules established by the Secretary, in the case of an organization that is providing benefits under a reasonable cost reimbursement contract under section 1395w–21(a)(2)(A)(i) of this title and that elects to provide qualified prescription drug coverage to a part D eligible individual who is enrolled under such a contract, the provisions of this part (and related provisions of part C of this subchapter) shall apply to the provision of such coverage under an MA–PD local plan described in section 1395–21(a)(2)(A)(i) of this title and coverage under such a contract that so provides qualified prescription drug coverage shall be deemed to be an MA–PD local plan.

(2) Limitation on enrollment
In applying paragraph (1), the organization may not enroll part D eligible individuals who are not enrolled under the reasonable cost reimbursement contract involved.

(3) Bids not included in determining national average monthly bid amount
The bid of an organization offering prescription drug coverage under this subsection shall not be taken into account in computing the national average monthly bid amount and low-income benchmark premium amount under this part.

(f) Application to PACE
(1) In general
Subject to paragraphs (2) and (3) and rules established by the Secretary, in the case of a PACE program under section 1395see of this title that elects to provide qualified prescription drug coverage to a part D eligible individual who is enrolled under such program, the provisions of this part (and related provisions of part C of this subchapter) shall apply to the provision of such coverage to such enrollee in a manner that is similar to the manner in which such provisions apply to the provision of such coverage under an MA–PD local plan described in section 1395w–21(a)(2)(A)(ii) of this title and a PACE program that so provides such coverage may be deemed to be an MA–PD local plan.

(2) Limitation on enrollment
In applying paragraph (1), the organization may not enroll part D eligible individuals who are not enrolled under the PACE program involved.

(3) Bids not included in determining standardized bid amount
The bid of an organization offering prescription drug coverage under this subsection is not be taken into account in computing any average benchmark bid amount and low-income benchmark premium amount under this part.


References in Text
Parts A and B of this subchapter, referred to in subsec. (a)(1)(B), are classified to section 1395c et seq. and section 1395j et seq., respectively, of this title.
Part C of this subchapter, referred to in subsecs. (c)(1), (2), (e)(1), and (f)(1), is classified to section 1395w–21 et seq. of this title.

§1395w–132. Special rules for employer-sponsored programs

(a) Subsidy payment
(1) In general
The Secretary shall provide in accordance with this subsection for payment to the sponsor of a qualified retiree prescription drug plan (as defined in paragraph (2)) of a special subsidy payment equal to the amount speci-
(3) Employer and union special subsidy amounts

(A) In general

For purposes of this subsection, the special subsidy payment amount under this paragraph for a qualifying covered retiree for a coverage year enrolled with the sponsor of a qualified retiree prescription drug plan is, for the portion of the retiree’s gross covered retiree plan-related prescription drug costs (as defined in subparagraph (C)(i)(I)) for such year that exceeds the cost threshold amount specified in subparagraph (B) and does not exceed the cost limit under such subparagraph, an amount equal to 28 percent of the allowable retiree costs (as defined in subparagraph (C)(i)) attributable to such gross covered prescription drug costs.

(B) Cost threshold and cost limit applicable

(i) In general

Subject to clause (ii)—

(I) the cost threshold under this subparagraph is equal to $250 for plan years that end in 2006; and

(II) the cost limit under this subparagraph is equal to $5,000 for plan years that end in 2006.

(ii) Indexing

The cost threshold and cost limit amounts specified in subclauses (I) and (II) of clause (i) for a plan year that ends after 2006 shall be adjusted in the same manner as the annual deductible and the annual out-of-pocket threshold, respectively, are annually adjusted under paragraphs (1) and (4)(B) of section 1395w–102(b) of this title.

(C) Definitions

For purposes of this paragraph:

(i) Allowable retiree costs

The term “allowable retiree costs” means, with respect to gross covered prescription drug costs under a qualified retiree prescription drug plan by a plan sponsor, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or by or on behalf of a qualifying covered retiree under the plan.

(ii) Gross covered retiree plan-related prescription drug costs

For purposes of this section, the term “gross covered retiree plan-related prescription drug costs” means, with respect to a qualifying covered retiree enrolled in a qualified retiree prescription drug plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year. Such costs shall be determined whether they are paid by the retiree or under the plan.

(iii) Coverage year

The term “coverage year” has the meaning given such term in section 1395w–115(b)(4) of this title.

(4) Qualifying covered retiree defined

For purposes of this subsection, the term “qualifying covered retiree” means a part D eligible individual who is not enrolled in a prescription drug plan or an MA–PD plan but is covered under a qualified retiree prescription drug plan.

(5) Payment methods, including provision of necessary information

The provisions of section 1395w–115(d) of this title (including paragraph (2), relating to re-
requirement for provision of information) shall apply to payments under this subsection in a manner similar to the manner in which they apply to payment under section 1395w–115(b) of this title.

(6) Construction

Nothing in this subsection shall be construed as—

(A) precluding a part D eligible individual who is covered under employment-based retiree health coverage from enrolling in a prescription drug plan or in an MA–PD plan; or

(B) precluding such employment-based retiree health coverage or an employer or other person from paying all or any portion of any premium required for coverage under a prescription drug plan or MA–PD plan on behalf of such an individual;

(C) preventing such employment-based retiree health coverage from providing coverage—

(i) that is better than standard prescription drug coverage to retirees who are covered under a qualified retiree prescription drug plan; or

(ii) that is supplemental to the benefits provided under a prescription drug plan or an MA–PD plan, including benefits to retirees who are not covered under a qualified retiree prescription drug plan but who are enrolled in such a prescription drug plan or MA–PD plan; or

(D) preventing employers to provide for flexibility in benefit design and pharmacy access provisions, without regard to the requirements for basic prescription drug coverage, so long as the actuarial equivalence requirement of paragraph (2)(A) is met.

(b) Application of MA waiver authority

The provisions of section 1395w–27(i) of this title shall apply with respect to prescription drug plans in relation to employment-based retiree health coverage in a manner similar to the manner in which they apply to an MA plan in relation to employers, including authorizing the establishment of separate premium amounts for enrollees in a prescription drug plan by reason of such coverage and limitations on enrollment to part D eligible individuals enrolled under such coverage.

(c) Definitions

For purposes of this section:

(1) Employment-based retiree health coverage

The term ‘‘employment-based retiree health coverage’’ means health insurance or other coverage of health care costs (whether provided by voluntary insurance coverage or pursuant to statutory or contractual obligation) for part D eligible individuals (or for such individuals and their spouses and dependents) under a group health plan based on their status as retired participants in such plan.

(2) Sponsor

The term ‘‘sponsor’’ means a plan sponsor, as defined in section 1002(16)(B) of title 29, in relation to a group health plan, except that, in the case of a plan maintained jointly by one employer and an employee organization and with respect to which the employer is the primary source of financing, such term means such employer.

(3) Group health plan

The term ‘‘group health plan’’ includes such a plan as defined in section 1107(1) of title 29 and also includes the following:

(A) Federal and State governmental plans

Such a plan established or maintained for its employees by the Government of the United States, by the government of any State or political subdivision thereof, or by any agency or instrumentality of any of the foregoing, including a health benefits plan offered under chapter 89 of title 5.

(B) Collectively bargained plans

Such a plan established or maintained under or pursuant to one or more collective bargaining agreements.

(C) Church plans

Such a plan established and maintained for its employees (or their beneficiaries) by a church or by a convention or association of churches which is exempt from tax under section 501 of the Internal Revenue Code of 1986.

(d) Interpretation

Nothing in this section shall preclude a part D eligible individual from obtaining coverage under a plan that—

(i) provides coverage for prescription drugs; and

(ii) is better than standard prescription drug coverage.

(e) Limitation on premium requirements

The Internal Revenue Code of 1986, referred to in subsection (c)(3)(C), is classified generally to Title 26, Internal Revenue Code.

(f) Mailing address

The mailing address of such a plan shall be identified in a plan document, and shall, if different from the mailing address of the plan’s sponsor, be included in such a plan document.

AMENDMENTS

2010—Subsec. (a)(2)(A). Pub. L. 111–152 inserted before period at end ‘‘, not taking into account the value of any discount or coverage provided during the gap in prescription drug coverage that occurs between the initial coverage limit under section 1395w–102(b)(3) of this title during the year and the out-of-pocket threshold specified in section 1395w–102(b)(4)(B) of this title’’.

References in Text

The Internal Revenue Code of 1986, referred to in subsec. (c)(3)(C), is classified generally to Title 26, Internal Revenue Code.
§ 1395w–133. State Pharmaceutical Assistance Programs

(a) Requirements for benefit coordination

(1) In general

Before July 1, 2005, the Secretary shall establish consistent with this section require-
§ 1395w–134. Coordination requirements for plans providing prescription drug coverage

(a) Application of benefit coordination requirements to additional plans

(1) In general

The Secretary shall apply the coordination requirements established under section 1395w–133(a) of this title to Rx plans described in subsection (b) of this section in the same manner as such requirements apply to a State Pharmaceutical Assistance Program.

(2) Application to treatment of certain out-of-pocket expenditures

To the extent specified by the Secretary, the requirements referred to in paragraph (1) shall apply to procedures established under section 1395w–102(b)(4)(D) of this title.

(b) User fees

(A) In general

The Secretary may impose user fees for the transmittal of information necessary for benefit coordination under section 1395w–102(b)(4)(D) of this title, and may retain a portion of such fees to defray the Secretary’s costs in carrying out procedures under section 1395w–102(b)(4)(D) of this title.

(B) Application

A user fee may not be imposed under subparagraph (A) with respect to a State Pharmaceutical Assistance Program.

(b) Rx Plan

An Rx plan described in this subsection is any of the following:

(1) Medicaid programs

A State plan under subchapter XIX of this chapter, including such a plan operating under a waiver under section 1315 of this title, if it meets the requirements of section 1395w–133(b)(2) of this title.

(2) Group health plans

An employer group health plan.

(3) FEHBP

The Federal employees health benefits plan under chapter 89 of title 5.

(4) Military coverage (including TRICARE)

Coverage under chapter 55 of title 10.

(5) Other prescription drug coverage

Such other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of part D eligible individuals as the Secretary may specify.

(c) Relation to other provisions

(1) Use of cost management tools

The requirements of this section shall not impair or prevent a PDP sponsor or MA orga-
nization from applying cost management tools (including differential payments) under all methods of operation.

(2) No affect on treatment of certain out-of-pocket expenditures

The requirements of this section shall not affect the application of the procedures established under section 1395w–102(b)(4)(D) of this title.


SUBPART 4—MEDICARE PRESCRIPTION DRUG DISCOUNT CARD AND TRANSITIONAL ASSISTANCE PROGRAM

§ 1395w–141. Medicare prescription drug discount card and transitional assistance program

(a) Establishment of program

(1) In general

The Secretary shall establish a program under this section—

(A) to endorse prescription drug discount card programs that meet the requirements of this section in order to provide access to prescription drug discounts through prescription drug card sponsors for discount card eligible individuals throughout the United States; and

(B) to provide for transitional assistance for transitional assistance eligible individuals enrolled in such endorsed programs.

(2) Period of operation

(A) Implementation deadline

The Secretary shall implement the program under this section so that discount cards and transitional assistance are first available by not later than 6 months after December 8, 2003.

(B) Expediting implementation

The Secretary shall promulgate regulations to carry out the program under this section which may be effective and final immediately on an interim basis as of the date of publication of the interim final regulation. If the Secretary provides for an interim final regulation, the Secretary shall provide for a period of public comments on such regulation after the date of publication. The Secretary may change or revise such regulation after completion of the period of public comment.

(C) Termination and transition

(i) In general

Subject to clause (ii)—

(I) the program under this section shall not apply to covered discount card drugs dispensed after December 31, 2005; and

(II) transitional assistance shall be available after such date to the extent the assistance relates to drugs dispensed on or before such date.

(ii) Transition

In the case of an individual who is enrolled in an endorsed discount card program as of December 31, 2005, during the individual’s transition period (if any) under clause (iii), in accordance with transition rules specified by the Secretary—

(I) such endorsed program may continue to apply to covered discount card drugs dispensed to the individual under the program during such transition period;

(II) no annual enrollment fee shall be applicable during the transition period; and

(III) the balance of any transitional assistance remaining on January 1, 2006, shall remain available for drugs dispensed during the individual’s transition period.

(iii) Transition period

The transition period under this clause for an individual is the period beginning on January 1, 2006, and ending in the case of an individual who—

(I) is enrolled in a prescription drug plan or an MA–PD plan before the last date of the initial enrollment period under section 1395w–101(b)(2)(A) of this title, on the effective date of the individual’s coverage under such part; or

(II) is not so enrolled, on the last day of such initial period.

(3) Voluntary nature of program

Nothing in this section shall be construed as requiring a discount card eligible individual to enroll in an endorsed discount card program under this section.

(4) Glossary and definitions of terms

For purposes of this section:

(A) Covered discount card drug

The term “covered discount card drug” has the meaning given the term “covered part D drug” in section 1395w–102(e) of this title.

(B) Discount card eligible individual

The term “discount card eligible individual” is defined in subsection (b)(1)(A) of this section.

(C) Endorsed discount card program; endorsed program

The terms “endorsed discount card program” and “endorsed program” mean a prescription drug discount card program that is endorsed (and for which the sponsor has a contract with the Secretary) under this section.

(D) Negotiated price

Negotiated prices are described in subsection (e)(1)(A)(ii) of this section.

(E) Prescription drug card sponsor; sponsor

The terms “prescription drug card sponsor” and “sponsor” are defined in subsection (h)(1)(A) of this section.
(F) State
The term “State” has the meaning given such term for purposes of subchapter XIX of this chapter.

(G) Transitional assistance eligible individual
The term “transitional assistance eligible individual” is defined in subsection (b)(2) of this section.

(b) Eligibility for discount card and for transitional assistance
For purposes of this section:

(1) Discount card eligible individual

(A) In general
The term “discount card eligible individual” means an individual who—

(i) is entitled to benefits, or enrolled, under part A of this subchapter or enrolled under part B of this subchapter; and

(ii) subject to paragraph (4), is not an individual described in subparagraph (B).

(B) Individual described
An individual described in this subparagraph is an individual described in subparagraph (A)(i) who is enrolled under subchapter XIX of this chapter (or under a waiver under section 1315 of this title of the requirement of such subchapter) and is entitled to any medical assistance for outpatient prescribed drugs described in section 1396d(a)(12) of this title.

(2) Transitional assistance eligible individual

(A) In general
Subject to subparagraph (B), the term “transitional assistance eligible individual” means a discount card eligible individual who resides in one of the 50 States or the District of Columbia and whose income (as determined under subsection (f)(1)(B) of this section) is not more than 135 percent of the poverty line (as defined in section 9902(2) of this title, including any revision required by such section) applicable to the family size involved (as determined under subsection (f)(1)(B) of this section).

(B) Exclusion of individuals with certain prescription drug coverage
Such term does not include an individual who has coverage of, or assistance for, covered discount card drugs under any of the following:

(i) A group health plan or health insurance coverage (as such terms are defined in section 300gg–91 of this title), other than coverage under a plan under part C of this subchapter and other than coverage consisting only of excepted benefits (as defined in such section).

(ii) Chapter 55 of title 10 (relating to medical and dental care for members of the uniformed services).

(iii) A plan under chapter 89 of title 5 (relating to the Federal employees’ health benefits program).

(3) Special transitional assistance eligible individual
The term “special transitional assistance eligible individual” means a transitional assistance eligible individual whose income (as determined under subsection (f)(1)(B) of this section) is not more than 100 percent of the poverty line (as defined in section 9902(2) of this title, including any revision required by such section) applicable to the family size involved (as determined under subsection (f)(1)(B) of this section).

(4) Treatment of medicaid medically needy
For purposes of this section, the Secretary shall provide for appropriate rules for the treatment of medically needy individuals described in section 1396a(a)(10)(C) of this title as discount card eligible individuals and as transitional assistance eligible individuals.

(c) Enrollment and enrollment fees

(1) Enrollment process
The Secretary shall establish a process through which a discount card eligible individual is enrolled and disenrolled in an endorsed discount card program under this section consistent with the following:

(A) Continuous open enrollment
Subject to the succeeding provisions of this paragraph and subsection (h)(9) of this section, a discount card eligible individual who is not enrolled in an endorsed discount card program and is residing in a State may enroll in any such endorsed program—

(i) that serves residents of the State; and

(ii) at any time beginning on the initial enrollment date, specified by the Secretary, and before January 1, 2006.

(B) Use of standard enrollment form
An enrollment in an endorsed program shall only be effected through completion of a standard enrollment form specified by the Secretary. Each sponsor of an endorsed program shall transmit to the Secretary (in a form and manner specified by the Secretary) information on individuals who complete such enrollment forms and, to the extent provided under subsection (f) of this section, information regarding certification as a transitional assistance eligible individual.

(C) Enrollment only in one program

(i) In general
Subject to clauses (ii) and (iii), a discount card eligible individual may be enrolled in only one endorsed discount card program under this section.

(ii) Change in endorsed program permitted for 2005
The Secretary shall establish a process, similar to (and coordinated with) the process for annual, coordinated elections under section 1385w–21(e)(3) of this title during 2004, under which an individual enrolled in an endorsed discount card program may change the endorsed program in which the individual is enrolled for 2005.

(iii) Additional exceptions
The Secretary shall permit an individual to change the endorsed discount card program in which the individual is enrolled in the case of an individual who changes resi-
dence to be outside the service area of such program and in such other exceptional cases as the Secretary may provide (taking into account the circumstances for special election periods under section 1395w–21(e)(4) of this title). Under the previous sentence, the Secretary may consider a change in residential setting (such as placement in a nursing facility) or enrollment in or disenrollment from a plan under part C of this subchapter through which the individual was enrolled in an endorsed program to be an exceptional circumstance.

(D) Disenrollment

(i) Voluntary

An individual may voluntarily disenroll from an endorsed discount card program at any time. In the case of such a voluntary disenrollment, the individual may not enroll in another endorsed program, except under such exceptional circumstances as the Secretary may recognize under subparagraph (C)(iii) or during the annual coordinated enrollment period provided under subparagraph (C)(ii).

(ii) Involuntary

An individual who is enrolled in an endorsed discount card program and not a transitional assistance eligible individual may be disenrolled by the sponsor of the program if the individual fails to pay any annual enrollment fee required under the program.

(E) Application to certain enrollees

In the case of a discount card eligible individual who is enrolled in a plan described in section 1395w–21(a)(2)(A) of this title or under a reasonable cost reimbursement contract under section 1395mm(h) of this title that is offered by an organization that also is a prescription discount card sponsor that offers an endorsed discount card program under which the individual may be enrolled and that has made an election to apply the special rules under subsection (h)(9)(B) of this section for such an endorsed program, the individual may only enroll in such an endorsed discount card program offered by that sponsor.

(2) Enrollment fees

(A) In general

Subject to the succeeding provisions of this paragraph, a prescription drug card sponsor may charge an annual enrollment fee for each discount card eligible individual enrolled in an endorsed discount card program offered by such sponsor. The annual enrollment fee for either 2004 or 2005 shall not be prorated for portions of a year. There shall be no annual enrollment fee for a year after 2005.

(B) Amount

No annual enrollment fee charged under subparagraph (A) may exceed $30.

(C) Uniform enrollment fee

A prescription drug card sponsor shall ensure that the annual enrollment fee (if any) for an endorsed discount card program is the same for all discount card eligible individuals enrolled in the program and residing in the State.

(D) Collection

The annual enrollment fee (if any) charged for enrollment in an endorsed program shall be collected by the sponsor of the program.

(E) Payment of fee for transitional assistance eligible individuals

Under subsection (g)(1)(A) of this section, the annual enrollment fee (if any) otherwise charged under this paragraph with respect to a transitional assistance eligible individual shall be paid by the Secretary on behalf of such individual.

(F) Optional payment of fee by State

(i) In general

The Secretary shall establish an arrangement under which a State may provide for payment of some or all of the enrollment fee for some or all enrollees who are not transitional assistance eligible individuals in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the enrollment fee shall be paid directly by the State to the sponsor.

(ii) No Federal matching available under medicaid or SCHIP

Expenditures made by a State for enrollment fees described in clause (i) shall not be treated as State expenditures for purposes of Federal matching payments under subchapter XIX or XXI of this chapter.

(G) Rules in case of changes in program enrollment during a year

The Secretary shall provide special rules in the case of payment of an annual enrollment fee for a discount card eligible individual who changes the endorsed program in which the individual is enrolled during a year.

(3) Issuance of discount card

Each prescription drug card sponsor of an endorsed discount card program shall issue, in a standard format specified by the Secretary, to each discount card eligible individual enrolled in such program a card that establishes proof of enrollment and that can be used in a coordinated manner to identify the sponsor, program, and individual for purposes of the program under this section.

(4) Period of access

In the case of a discount card eligible individual who enrolls in an endorsed program, access to negotiated prices and transitional assistance, if any, under such endorsed program shall take effect on such date as the Secretary shall specify.

(d) Provision of information on enrollment and program features

(1) Secretarial responsibilities

(A) In general

The Secretary shall provide for activities under this subsection to broadly disseminate
information to discount card eligible individuals (and prospective eligible individuals) regarding—

(i) enrollment in endorsed discount card programs; and
(ii) the features of the program under this section, including the availability of transitional assistance.

(B) **Promotion of informed choice**

In order to promote informed choice among endorsed prescription drug discount card programs, the Secretary shall provide for the dissemination of information which—

(i) compares the annual enrollment fee and other features of such programs, which may include comparative prices for covered discount card drugs; and
(ii) includes educational materials on the variability of discounts on prices of covered discount card drugs under an endorsed program.

The dissemination of information under clause (i) shall, to the extent practicable, be coordinated with the dissemination of educational information on other medicare options.

(C) **Special rule for initial enrollment date under the program**

To the extent practicable, the Secretary shall ensure, through the activities described in subparagraphs (A) and (B), that discount card eligible individuals are provided with such information at least 30 days prior to the initial enrollment date specified under subsection (c)(1)(A)(ii) of this section.

(D) **Use of medicare toll-free number**

The Secretary shall provide through the toll-free telephone number 1–800–MEDICARE for the receipt and response to inquiries and complaints concerning the program under this section and endorsed programs.

(2) **Prescription drug card sponsor responsibilities**

(A) **In general**

Each prescription drug card sponsor that offers an endorsed discount card program shall make available to discount card eligible individuals (through the Internet and otherwise) information that the Secretary identifies as being necessary to promote informed choice among endorsed discount card programs by such individuals, including information on enrollment fees and negotiated prices for covered discount card drugs charged to such individuals.

(B) **Response to enrollee questions**

Each sponsor offering an endorsed discount card program shall have a mechanism (including a toll-free telephone number) for providing upon request specific information (such as negotiated prices and the amount of transitional assistance remaining available through the program) to discount card eligible individuals enrolled in the program. The sponsor shall inform transitional assistance eligible individuals enrolled in the program of the availability of such toll-free telephone number to provide information on the amount of available transitional assistance.

(C) **Information on balance of transitional assistance available at point-of-sale**

Each sponsor offering an endorsed discount card program shall have a mechanism so that information on the amount of transitional assistance remaining under subsection (g)(1)(B) of this section is available (electronically or by telephone) at the point-of-sale of covered discount card drugs.

(3) **Public disclosure of pharmaceutical prices for equivalent drugs**

(A) **In general**

A prescription drug card sponsor offering an endorsed discount card program shall provide that each pharmacy that dispenses a covered discount card drug shall inform a discount card eligible individual enrolled in the program of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered discount card drug under the program that is therapeutically equivalent and bioequivalent and available at such pharmacy.

(B) **Timing of notice**

(i) **In general**

Subject to clause (ii), the information under subparagraph (A) shall be provided at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

(ii) **Waiver**

The Secretary may waive clause (i) in such circumstances as the Secretary may specify.

(e) **Discount card features**

(1) **Savings to enrollees through negotiated prices**

(A) **Access to negotiated prices**

(i) **In general**

Each prescription drug card sponsor that offers an endorsed discount card program shall provide each discount card eligible individual enrolled in the program with access to negotiated prices.

(ii) **Negotiated prices**

For purposes of this section, negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered discount card drugs, and include any dispensing fees for such drugs.

(B) **Ensuring pharmacy access**

Each prescription drug card sponsor offering an endorsed discount card program shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than solely by mail order) drugs directly to enrollees to ensure convenient access to covered discount card drugs at negotiated prices (consistent with rules established by the Secretary). The Secretary shall...
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Eligibility procedures for endorsed programs and transitional assistance

(A) Procedures

The determination of whether an individual is a discount card eligible individual or a transitional assistance eligible individual (as defined in subsection (b) of this section) shall be determined under procedures specified by the Secretary consistent with this subsection.

(B) Income and family size determinations

For purposes of this section, the Secretary shall define the terms “income” and “family size” and shall specify the methods and period for which they are determined. If under such methods income or family size is determined based on the income or family size for prior periods of time, the Secretary shall permit (whether through a process of reconsideration or otherwise) an individual whose income or family size has changed to elect to have eligibility for transitional assistance determined based on income or family size for a more recent period.

(2) Use of self-certification for transitional assistance

(A) In general

Under the procedures specified under paragraph (1)(A) an individual who wishes to be treated as a transitional assistance eligible individual or a special transitional assistance eligible individual under this section (or another qualified person on such individual’s behalf) shall certify on the enrollment form under subsection (c)(1)(B) of this section (or similar form specified by the Secretary), through a simplified means specified by the Secretary and under penalty of perjury or similar sanction for false statements, as to the amount of the individual’s income, family size, and individual’s pre-scription drug coverage (if any) insofar as they relate to eligibility to be a transitional assistance eligible individual or a special transitional assistance eligible individual. Such certification shall be deemed as consent to verification of respective eligibility under paragraph (3). A certification under this paragraph may be provided before, on, or after the time of enrollment under an endorsed program.

(B) Treatment of self-certification

The Secretary shall treat a certification under subparagraph (A) that is verified under paragraph (3) as a determination that the individual involved is a transitional assistance eligible individual or special transitional assistance eligible individual (as the case may be) for the entire period of the enrollment of the individual in any endorsed program.

(3) Verification

(A) In general

The Secretary shall establish methods (which may include the use of sampling and the use of information described in subparagraph (B)) to verify eligibility for individuals who seek to enroll in an endorsed program and for individuals who provide a certification under paragraph (2).

(B) Information described

The information described in this subparagraph is as follows:

(i) Medicaid-related information

Information on eligibility under subchapter XIX of this chapter and provided to the Secretary under arrangements between the Secretary and States in order to verify the eligibility of individuals who seek to enroll in an endorsed program and of individuals who provide certification under paragraph (2).
(ii) Social security information

Financial information made available to the Secretary under arrangements between the Secretary and the Commissioner of Social Security in order to verify the eligibility of individuals who provide such certification.

(iii) Information from Secretary of the Treasury

Financial information made available to the Secretary under section 6103(b)(19) of the Internal Revenue Code of 1986 in order to verify the eligibility of individuals who provide such certification.

(C) Verification in cases of medicaid enrollees

(i) In general

Nothing in this section shall be construed as preventing the Secretary from finding that a discount card eligible individual meets the income requirements under subsection (b)(2)(A) of this section if the individual is within a category of discount card eligible individuals who are enrolled under subchapter XIX of this chapter (such as qualified medicare beneficiaries (QMBs), specified low-income medicare beneficiaries (SLMBs), and certain qualified individuals (QI–1s)).

(ii) Availability of information for verification purposes

As a condition of provision of Federal financial participation to a State that is one of the 50 States or the District of Columbia under subchapter XIX of this chapter, for purposes of carrying out this section, the State shall provide the information it submits to the Secretary relating to such subchapter in a manner specified by the Secretary that permits the Secretary to identify individuals who are described in subsection (b)(1)(B) of this section or are transitional assistance eligible individuals or special transitional assistance eligible individuals.

(4) Reconsideration

(A) In general

The Secretary shall establish a process under which a transitional assistance eligible individual, who is determined through the certification and verification methods under paragraphs (2) and (3) not to be a transitional assistance eligible individual or a special transitional assistance eligible individual, may request a reconsideration of the determination.

(B) Contract authority

The Secretary may enter into a contract to perform the reconsiderations requested under subparagraph (A).

(C) Communication of results

Under the process under subparagraph (A) the results of such reconsideration shall be communicated to the individual and the prescription drug card sponsor involved.

(g) Transitional assistance

(1) Provision of transitional assistance

An individual who is a transitional assistance eligible individual (as determined under this section) and who is enrolled with an endorsed program is entitled—

(A) to have payment made of any annual enrollment fee charged under subsection (c)(2) of this section for enrollment under the program; and

(B) to have payment made, up to the amount specified in paragraph (2), under such endorsed program of 90 percent (or 95 percent in the case of a special transitional assistance eligible individual) of the costs incurred for covered discount card drugs obtained through the program taking into account the negotiated price (if any) for the drug under the program.

(2) Limitation on dollar amount

(A) In general

Subject to subparagraph (B), the amount specified in this paragraph for a transitional assistance eligible individual—

(i) for costs incurred during 2004, is $600; or

(ii) for costs incurred during 2005, is—

(I) $600, plus

(II) except as provided in subparagraph (E), the amount by which the amount available under this paragraph for 2004 for that individual exceeds the amount of payment made under paragraph (1)(B) for that individual for costs incurred during 2004.

(B) Proration

(i) In general

In the case of an individual not described in clause (ii) with respect to 2005, the Secretary may prorate the amount specified in subparagraph (A) for the balance of the year involved in a manner specified by the Secretary.

(ii) Individual described

An individual described in this clause is a transitional assistance eligible individual who—

(I) with respect to 2004, enrolls in an endorsed program, and provides a certification under subsection (f)(2) of this section, before the initial implementation date of the program under this section; and

(II) with respect to 2005, is enrolled in an endorsed program, and has provided such a certification, before February 1, 2005.

(C) Accounting for available balances in cases of changes in program enrollment

In the case of a transitional assistance eligible individual who changes the endorsed discount card program in which the individual is enrolled under this section, the Secretary shall provide a process under which the Secretary provides to the sponsor of the endorsed program in which the individual enrolls information concerning the balance
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of amounts available on behalf of the individual under this paragraph.

(D) Limitation on use of funds

Pursuant to subsection (a)(2)(C) of this section, no assistance shall be provided under paragraph (1)(B) with respect to covered discount card drugs dispensed after December 31, 2005.

(E) No rollover permitted in case of voluntary disenrollment

Except in such exceptional cases as the Secretary may provide, in the case of a transitional assistance eligible individual who voluntarily disenrolls from an endorsed plan, the provisions of subclause (II) of subparagraph (A)(ii) shall not apply.

(3) Payment

The Secretary shall provide a method for the reimbursement of prescription drug card sponsors for assistance provided under this subsection.

(4) Coverage of coinsurance

(A) Waiver permitted by pharmacy

Nothing in this section shall be construed as precluding a pharmacy from reducing or waiving the application of coinsurance imposed under paragraph (1)(B) in accordance with section 1320a-7b(b)(3)(G) of this title.

(B) Optional payment of coinsurance by State

(i) In general

The Secretary shall establish an arrangement under which a State may provide for payment of some or all of the coinsurance under paragraph (1)(B) for some or all enrollees in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the coinsurance shall be paid directly by the State to the pharmacy involved.

(ii) No Federal matching available under medicaid or SCHIP

Expenditures made by a State for coinsurance described in clause (i) shall not be treated as State expenditures for purposes of Federal matching payments under subchapter XIX or XXI of this chapter.

(iii) Not treated as medicare cost-sharing

Coinsurance described in paragraph (1)(B) shall not be treated as coinsurance under this subchapter for purposes of section 1396d(p)(3)(B) of this title.

(C) Treatment of coinsurance

The amount of any coinsurance imposed under paragraph (1)(B), whether paid or waived under this paragraph, shall not be taken into account in applying the limitation in dollar amount under paragraph (2).

(5) Ensuring access to transitional assistance for qualified residents of long-term care facilities and American Indians

(A) Residents of long-term care facilities

The Secretary shall establish procedures and may waive requirements of this section as necessary to negotiate arrangements with sponsors to provide arrangements with pharmacies that support long-term care facilities in order to ensure access to transitional assistance for transitional assistance eligible individuals who reside in long-term care facilities.

(B) American Indians

The Secretary shall establish procedures and may waive requirements of this section to ensure that, for purposes of providing transitional assistance, pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 1603 of title 25) have the opportunity to participate in the pharmacy networks of at least two endorsed programs in each of the 50 States and the District of Columbia where such a pharmacy operates.

(6) No impact on benefits under other programs

The availability of negotiated prices or transitional assistance under this section shall not be treated as benefits or otherwise taken into account in determining an individual’s eligibility for, or the amount of benefits under, any other Federal program.

(7) Disregard for purposes of part C

Nonuniformity of benefits resulting from the implementation of this section (including the provision or nonprovision of transitional assistance and the payment or waiver of any enrollment fee under this section) shall not be taken into account in applying section 1395w–24(f) of this title.

(h) Qualification of prescription drug card sponsors and endorsement of discount card programs; beneficiary protections

(1) Prescription drug card sponsor and qualifications

(A) Prescription drug card sponsor and sponsor defined

For purposes of this section, the terms “prescription drug card sponsor” and “sponsor” mean any nongovernmental entity that the Secretary determines to be appropriate to offer an endorsed discount card program under this section, which may include—

(i) a pharmaceutical benefit management company;

(ii) a wholesale or retail pharmacy delivery system;

(iii) an insurer (including an insurer that offers medicare supplemental policies under section 1395ss of this title);

(iv) an organization offering a plan under part C of this subchapter; or

(v) any combination of the entities described in clauses (i) through (iv).

(B) Administrative qualifications

Each endorsed discount card program shall be operated directly, or through arrangements with an affiliated organization (or organizations), by one or more entities that have demonstrated experience and expertise in operating such a program or a similar
program and that meets such business stability and integrity requirements as the Secretary may specify.

(C) Accounting for transitional assistance

The sponsor of an endorsed discount card program shall have arrangements satisfactory to the Secretary to account for the assistance provided under subsection (g) of this section on behalf of transitional assistance eligible individuals.

(2) Applications for program endorsement

(A) Submission

Each prescription drug card sponsor that seeks endorsement of a prescription drug discount card program under this section shall submit to the Secretary, at such time and in such manner as the Secretary may specify, an application containing such information as the Secretary may require.

(B) Approval; compliance with applicable requirements

The Secretary shall review the application submitted under subparagraph (A) and shall determine whether to endorse the prescription drug discount card program. The Secretary may not endorse such a program unless—

(i) the program and prescription drug card sponsor offering the program comply with the applicable requirements under this section; and

(ii) the sponsor has entered into a contract with the Secretary to carry out such requirements.

(C) Termination of endorsement and contracts

An endorsement of an endorsed program and a contract under subparagraph (B) shall be for the duration of the program under this section (including any transition applicable under subsection (a)(2)(C)(i) of this section), except that the Secretary may, with notice and for cause (as defined by the Secretary), terminate such endorsement and contract.

(D) Ensuring choice of programs

(i) In general

The Secretary shall ensure that there is available to each discount card eligible individual a choice of at least 2 endorsed programs (each offered by a different sponsor).

(ii) Limitation on number

The Secretary may limit (but not below 2) the number of sponsors in a State that are awarded contracts under this paragraph.

(3) Service area encompassing entire States

Except as provided in paragraph (9), if a prescription drug card sponsor that offers an endorsed program enrolls in the program individuals residing in any part of a State, the sponsor must permit any discount card eligible individual residing in any portion of the State to enroll in the program.

(4) Savings to medicare beneficiaries

Each prescription drug card sponsor that offers an endorsed discount card program shall pass on to discount card eligible individuals enrolled in the program negotiated prices on covered discount card drugs, including discounts negotiated with pharmacies and manufacturers, to the extent disclosed under subsection (i)(1) of this section.

(5) Grievance mechanism

Each prescription drug card sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor carries out the endorsed discount card program) and enrollees in endorsed discount card programs of the sponsor under this section in a manner similar to that required under section 1395w–22(f) of this title.

(6) Confidentiality of enrollee records

(A) In general

For purposes of the program under this section, the operations of an endorsed program are covered functions and a prescription drug card sponsor is a covered entity for purposes of applying part C of subchapter XI of this chapter and all regulatory provisions promulgated thereunder, including regulations (relating to privacy) adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(B) Waiver authority

In order to promote participation of sponsors in the program under this section, the Secretary may waive such relevant portions of regulations relating to privacy referred to in subparagraph (A), for such appropriate, limited period of time, as the Secretary specifies.

(7) Limitation on provision and marketing of products and services

The sponsor of an endorsed discount card program—

(A) may provide under the program—

(i) a product or service only if the product or service is directly related to a covered discount card drug; or

(ii) a discount price for nonprescription drugs; and

(B) may, to the extent otherwise permitted under paragraph (6) (relating to application of HIPAA requirements), market a product or service under the program only if the product or service is directly related to—

(i) a covered discount card drug; or

(ii) a drug described in subparagraph (A)(ii) and the marketing consists of information on the discounted price made available for the drug involved.

(8) Additional protections

Each endorsed discount card program shall meet such additional requirements as the Secretary identifies to protect and promote the interest of discount card eligible individuals, including requirements that ensure that discount card eligible individuals enrolled in en-

1 See References in Text note below.
Disclosure and oversight

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The Secretary may waive any provision of subsection (b)(1)(A)(i) of this section made available through a pharmacy network (and not only through mail order) and the network used by the sponsor is approved by the Secretary.

(iii) Sponsor requirements

The Secretary may waive the application of such requirements for a sponsor as the Secretary determines to be duplicative or to conflict with a requirement of the organization under part C of this subchapter or section 1395mm of this title (as the case may be) or to be necessary in order to improve coordination of this section with the benefits under such part or section.

(i) Disclosure and oversight

(1) Disclosure

Each prescription drug card sponsor offering an endorsed discount card program shall disclose to the Secretary (in a manner specified by the Secretary) information relating to program performance, use of prescription drugs by discount card eligible individuals enrolled in the program, the extent to which negotiated price concessions described in subsection (e)(1)(A)(ii) of this section are made available to the entity by a manufacturer are passed through to enrollees through pharmacies or otherwise, and such other information as the Secretary may specify. The provisions of section 1396c–5(b)(3)(D) of this title shall apply to drug pricing data reported under the previous sentence (other than data in aggregate form).

(2) Oversight; audit and inspection authority

The Secretary shall provide appropriate oversight to ensure compliance of endorsed discount card programs and their sponsors with the requirements of this section. The Secretary shall have the right to audit and inspect any books and records of a prescription discount card sponsor (and of any affiliated organization referred to in subsection (h)(1)(B) of this section) that pertain to the endorsed discount card program under this section, including amounts payable to the sponsor under this section.

(3) Sanctions for abusive practices

The Secretary may implement intermediate sanctions or may revoke the endorsement of a program offered by a sponsor under this section if the Secretary determines that the sponsor or the program no longer meets the applicable requirements of this section or that the sponsor has engaged in false or misleading marketing practices. The Secretary may impose a civil money penalty in an amount not to exceed $10,000 for conduct that a party knows or should know is a violation of this section. The provisions of section 1320a–7a of this title (other than subsections (a) and (b) and the second sentence of subsection (f)) 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.

(j) Treatment of territories

(1) In general

The Secretary may waive any provision of this section (including subsection (b)(2)(D)) in the case of a resident of a State (other than the 50 States and the District of Columbia) insofar as the Secretary determines it is necessary to secure access to negotiated prices for discount card eligible individuals (or, at the option of the Secretary, individuals described in subsection (b)(1)(A)(i) of this section).

(2) Transitional assistance

(A) In general

In the case of a State, other than the 50 States and the District of Columbia, if the State establishes a plan described in subparagraph (B) (for providing transitional assistance with respect to the provision of prescription drugs to some or all individuals residing in the State who are described in subparagraph (B)(i)), the Secretary shall pay to the State for the entire period of the operation of this section an amount equal to the amount allotted to the State under subparagraph (C).

(B) Plan

The plan described in this subparagraph is a plan that—

(i) provides transitional assistance with respect to the provision of covered discount card drugs to some or all individuals
who are entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, who reside in the State, and who have income below 135 percent of the poverty line; and
(i) assures that amounts received by the State under this paragraph are used only for such assistance.

(C) Allotment limit

The amount described in this subparagraph for a State is equal to $35,000,000 multiplied by the ratio (as estimated by the Secretary) of—

(i) the number of individuals who are entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter and who reside in the State (as determined by the Secretary as of July 1, 2003), to

(ii) the sum of such numbers for all States to which this paragraph applies.

(D) Continued availability of funds

Amounts made available to a State under this paragraph which are not used under this paragraph shall be added to the amount available to that State for purposes of carrying out section 1396u–5(e) of this title.

(k) Funding

(1) Establishment of Transitional Assistance Account

(A) In general

There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1395f of this title an account to be known as the “Transitional Assistance Account” (in this subsection referred to as the “Account”).

(B) Funds

The Account shall consist of such gifts and bequests as may be made as provided in section 401(i)(1) of this title, accrued interest on balances in the Account, and such amounts as may be deposited in, or appropriated to, the Account as provided in this subsection.

(C) Separate from rest of Trust Fund

Funds provided under this subsection to the Account shall be kept separate from all other funds within the Federal Supplementary Medical Insurance Trust Fund, but shall be invested, and such investments redeemed, in the same manner as all other funds and investments within such Trust Fund.

(2) Payments from account

(A) In general

The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments for transitional assistance provided under subsections (g) and (j)(2) of this section.

(B) Treatment in relation to part B premium

Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1395r of this title.

(3) Appropriations to cover benefits

There are appropriated to the Account in a fiscal year, out of any moneys in the Treasury not otherwise appropriated, an amount equal to the payments made from the Account in the year.

(4) For administrative expenses

There are authorized to be appropriated to the Secretary such sums as may be necessary to carry out the Secretary’s responsibilities under this section.

(5) Transfer of any remaining balance to Medicare Prescription Drug Account

Any balance remaining in the Account after the Secretary determines that funds in the Account are no longer necessary to carry out the program under this section shall be transferred and deposited into the Medicare Prescription Drug Account under section 1395w–116 of this title.

(6) Construction

Nothing in this section shall be construed as authorizing the Secretary to provide for payment (other than payment of an enrollment fee on behalf of a transitional assistance eligible individual under subsection (g)(1)(A) of this section) to a sponsor for administrative expenses incurred by the sponsor in carrying out this section (including in administering the transitional assistance provisions of subsections (f) and (g) of this section).


REFERENCES IN TEXT

Parts A and B of this subchapter, referred to in subsec. (b)(1)(A)(i) and (j)(2)(B)(i), (C)(i), are classified to section 1395c et seq. and section 1396 et seq., respectively, of this title.

Part C of this subchapter, referred to in subsec. (b)(2)(B)(i), (c)(1)(C)(i)(ii), (g)(7), and (h)(1)(A)(iv), (9), is classified to section 1395w–21 et seq. of this title.


Part C of subchapter XI of this chapter, referred to in subsec. (h)(6)(A), is classified to section 1320d et seq. of this title.

Section 266(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (h)(6)(A), is section 266(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

RULES FOR IMPLEMENTATION


‘(1) In promulgating regulations pursuant to subsection (a)(2)(B) of such section 1860D–31 [subsection (a)(2)(B) of this section]—

‘(A) section 1871(a)(3) of the Social Security Act (42 U.S.C. 1395hh(a)(3)), as added by section 902(a)(1), shall not apply;

‘(B) chapter 35 of title 44, United States Code, shall not apply; and

‘(C) sections 553(d) and 801(a)(3)(A) of title 5, United States Code, shall not apply.

‘(2) Section 1857(c)(5) of the Social Security Act (42 U.S.C. 1395w–27(c)(5)) shall apply with respect to sec-
§ 1395w–151 Definitions; treatment of references to provisions in part C

(a) Definitions

For purposes of this part:

(1) Basic prescription drug coverage

The term “basic prescription drug coverage” is defined in section 1395w–102(a)(3) of this title.

(2) Covered part D drug

The term “covered part D drug” is defined in section 1395w–102(e) of this title.

(3) Creditable prescription drug coverage

The term “creditable prescription drug coverage” has the meaning given such term in section 1395w–113(b)(4) of this title.

(4) Part D eligible individual

The term “part D eligible individual” has the meaning given such term in section 1395w–101(a)(3)(A) of this title.

(5) Fallback prescription drug plan

The term “fallback prescription drug plan” has the meaning given such term in section 1395w–111(g)(4) of this title.

(6) Initial coverage limit

The term “initial coverage limit” means such limit as established under section 1395w–102(b)(3) of this title, or, in the case of coverage that is not standard prescription drug coverage, the comparable limit (if any) established under the coverage.

(7) Insurance risk

The term “insurance risk” means, with respect to a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitution.

(8) MA plan

The term “MA plan” has the meaning given such term in section 1395w–101(a)(3)(B) of this title.

(9) MA–PD plan

The term “MA–PD plan” has the meaning given such term in section 1395w–101(a)(3)(C) of this title.

(10) Medicare Prescription Drug Account

The term “Medicare Prescription Drug Account” means the Account created under section 1395w–116(a) of this title.

(11) PDP approved bid

The term “PDP approved bid” has the meaning given such term in section 1395w–113(a)(6) of this title.

(12) PDP region

The term “PDP region” means such a region as provided under section 1395w–111(a)(2) of this title.

(13) PDP sponsor

The term “PDP sponsor” means a non-governmental entity that is certified under this part as meeting the requirements and standards of this part for such a sponsor.

(14) Prescription drug plan

The term “prescription drug plan” means prescription drug coverage that is offered—

(A) under a policy, contract, or plan that has been approved under section 1395w–111(e) of this title; and

(B) by a PDP sponsor pursuant to, and in accordance with, a contract between the Secretary and the sponsor under section 1395w–112(b) of this title.

(15) Qualified prescription drug coverage

The term “qualified prescription drug coverage” is defined in section 1395w–102(a)(1) of this title.

(16) Standard prescription drug coverage

The term “standard prescription drug coverage” is defined in section 1395w–102(b) of this title.

(17) State Pharmaceutical Assistance Program

The term “State Pharmaceutical Assistance Program” has the meaning given such term in section 1395w–136(b) of this title.

(18) Subsidy eligible individual

The term “subsidy eligible individual” has the meaning given such term in section 1395w–114(a)(3)(A) of this title.

(b) Application of part C provisions under this part

For purposes of applying provisions of part C of this subchapter under this part with respect to a prescription drug plan and a PDP sponsor, unless otherwise provided in this part such provisions shall be applied as if—

(1) any reference to an MA plan included a reference to a prescription drug plan;

(2) any reference to an MA organization or a provider-sponsored organization included a reference to a PDP sponsor;

(3) any reference to a contract under section 1395w–27 of this title included a reference to a contract under section 1395w–112(b) of this title;

(4) any reference to part C of this subchapter included a reference to this part; and

Note: See References in Text note below.
§ 1395w–152. Miscellaneous provisions

(a) Access to coverage in territories

The Secretary may waive such requirements of this part, including section 1395w–103(a)(1) of this title, insofar as the Secretary determines it is necessary to secure access to qualified prescription drug coverage for part D eligible individuals residing in a State (other than the 50 States and the District of Columbia).

(b) Application of demonstration authority

The provisions of section 402 of the Social Security Amendments of 1967 (Public Law 90–248) shall apply with respect to this part and part C of this subchapter in the same manner it applies with respect to parts A and B of this subchapter, including section 1395w–103(a)(1) of this title, except that any reference with respect to a Trust Fund in relation to an experiment or demonstration project relating to prescription drug coverage under this part shall be deemed a reference to the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance Trust Fund.

(c) Coverage gap rebate for 2010

(1) In general

In the case of an individual described in paragraphs (A) through (D) of section 1395w–114a(g)(1) of this title who as of the last day of a calendar quarter in 2010 has incurred costs for covered part D drugs so that the individual has exceeded the initial coverage limit under section 1395w–102(b)(3) of this title for 2010, the Secretary shall provide for payment from the Medicare Prescription Drug Account of $250 to the individual by not later than the 15th day of the third month following the end of such quarter.

(2) Limitation

The Secretary shall provide only 1 payment under this subsection with respect to any individual.

§ 1395w–153. Condition for coverage of drugs under this part

(a) In general

In order for coverage to be available under this part for covered part D drugs (as defined in section 1395w–102(e) of this title) of a manufacturer, the manufacturer must—

(1) participate in the Medicare coverage gap discount program under section 1395w–114a of this title;

(2) have entered into and have in effect an agreement described in subsection (b) of such section with the Secretary; and

(3) have entered into and have in effect, under terms and conditions specified by the Secretary, a contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of such section.

(b) Effective date

Subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011.

(c) Authorizing coverage for drugs not covered under agreements

Subsection (a) shall not apply to the dispensing of a covered part D drug if—

(1) the Secretary has made a determination that the availability of the drug is essential to the health of beneficiaries under this part; or

(2) the Secretary determines that in the period beginning on January 1, 2011, and December 31, 2011, there were extenuating circumstances.

(d) Definition of manufacturer

In this section, the term “manufacturer” has the meaning given such term in section 1395w–114a(g)(5) of this title.

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

(a) In general

The Secretary shall develop and maintain a complaint system, that is widely known and easy to use, to collect and maintain information on MA–PD plan and prescription drug plan complaints.
§ 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 Osteopathic Association or, in the case of services in a hospital or osteopathic hospital by an intern or resident-in-training in the field of dentistry, approved by the Council on Dental Education of the American 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 podiatry, approved by the Council on Podiatric Medical Education of the American Podiatric Medical Association; or
(7) a physician where the hospital has a teaching program approved as specified in paragraph (6), if (A) the hospital elects to receive any payment due under this subchapter for reasonable costs of such services, and (B) all physicians in such hospital agree not to bill charges for professional services rendered
in such hospital to individuals covered under the insurance program established by this subchapter.

(c) Inpatient psychiatric hospital services

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

(d) Supplier

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

(e) Hospital

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

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

(2) maintains clinical records on all patients;

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

(4) has a requirement that every patient with respect to whom payment may be made under this subchapter must be under the care of a physician, except that a patient receiving qualified psychologist services (as defined in subsection (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 requirement of this paragraph for any one-year period with respect to any institution, insofar as such requirement relates to the provision of twenty-four-hour nursing service rendered or supervised by a registered professional nurse (except that in any event a registered professional nurse must be present on the premises to render or supervise the nursing service provided, during at least the regular daytime shift), where immediately preceding such one-year period he finds that—

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

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

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

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

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

(8) has in effect an overall plan and budget that meets the requirements of subsection (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 subsection. For purposes of sections 1395f(d) and 1395n(b) of this title (including determination of whether an individual received inpatient hospital services or diagnostic services for purposes of such sections), section 1395f(f)(2) of this title, and subsection (i) of this section, such term includes any institution which (1) meets the requirements of paragraphs (5) and (7) of this subsection, (ii) is not primarily engaged in providing the services described in subsection (j)(1)(A) of this section and (iii) is primarily engaged in providing, by or under the supervision of individuals referred to in paragraph (1) of subsection (r) of this section, to inpatients diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. For purposes of section 1395f(f)(1) of this title, such term includes an institution which (i) is a hospital for purposes of sections 1395f(d), 1395f(f)(2), and 1395n(b) of this title and (ii) is accredited by a national accreditation body recognized by the Secretary under section 1395b(a) of this title, or is accredited by or approved by a program of the country in which such institution is located if the Secretary finds the accreditation or comparable approval standards of such program to be essentially equivalent to those of such a national accreditation body. 1 Notwithstanding the preceding provisions of this subsection, such term shall not, except for purposes of subsection (a)(2) of this section, include any institution which is primarily for the care and treatment of mental diseases unless it is a psychiatric hospital (as defined in subsection (f) of this section). The term “hospital” 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 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 pro-

1 So in original.
vided in regulations consistent with section 1395l-5 of this title. For provisions deeming certain requirements of this subsection to be met in the case of accredited institutions, see section 1395bbb 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 (I) may waive, for such period as he deems appropriate, specific provisions of such requirements which if rigidly applied would result in unreasonable hardship for such a facility and which, if not applied, would not jeopardize the health and safety of patients, and (II) may accept a facility’s compliance with all applicable State codes relating to fire and safety in lieu of compliance with the fire and safety requirements promulgated under paragraph (9), if he determines that such State has in effect fire and safety codes, imposed by State law, which adequately protect patients.

The term “hospital” does not include, unless the context otherwise requires, a critical access hospital (as defined in subsection (mm)(1) 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 section, except that “occupational” shall be substituted for “physical” each place it appears therein.

(h) Extended care services

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

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

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

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

(4) medical social services;

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

(6) medical services provided by an intern or resident-in-training of a hospital with which the facility has in effect a transfer agreement (meeting the requirements of subsection (l) 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 not to have been discharged from a skilled nursing facility if, within 30 days after discharge therefrom, he is admitted to such facility or any other skilled nursing facility.

(j) Skilled nursing facility

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

(k) Utilization review

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

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

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

(3) for such review, in each case of inpatient hospital services or extended care services furnished to such an individual during a continuous period of extended duration, as of such days of such period (which may differ for different classes of cases) as may be specified in regulations, with such review to be made as promptly as possible, after each day so specified, and in no event later than one week following such day; and

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

The review committee must be composed as provided in clause (B) of paragraph (2) rather than as provided in clause (A) of such paragraph in the case of any hospital or skilled nursing facility where, because of the small size of the institution, or (in the case of a skilled nursing facility) because of lack of an organized medical staff, or for such other reason or reasons as may be included in regulations, it is impracticable for the institution to have a properly functioning staff committee for the purposes of this subsection. If the Secretary determines that the utilization review procedures established pursuant to subchapter XIX 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 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 1395bbb(a) of this title and such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization;

(7) provides the Secretary with a surety bond—

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

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

(C) for a year in the period described in subparagraph (A) in an amount that is equal to the lesser of $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-
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 (k), (m), (p)(1), and (s) of this section and sections 1395f(a), 1395k(a)(2)(F)(ii), and 1395m 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 as such by the State in which he performs them, (4) such by the State in which he performs them, or (5)

(s) Medical and other health services

The term ‘medical and other health services’ means any of the following items or services:

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

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

(C) diagnostic services which are—

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

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

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

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

(F) home dialysis supplies and equipment, self-care home dialysis support services, and institutional dialysis services and supplies, and, for items and services furnished on or after January 1, 2011, renal dialysis services (as defined in section 1395rr(b)(14)(B) of this title);

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

(H)(i) services furnished pursuant to a contract under section 1395nn of this title to a member of an eligible organization by a physi-

(i) services furnished pursuant to a contract under section 1395nn of this title to a member of an eligible organization by a physi-

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

(J) prescription drugs used in immuno-suppressive therapy furnished, to an individual who receives an organ transplant for which payment is made under this subchapter;
(K)(i) services which would be physicians' services and services described in subsections (ww)(1) and (hhh) 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,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 collaboration (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;

(iii) 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 clinical social worker (as defined in subsection (ww)(1)) 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);

(6) 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

(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 (uu) of this section) for individuals determined to be at high risk for glaucoma, individuals with a family history of glaucoma and individuals with diabetes;

(V) medical nutrition therapy services (as defined in subsection (vv)(1) 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);

(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));

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

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

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

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2 So in original. Probably should be followed by “and”.

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

(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) durable medical equipment or the use of other methods of transportation is contraindicated by the individual's condition, but, subject to section 1395m(14) of this title, only to the extent provided in regulations;

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

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

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

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

(11) services of a certified registered nurse anesthetist (as defined in subsection (bb) 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) 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, 4 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 1395n(e) of this title, a fund.

(v) Reasonable costs

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

(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

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4 So in original. Probably should be "have".
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 subsection (c) of 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 subsection or 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 psychological well-being of each resident eligible for benefits under this subchapter) of such facilities complying with the requirements of subsections (b), (c), (d) of section 1395i–3 of this title (including the costs of conducting nurse aide training and competency evaluation programs and competency evaluation programs).

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

(G)(i) In any case in which a hospital provides inpatient services to an individual that would constitute post-hospital extended care services if provided by a skilled nursing facility and a quality 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 (II), the payment rate referred to in clause (i) is a rate equal to the estimated adjusted State-wide average rate per patient-day paid for services provided in skilled nursing facilities under the State plan approved under subchapter XIX of this chapter 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 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 subparagraph), be deemed to be a day on which the individual received inpatient hospital services.

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

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

(i) any costs incurred in connection with bonding or establishing an escrow account by any such agency as a result of the surety bond requirement described in subsection (a)(7) of this section and the financial security requirement described in subsection (a)(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 or claim for reimbursement for services furnished by the agency, to the extent that such cost exceeds the reasonable value of the services furnished on behalf of such agency.

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

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

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

The Secretary shall prescribe in regulation criteria and procedures which the Secretary shall use in obtaining access to books, documents, and records under clauses required in contracts and subcontracts under this subparagraph. (J) Such regulations may not provide for any inpatient routine salary cost differential as a reimbursable cost for hospitals and skilled nursing facilities.

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

(II) serious impairment to bodily functions; or

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

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

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

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

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

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

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

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

(iii) Not later than July 1, 1991, and annually thereafter (but not for cost reporting periods beginning on or after July 1, 1994, and before July 1, 1996, or on or after July 1, 1997, and before October 1, 1997), the Secretary shall establish limits under this subparagraph for cost reporting
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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)(3)(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 (v)(I), the Secretary shall provide for an interim system of limits. Payment shall not exceed the costs determined under the preceding provisions of this subparagraph or, if lower, the product of—

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

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

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

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

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

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

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

(viii)(I) In the case of a provider with a 12-month cost reporting period ending in fiscal year 1994, if the limit imposed under clause (v) (determined without regard to this subclause) for a cost reporting period beginning during or after fiscal year 1999 is less than the median described in clause (vi)(I) (but determined as if any reference in clause (v) to “98 percent” were a reference to “100 percent”), the limit otherwise imposed under clause (v) for such provider and period shall be increased by 1/2 of such difference.

(II) Subject to subclause (IV), no new providers and those providers without a 12-month cost reporting period ending in fiscal year 1994, but for which the first cost reporting period begins before fiscal year 1999, for cost reporting periods beginning during or after fiscal year 1999, the per beneficiary limitation described in clause (vi)(I) shall be equal to the median described in such clause (determined as if any reference in clause (v) to “98 percent” were a reference to “100 percent”).

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

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

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

(ix) Notwithstanding the per beneficiary limit under clause (vii), 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-
amounts of such payments otherwise established
hospital services, the Secretary shall reduce the
may be made under this subchapter with respect
under this subchapter by 15 percent for pay-
determining the amount of the payments that
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 attrib-
tutable to portions of cost reporting periods
occurring during fiscal years 1992 through 1999
and until the first date that the prospective pay-
ment system under section 1395(t) of this title
is implemented.

(ii) The Secretary shall reduce the reasonable
cost of outpatient hospital services (other than
the capital-related costs of such services) other-
wise determined pursuant to section
1395(a)(2)(B)(i)(I) of this title by 5.8 percent for
payments attributable to portions of cost re-
porting periods occurring during fiscal years
1991 through 1999 and until the first date that
the prospective payment system under section
1395(t) of this title is implemented.

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

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

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

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

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

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

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

(U) In determining the reasonable cost of am-
bulance 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 appli-
cation 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 pe-
riod ending with the midpoint of the fiscal year
involved reduced by 1.0 percentage point. For
ambulance services provided after June 30, 1998,
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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—

(1) 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 or part B of this subchapter, as the case may be, is consistent with the purposes of this title.

(V) In determining such reasonable costs for 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-
Arrangements for certain services; payments 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.

**Sections (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.

**Sections (x) State and United States**

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

**Sections (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 (sa)(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 1395i–5 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 1395e(a)(3) of this title).

(4) For purposes of subsection (i) 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
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 1320b–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 1320b–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 1320b–1 of this title by reason of section 1320b–1(i) of this title);

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

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

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

(1) The term ‘‘rural health clinic services’’ means—

(A) physicians’ services and such services and supplies as are covered under subsection (s)(2)(A) 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 (I) 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 any service provided by a rural health clinic, as defined in paragraph (2)(B), which is in operation and qualifies as a rural health clinic under this subchapter, and is furnished to an individual as an outpatient service (not in excess of the amount customarily charged for such items and services by such clinic), pursuant to subsections (a) and (b) of section 1395x of this title, 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 for approval as such a clinic, the Secretary shall notify the facility of the determination or the application (whichever is later). The term “rural health clinic” means a facility which—

(A) is in operation; (B) 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(l–7)], (II) as a health professional shortage area described in section 322(a)(1)(A) of that Act [42 U.S.C. 254a(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. 254c(a)(1)(B)], (II) has filed 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 1395x 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 requirements 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 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 subparagraph (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) is 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. 254c(a)(1)(B)], (II) has filed with the Secretary an agreement 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 1395x of this title, 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 for approval as such a clinic, the Secretary shall notify the facility of the determination or the application (whichever is later).

(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.
(b) Services of a certified registered nurse anesthetist

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

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

(cc) Comprehensive outpatient rehabilitation facility services

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

(A) physicians' services;

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

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

(D) social and psychological services;

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

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

(G) supplies and durable medical equipment; and

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

excepting, 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-
(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) is primarily engaged in providing the care and services described in paragraph (1) and makes such services available (as needed) on a 24-hour basis and which also provides bereavement counseling for the immediate family of terminally ill individuals and services described in section 1395d(a)(5) of this title,
(ii) provides for such care and services in individuals’ homes, on an outpatient basis, and on a short-term inpatient basis, directly or under arrangements made by the agency or organization, except that—
(I) the agency or organization must routinely provide directly substantially all of each of the services described in subparagraphs (A), (C), and (H) of paragraph (1), except as otherwise provided in paragraph (5), and
(II) in the case of other services described in paragraph (1) which are not provided directly by the agency or organization, the agency or organization must maintain professional management responsibility for all such services furnished to an individual, regardless of the location or facility in which such services are furnished; and
(iii) provides assurances satisfactory to the Secretary that the aggregate number of days of inpatient care described in paragraph (1)(G) provided in any 12-month period to individuals who have an election in effect under section 1395d(d) of this title with respect to that agency or organization does not exceed 20 percent of the aggregate number of days during that period on which such elections for such individuals are in effect;
(B) has an interdisciplinary group of personnel which—
(i) includes at least—
(I) one physician (as defined in subsection (r)(1) of this section),
(II) one registered professional nurse, and
(III) one social worker,
employed by or, in the case of a physician described in subparagraph (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) 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
other type of provider. The Secretary shall coordinate surveys for determining certification under this subchapter so as to provide, to the extent feasible, for simultaneous surveys of an entity which seeks to be certified as a hospice program and as a provider of services of another type.

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

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

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

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

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

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

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

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

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

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

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

(ee) Discharge planning process

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

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

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

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

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

(D) A discharge planning evaluation must include an evaluation of a patient’s likely need for appropriate post-hospital services, including hospice care and post-hospital extended care services, and the availability of those services, including the availability of home health services through individuals and entities that participate in the program under this subchapter and that serve the area in which the patient resides and that request to be listed by the hospital as available and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this subchapter and that serve the area in which the patient resides.

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

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

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

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

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

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

(3) With respect to a discharge plan for an individual who is enrolled with a Medicare+Choice organization under a Medicare+Choice plan and is furnished inpatient hospital services by a hospital under a contract with the organization—
   (A) the discharge planning evaluation under paragraph (2)(D) is not required to include information on the availability of home health services through individuals and entities which do not have a contract with the organization; and
   (B) notwithstanding subparagraph (H)(i)
, the plan may specify or limit the provider (or providers) of post-hospital home health services or other post-hospital services under the plan.

(ff) Partial hospitalization services

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

(2) The items and services described in this paragraph are—
   (A) individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law),
   (B) occupational therapy requiring the skills of a qualified occupational therapist,
   (C) services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients,
   (D) drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered),
   (E) individualized activity therapies that are not primarily recreational or diversionary,
   (F) family counseling (the primary purpose of which is treatment of the individual’s condition),
   (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 func-

*So in original. Probably should be “paragraph (2)(H)(i)”.

(tional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish (taking into account accepted norms of medical practice and the reasonable expectation of patient improvement).

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

(B) For purposes of subparagraph (A), the term “community mental health center” means an entity that—
   (i) provides the mental health services described in section 1913(c)(1) of the Public Health Service Act [42 U.S.C. 300x–2(c)(1)]; or
   (ii) in the case of an entity operating in a State that by law precludes the entity from providing itself the service described in subparagraph (E) of such section, provides for such service by contract with an approved organization or entity (as determined by the Secretary);
   (iii) meets applicable licensing or certification requirements for community mental health centers in the State in which it is located;
   (iv) provides at least 40 percent of its services to individuals who are not eligible for benefits under this subchapter; and
   (v) 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


(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) as would otherwise be covered if furnished by a physician.

(ii) Qualified psychologist services

The term “qualified psychologist services” means services furnished by a licensed psychologist 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.

(j) Screening mammography

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

(kk) Covered osteoporosis drug

The term “covered osteoporosis drug” means an injectable drug approved for the treatment of post-menopausal osteoporosis provided to an individual by a home health agency if, in accordance with regulations promulgated by the Secretary—
(1) the individual’s attending physician certifies that the individual has suffered a bone fracture related to post-menopausal osteoporosis and that the individual is unable to learn the skills needed to self-administer such drug or is otherwise physically or mentally incapable of self-administering such drug; and
(2) the individual is confined to the individual’s home (except when receiving items and services referred to in subsection (m)(7) 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).

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

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

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

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

(oo) Prostate cancer screening tests

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

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

(A) A digital rectal examination.

(B) A prostate-specific antigen blood test.

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

(pp) Colorectal cancer screening tests

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

(A) Screening fecal occult blood test.

(B) Screening flexible sigmoidoscopy.

(C) Screening colonoscopy.

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

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

(qq) Diabetes outpatient self-management training services

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

(2) In paragraph (1)—

(A) a “certified provider” is a physician, or other individual or entity designated by the Secretary, that, in addition to providing diabetes outpatient self-management training services, provides other items or services for which payment may be made under this subchapter; and

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

(rr) Bone mass measurement

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

Religious nonmedical health care institution

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

(A) is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986 and is exempt from taxes under subsection (a) of such section;
(B) is lawfully operated under all applicable Federal, State, and local laws and regulations;
(C) provides only nonmedical nursing items and services exclusively to patients who choose to rely solely upon a religious method of healing and for whom the acceptance of medical health services would be inconsistent with their religious beliefs;
(D) provides such nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of such patients;
(E) provides such nonmedical items and services to inpatients on a 24-hour basis;
(F) on the basis of its religious beliefs, does not provide through its personnel or otherwise medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients;
(G)(i) is not owned by, under common ownership with, or has an ownership interest in, a provider of medical treatment or services;
(ii) is not affiliated with—
(I) a provider of medical treatment or services, or
(II) an individual who has an ownership interest in a provider of medical treatment or services;
(H) has in effect a utilization review plan which—
(i) provides for the review of admissions to the institution, of the duration of stays therein, of cases of continuous extended duration, and of the items and services furnished by the institution,
(ii) requires that such reviews be made by an appropriate committee of the institution that includes the individuals responsible for overall administration and for supervision of nursing personnel at the institution,
(iii) provides that records be maintained of the meetings, decisions, and actions of such committee, and
(iv) meets such other requirements as the Secretary finds necessary to establish an effective utilization review plan;
(I) provides the Secretary with such information as the Secretary may require to implement section 1395i–5 of this title, including information relating to quality of care and coverage determinations; and
(J) meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.

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

(A)(i) In administering this subsection and section 1395i–5 of this title, the Secretary shall not require any patient of a religious nonmedical health care institution to undergo medical screening, examination, diagnosis, prognosis, or treatment or to accept any other medical health care service, if such patient (or legal representative of the patient) objects thereto on religious grounds.
(ii) Clause (i) shall not be construed as preventing the Secretary from requiring under section 1395i–5(a)(2) of this title the provision of sufficient information regarding an individual's condition as a condition for receipt of benefits under part A 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.

(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 1395i-3(a)(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 were initiated within 14 days after the date of such discharge.

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 were initiated within 14 days after the date of such discharge.

(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 (pp).

(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 (bbb).

(M) An electrocardiogram.

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

(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 tests, as the Secretary determines appropriate, in consultation with appropriate organizations.

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

   (A) Hypertension.

   (B) Dyslipidemia.

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

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

   (E) Previous identification of impaired glucose tolerance.

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

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

      (ii) A family history of diabetes.

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

      (iv) 65 years of age or older.

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

(zz) Intravenous immune globulin

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

(aaa) Extended care in religious nonmedical health care institutions

(1) The term “home health agency” also includes a religious nonmedical health care institution (as defined in subsection (ss)(1) 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 1395i–5 of this title.

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

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

   (ii) after December 31, 2006.

(bbb) Ultrasound screening for abdominal aortic aneurysm

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

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

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

(ccc) Long-term care hospital

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

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

(2) has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days, or meets the requirements of clause (II) 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
following:

(A) or (C) of paragraph (3) that identify medical means services not described in subparagraph (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 expenditure, regularly evaluates patients through-out 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 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 expenditure, regularly evaluates patients through-out 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;

(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;
(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 10 in the program.

(ff) Pulmonary rehabilitation program

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

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

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

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(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) a medical professional (including a health educator, registered diettian, 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); and

(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)(i)(I). The Secretary may utilize any health risk assessment developed under section 300u–12(f) of this title as part of the requirement to develop a personalized prevention plan to comply with this subparagraph.

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

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

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

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

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

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

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

(G) A beneficiary shall be eligible to receive only an initial preventive physical examination...

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 4071(b) of Pub. L. 100–203, which is set out as a note below.

Section 4072(e) of the Omnibus Budget Reconciliation Act of 1987, referred to in subsec. (s)(12), is section 4072(e) of Pub. L. 100–203, which is set out as a note below.

The Public Health Service Act, referred to in subsec. (v)(1)(M), is act July 1, 1944, ch. 273, 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 (§201 et seq.) and XIV (§300 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 254b of this title and was omitted in the general amendment of subpart I (§254b et seq.) of part D of subchapter II of chapter 6A of this title by Pub. L. 104–299, §2, Oct. 11, 1996, 110 Stat. 3626.

The Indian Self-Determination Act, referred to in subsec. (aa)(4)(D), is title I of Pub. L. 93–638, Jan. 4, 1975, 88 Stat. 2206, which is classified principally to part A (§450 et seq.) of subchapter II of chapter 14 of Title 25 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 450 of Title 25 and Tables.


For complete classification of this Act to the Code, see Short Title note set out under section 1601 of Title 25 and Tables.


AMENDMENTS

2009—Subsec. (o)(7)(C), Pub. L. 111–148, §4602(g)(2), which directed amendment by inserting “that the Secretary determines is commensurate with the volume of the billing of the home health agency” before semi-colon “at the end”, was executed by making the insertion before “and” to reflect the probable intent of Congress.

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


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


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

Subsec. (dd)(1), Pub. L. 111–148, §4104(a)(2), substituted “not described in subparagraph (A) or (C) of paragraph (3)” for “not otherwise described in this subchapter”.


Subsec. (hhh), Pub. L. 111–148, §4103(b), added subsec. (hhh).

Subsec. (hhh)(4)(G), Pub. L. 111–148, §10402(b), amended subpar. (G) generally. Prior to amendment, subpar. (G) read as follows: “(G)(i) A beneficiary shall only be eligible to receive an initial preventive physical examination (as defined under subsection (ww)(1)) at any time during the 12-month period after the date that the beneficiary’s coverage begins under part B of this subchapter and shall be eligible to receive personalized prevention plans 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” for “and” and (ii) is accredited by a national accreditation body recognized by the Secretary under section 1366b(a) of this title, or is accredited by or approved by a program of the country in which such institution is located if the Secretary finds the accreditation or comparable approval standards of such program to be essentially equivalent to those of such a national accreditation body.” for “and (ii) is accredited by the Joint Commission on Accreditation of Hospitals, or is accredited by or approved by a program of the country in which such institution is located if the Secretary finds the accreditation or comparable approval standards of such program to be essentially equivalent to those of the Joint Commission on Accreditation of Hospitals”.

Subsec. (p), Pub. L. 110–275, §143(b)(5), struck out third sentence in concluding provisions, which read as follows: “The term ‘outpatient physical therapy services’ also includes speech-language pathology services furnished by a provider of services, a clinic, 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 subchapter.”

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

Subsec. (s)(2)(F), Pub. L. 110–275, §155(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 semi-colon 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 this subparagraph unless the compendia has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.’” at end.


Subsec. (ll)(2) to (4). Pub. L. 110–275, § 143(a), added par. (2) and redesignated former pars. (2) and (3) as (3) and (4), respectively.

Subsec. (ww)(1). Pub. L. 110–275, § 101(b)(1)(A), inserted “‘body mass index,’ after ‘weight’, struck out ‘‘, and an electrocardiogram’’ after “blood pressure’, and inserted “and end-of-life planning (as defined in paragraph (3) of this section)’”.


Subsec. (dd). Pub. L. 110–275, § 101(a)(1)(B), inserted “‘or nurse practitioner (as defined in subsection (aa)(5) of this title)’”.


Subsec. (aa)(3). Pub. L. 109–171, § 5114(a)(1), substituted “‘and services described in subsections (qq) and (vv)’, and for ‘‘, and in subpar. (A) and ‘‘section 339 for ‘‘, ‘‘sections 329, 330, and 340’’ in subpar. (B) and inserted ‘‘by the center or by a health care professional under contract with the center’’ after ‘‘outpatient of a Federally qualified health center’’ in concluding provisions.


Subsec. (ss)(2)(A). Pub. L. 108–173, § 802(b)(2), inserted “‘or would have been so included but for the application of section 1395w–3b of this title’” after “in the physicians’ bills”.


Pub. L. 108–173, § 736(d)(2), inserted “‘and services described in subsection (ww)(1) of this section’” after “services which would be physicians’ services’”.

Subsec. (ss)(2)(K)(ii). Pub. L. 108–173, § 736(b)(11), substituted “‘including drugs and biologicals which are not usually self-administered by the patient’” for “‘including drugs and biologicals which cannot, as determined in accordance with regulations, be self-administered’”.

Subsec. (ss)(2)(J). Pub. L. 106–554, § 1(a)(6) [title I, § 113(a)], struck out provisions limiting application to drugs furnished within 12 months after the date of the transplant procedure for drugs furnished before 1986, to within 30 months after the date of the transplant procedure for drugs furnished during 1995, and to within 12 months after the date of the transplant procedure for drugs furnished during 1996, to within 30 months after the date of the transplant procedure for drugs furnished after 1995, to within 36 months after the date of the transplant procedure for drugs furnished during 1997, and to within 36 months after the date of the transplant procedure plus additional number of months provided under section 1395k(b) for drugs furnished during any year after 1997.


Subsec. (tt)(1). Pub. L. 106–554, § 1(a)(6) [title IV, § 430(b)], inserted “‘including contrast agents’” after “‘only such drugs’”.

Subsec. (vv)(1)(L)(x). Pub. L. 106–554, § 1(a)(6) [title V, § 502(a)], struck out “‘2001,’ after ‘‘2000,’” and inserted at end “‘With respect to cost reporting periods beginning during fiscal year 2001, the update to any limit under this subparagraph shall be the home health market basket index.’’
added cls. (i) to (iii), and struck out former cls. (i) and § 431(a)], substituted “‘entity that—’” for “‘entity—’”, added cl. (iv). Subsec. (ff)(3)(B). Pub. L. 106–554, § 1(a)(6) [title IV, § 541(2)], substituted “‘during fiscal year 2000’” for “‘during fiscal year 2000’” and “‘and’” for “‘and year period at end.’” Subsec. (vii)(IV). Pub. L. 105–105, § 4201(c)(1), substituted “‘critical access’” for “‘critical access for rural primary care’” in last sentence. Subsec. (h). Pub. L. 105–33, § 4432(b)(5)(D)(ii), inserted “‘and’” for “‘or’” by others under arrangements with them made by the facility” after “skilled nursing facilities”. Subsec. (m). Pub. L. 105–33, § 4612(a), inserted at end of closing provisions “‘For purposes of paragraphs (1) and (2), the term ‘part-time or intermittent services’ means skilled nursing and home health aide services furnished any number of days per week as long as they are furnished (combined) less than 8 hours each day and 28 or fewer hours each week or (subject to review on a case-by-case basis as to the need for care, less than 8 hours each day and 35 or fewer hours per week). For purposes of sections 1395f(a)(2)(C) and 1395n(a)(2)(A) of this title, ‘intermittent’ means skilled nursing care that is either provided or needed on fewer than 7 days each week, or less than 8 hours of each day for periods of 21 days or less (with extensions in exceptional circumstances when the need for additional care is finite and predictable).’” Subsec. (n). Pub. L. 105–33, § 4105(b)(1), inserted before semicolon in first sentence “‘and includes blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes or to the individual’s use of insulin (as determined under standards established by the Secretary in consultation with the appropriate organizations)’” Subsec. (o). Pub. L. 105–33, § 4312(b)(1)(D), inserted at end of closing provisions “‘The Secretary may waive the requirement of a surety bond under paragraph (7) in the case of an agency or organization that provides a comparable surety bond under State law.’” Subsec. (r). Pub. L. 105–33, § 4312(b)(1)(A)–(C), added par. (7) and redesignated former par. (7) as (8). Subsec. (p). Pub. L. 105–33, § 4312(e)(2), inserted at end of closing provisions “‘The Secretary may waive the requirement of a surety bond under paragraph (4)(A)(v) in the case of a clinic or agency that provides a comparable surety bond under State law.’” Subsec. (r). Pub. L. 105–33, § 4513(a)(1), struck out “‘demonstrated by x-ray to exist’” following “‘to correct a subluxation’.” Subsec. (s)(2)(K)(vi). Pub. L. 105–33, § 4511(a)(2)(A)(ii), 4512(a), struck out “‘(v) in a hospital, skilled nursing facility, or nursing facility (as defined in section 1396d(a)(2)(B)(i) of this title), (ii) as an assistant at surgery, or (iii) in a rural area (as defined in section 1396w(d)(2)(D) of this title) that is designated, under section 330A(1)(A) of the Public Health Service Act, as a health professional shortage area,’’ after “‘physician (as so defined)’” and inserted at end “‘and such services and supplies furnished as incident to such services would be covered under subparagraph (A) if furnished incident to a physician’s professional service; and but only if no facility or
Subsec. (dd)(1)(B). Pub. L. 103–432, §146(b)(5), substituted “substituted “therapy, or speech-language pathology services” for “therapy or speech-language pathology”.

Subsec. (ee)(2)(D). Pub. L. 103–432, §146(a), inserted “including hospice services,” after “post-hospital services”.


Pub. L. 103–432, §147(f)(6)(A), (B)(i), amended subsec. (j), defining “covered osteoporosis drug”, in introductory provisions, by striking out “a bone fracture related to” before “post-menopausal osteoporosis” and substituting “individual by a home health agency if” for “individual if”, and in par. (1), by substituting “individual has suffered a bone fracture related to post-menopausal osteoporosis and that the individual” for “patient”.


Subsec. (t). Pub. L. 103–66, §13553(b), designated existing provisions as par. (1), inserted “and paragraph (2)” and added par. (2).

Subsec. (v)(1)(B). Pub. L. 103–66, §13603(c)(1), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: “Such regulations in the case of extended care services furnished by proprietary facilities shall include provision for specific recognition of a reasonable return on equity capital, including necessary working capital, invested in the facility and used in the furnishing of such services, in lieu of other allowances to the extent that they reflect similar items. The rate of return recognized pursuant to the preceding sentence for determining the reasonable cost of any services furnished in any cost reporting period shall be equal to the average of the rates of interest, for each of the months any part of which is included in the period, on obligations issued for purchase by the Federal Home Loan Insurance Trust Fund.”


Subsec. (gg)(2). Pub. L. 103–66, §13554(a), substituted a period for “and performs services in the area of management of the care of mothers and babies throughout the maternity cycle.”

1980—Subsec. (gg)(3). Pub. L. 101–508, §415(a)(1), as amended by Pub. L. 103–432, §147(f)(3), struck out “including clinical psychologist (as defined by the Secretary)” after “the hospital or by others”. Subsec. (h)(4). Pub. L. 101–508, §415(a)(2), as amended by Pub. L. 103–432, §147(f)(3), substituted “services described by subsection (e)(2)(K)(i) of this section, certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist; and” for “and anesthesia services provided by a certified registered nurse anesthetist; and”.

Subsec. (m). Pub. L. 101–508, §4152(a)(2), inserted at end “With respect to a seat-lift chair, such term includes only the seat-lift mechanism and does not include the chair.”


Subsec. (v)(1)(E). Pub. L. 101–508, §4008(b)(2)(A)(i), substituted “the costs (including the costs of services required to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident eligible for benefits under this subchapter)” for “the costs of such facilities” in second sentence.

Subsec. (v)(1)(L)(iii). Pub. L. 101–508, §4207(d)(1), formerly §4207(d)(1), as renumbered by Pub. L. 103–622, §160(d)(4), amended cl. (iii) generally. Prior to amendment, cl. (iii) read as follows: “In establishing limits under this subparagraph, the Secretary shall—(I) utilize a wage index that is based on verified wage data obtained from home health agencies, and (II) base such limits on the most recent verified wage data available, which data may be for cost reporting periods beginning no earlier than July 1, 1995. In the case of a home health agency that refuses to provide data, or deliberately provides false data, respecting wages for purposes of this clause upon the request of the Secretary, the Secretary may withhold up to 5 percent of the amount of the payments otherwise payable to the agency under this subchapter until such date as the Secretary determines that such data has been satisfactorily provided.”


Subsec. (v)(1)(S)(ii)(IV). Pub. L. 101–508, §4151(a)(2), substituted “Subclauses (I) and (II)” for “Subclause (I)” and “costs of hospital outpatient services provided by any hospital” for “capital-related costs of any hospital”.

Pub. L. 101–508, §4151(a)(2), substituted “section 1395vv(d)(5)(D)(iii) of this title or a rural primary care hospital (as defined in subsection (mm)(1) of this section)” for “section 1395vv(d)(5)(D)(iii) of this title”.

Pub. L. 101–508, §415(b)(1)(B), substituted “subclauses (I) and (II)” for “subclause (I)” and “the costs reflected” for “capital-related costs reflected.”


Pub. L. 101–508, §416(b)(1), inserted at end “If a State agency has determined under section 1395aa(a) of this title that a facility is a rural health clinic and the facility has applied to the Secretary for certification as such a clinic, the Secretary shall notify the facility of the the Secretary’s approval or disapproval of the certification not later than 60 days after the date of the State agency determination or the application (whichever is later).”


Pub. L. 101–508, §416(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, §415(d), substituted “The term ‘physician assistant’, the term ‘nurse practitioner’, and the term ‘clinical nurse specialist’ mean, for purposes of paragraphs (1) and (2), a physician assistant or nurse practitioner who performs”, for “The term ‘physician assistant’ and the term ‘nurse practitioner’ mean, for the purposes of paragraphs (1) and (2), a physician assistant or nurse practitioner who performs”.

Subsec. (aa)(4) to (6). Pub. L. 101–508, §416(a)(2)(B), (C), added par. (4) and redesignated former pars. (3) and (4) as (5) and (6), respectively.


Subsec. (ff)(3). Pub. L. 101–508, §416(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, §6003(g)(3)(D)(x)(I), inserted at end “The term ‘hospital’ does not include, unless the context otherwise requires, a rural primary care hospital (as defined in subsection (mm)(1) of this section).”

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

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

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


Pub. L. 101–234, §101(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 enacted 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, §101(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, §101(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. (13) as (16) by Pub. L. 101–239, §6115(a)(1)(C), see 1988 Amendment note below.


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, §203(e)(1), and provided that the provisions of law amended or repealed by such section are restored or revived as if such section had not been enacted, see 1988 Amendment note below.

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

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. (m). Pub. L. 100–360, §206(a), inserted at end “For purposes of paragraphs (1) and (4) and sections 1395(a)(2)(C) and 1395a(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. (p)(6), §424(a), inserted at end “Nothing in this subsection shall be construed as requiring, with respect to outpatients who are not entitled to benefits under this subchapter, a physical therapist to provide outpatient physical therapy services only to outpatients who are under the care of a physician or pursuant to a plan of care established by a physician.”

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(III) in a rural area (as defined in section 1395ww(d)(2)(D) of this title) that is designated, under section 332(a)(1)(A) of the Public Health Service Act, as a health manpower shortage area," for "or as an assistant at surgery".


Subsec. (a)(3). Pub. L. 100–203, § 4073(a), inserted "influenza vaccine and its administration" before semicolon.


Subsec. (a)(5). Pub. L. 100–203, § 4073(a), redesignated pars. (2) and (3) as (3) and (4), respectively. Former par. (4) redesignated (5).


Subsec. (n). Pub. L. 99–999, § 3921(b)(1)(X), substituted "as his home" for "at his home".

Subsec. (r)(4). Pub. L. 99–999, § 3936(a), amended cl. (4) generally. Prior to amendment, cl. (4) read as follows: "a doctor of optometry who is legally authorized to practice optometry by the State in which he performs such function, but only with respect to services related to the condition of aphakia, or"

Subsec. (s)(2)(D). Pub. L. 99–999, § 3937(d)(2), inserted "and outpatient optical therapy services".


Subsec. (s)(11) to (15). Pub. L. 99–999, § 3920(b), added subpar. (11) and redesignated former pars. (11) to (14) as (12) to (15), respectively.

Subsec. (v)(1)(B). Pub. L. 99–999, § 3910(b)(2), substituted "any cost reporting period shall be equal to" for "any fiscal period shall not exceed one and one-half times" and "the period" for "such fiscal period".


Subsec. (v)(1)(L). Pub. L. 99–999, § 3913(a), inserted "(i)" after "(L)" struck out "the 75th percentile of such costs per visit for free standing home health agencies, or, in the judgment of the Secretary, such lower percentile or comparable or lower limit (based on or related to the mean of the costs of such agencies or otherwise) as the Secretary may determine," and substituted in lieu "for cost reporting periods beginning on or after"

"(i) July 1, 1985, and before July 1, 1986, 120 percent, "(ii) July 1, 1986, and before July 1, 1987, 115 percent, or

"(III) July 1, 1987, 112 percent, of the mean of the labor-related and nonlabor per visit costs for free standing home health agencies.

"(ii) Effective for cost reporting periods beginning on or after July 1, 1986, such limitations shall be applied on an aggregate basis for the agency, rather than on a discipline specific basis, with appropriate adjustment for administrative and general costs of hospital-based agencies.

Subsec. (v)(1)(O)(i). Pub. L. 99–272, § 9219(b)(3)(A), in subpar. (i) of section (including through the operation of subsection (g) of this section) or" before "un-


Subsec. (v)(5)(A). Pub. L. 99–999, § 3937(d)(3), inserted "including through the operation of subsection (g) of this section" after "subsection (p) of this section".


1984—Subsec. (d). Pub. L. 98–369, § 2335(b)(1), struck out subsec. (d) which defined "inpatient tuberculosis hospital services" as inpatient hospital services furnished to an inpatient of a tuberculosis hospital unless it is a tuberculosis hospital (as defined in subsection (g) of this section) or before "unless it is a psychiatric hospital" in provisions following subcl. (III).

Subsec. (e). Pub. L. 98–369, § 2335(b)(2), struck out "or tuberculosis unless it is a tuberculosis hospital (as defined in subsection (g) of this section)" or "before unless it is a psychiatric hospital" in provisions following subcl. (III).

Subsec. (f). Pub. L. 98–369, § 2340(a), struck out par. (5) which provided that "psychiatric hospital" meant an institution which was accredited by the Joint Commission on Accreditation of Hospitals, and struck out "if
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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".

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. 98–431, §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)(D). Pub. L. 98–261, by 1972 Amendment note below, substituted "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. (p)(1). Pub. L. 98–369, §2341(a), substituted "paragraph (1) or (3) of subsection (r) of this section" for "for purposes of subsection (r) of this section".

Subsec. (p)(2). Pub. L. 98–369, §2341(a), substituted "by a physician as so defined or by a qualified physical therapist and is periodically reviewed by a physician (as so defined)" for "", and is periodically reviewed, by a physician (as so defined)."

Subsec. (r)(3). Pub. L. 98–617, §3(b)(7), substituted "under subsections (k), (m), and (p) of this section and sections 1396a(a), 1396a(a)(2)(F)(i)(i), and 1395n of this title for "under subsections (k) and (m) and sections 1395a(a) and 1395n of this title before "is consistent with the policy".

Pub. L. 98–369, §2341(c), substituted "for the purposes of subsections (k), (m), and (p) of this section for "for the purposes of subsections (k) and (m) of this section", and substituted "sections 1395(a), 1395(b)(2)(P)(i), and 1395n of this title but only if" for "sections 1396a(a) and 1395n of this title but only if".

Subsec. (s)(2)(H). Pub. L. 98–369, §2322(a), designated existing provisions as cl. (i) and added cl. (ii).


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

Subsec. (a)(11). Pub. L. 98–369, §2364(b)(20), struck out "or" before "home health agency".

Subsec. (v)(1)(B). Pub. L. 98–369, §2354(b)(22)(A), reenacted provisions of section 1320a–1(g)(1) of this title in which the hospital is located)" for "$100,000".

1982—Subsec. (e)(C). Pub. L. 97–248, §128(d)(2), substituted "(i) may for "may (i)."


Subsec. (u). Pub. L. 97–248, §128(d)(1), inserted "hospital program" after "home health agency".

Subsec. (v)(1)(E). Pub. L. 97–248, §102(a), struck out provisions that this subparagraph would not apply to any skilled nursing facility that either was a distinct part of or directly operated by a hospital or was in a close, formal satellite relationship with a participating hospital, and in the case of the latter, the reasonable cost of any services furnished by such facility as determined by the Secretary under this subsection would not exceed 150 percent of the costs determined by the Secretary under this paragraph if such facility were determined by the Secretary to be a hospital (as defined in clause (ii)) for "provided in an emergency room"; and added cl. (ii).


Subsec. (z)(2). Pub. L. 98–369, §2354(b)(26), substituted paragraph (1)" for subparagraph (1).


Substituted "and durable medical equipment" for ", appliances, and equipment, including the purchase or rental of equipment".


Subsec. (d)(2)(A)(1)(I). Pub. L. 98–369, §2343(a), inserted "except as otherwise provided in paragraph (5)".


Subsec. (v)(2)(A). Pub. L. 98–21, §3231(a)(1), substituted "the amount that would be taken into account with respect to" for "an amount equal to the reasonable cost of the service"

Subsec. (v)(2)(B). Pub. L. 98–21, §3231(a)(3), struck out "the equivalent of the reasonable cost of" after "only".

Subsec. (v)(3). Pub. L. 98–21, §3231(a)(4), substituted "the amount otherwise payable under this subsection for such bed and board furnished in semiprivate accommodations for "the reasonable cost of such bed and board furnished in semiprivate accommodations (determined pursuant to paragraph (1))".


See 1982 Amendment note below.

Subsec. (a)(2). Pub. L. 98–261, §607(d)(1), designated existing provisions as subpar. (A) and added subpar. (B).

Pub. L. 98–21, §607(b)(2), substituted "$650,000 (or such lesser amount as may be established by the State under section 1320a–1(g)(1) of this title in which the hospital is located)" for "$100,000".

1982—Subsec. (e)(C). Pub. L. 97–248, §128(d)(2), substituted "(i) may for "may (i)."


Subsec. (u). Pub. L. 97–248, §128(d)(1), inserted "hospital program" after "home health agency".

Subsec. (v)(1)(E). Pub. L. 97–248, §102(a), struck out provisions that this subparagraph would not apply to any skilled nursing facility that either was a distinct part of or directly operated by a hospital or was in a close, formal satellite relationship with a participating hospital, and in the case of the latter, the reasonable cost of any services furnished by such facility as determined by the Secretary under this subsection would not exceed 150 percent of the costs determined by the application of this subparagraph, redesignated the remainder as cl. (ii), and added cl. (i).


Subsec. (v)(1)(H)(iii). Pub. L. 97–248, §110(b)(1), struck out "(i)" and "", and (II) which determines the amount payable by the home health agency on the basis of a percentage of the agency's reimbursement or claim for reimbursement for services furnished by the agency".


Subsec. (v)(1)(J). Pub. L. 97–248, §103(a), substituted provisions that cost regulations may not provide for
any inpatient routine salary cost differential as a reimbursable cost for hospitals and skilled nursing facilities for provisions that such regulations would provide that any inpatient routine nursing salary cost differential would be allowable as a reimbursable cost of hospitals, at a rate not to exceed 5 percent, to be applied under the same methodology used for the nursing salary cost differential for the month of April 1981.

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


Subsec. (v)(7). Pub. L. 97-248, §108(d), redesignated existing provisions as subpar. (A) and added subpar. (B).


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


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 elect to be treated as a single hospital, and beginning two years after the date this subparagraph is first applied with respect to a hospital, the Secretary, to the extent feasible, shall not treat as an inpatient an individual with respect to whom payment was made to the hospital only because of this subparagraph or section 1396a(h) of this title for such determination.


Subsec. (w)(1). Pub. L. 97-35, §2144(a), designated existing provisions as cl. (1) and added cl. (ii).

Subsec. (w)(2). Pub. L. 97-35, §2190(c)(9), substituted “subchapter XIX of this chapter” for “subchapter V or XIX of this chapter”.

Subsec. (bb). Pub. L. 97-35, §2212(d), struck out subsec. (bb) which defined “alcohol detoxification facility services” and “detoxification facility”.

1980—Subsec. (b)(7). Pub. L. 96-499, §194(a)(1), provided that par. (4) was not to apply to services provided in a hospital by a physician where the hospital had a teaching program approved as specified in par. (e) if the hospital elected to receive payment for reasonable costs of such services and all physicians in such hospital agreed not to bill charges for professional services rendered in such hospital to individuals covered under the insurance program established by this subchapter.

Subsec. (e). Pub. L. 96-499, §930(k), substituted “subsection (i)” for “subsections (i) and (m)” in text preceding par. (1) and in text following par. (9).

Pub. L. 96-499, §949, in text following par. (9), inserted provision defining “hospital” as a facility of fifty beds or less located in an area determined by the Secretary to meet definition relating to a rural area described in subpar. (A) of par. (5) and prescribing exceptions to such definition.

Subsec. (i). Pub. L. 96-499, §950, substituted “30 days” for “14 days” in three places and struck out former cl. (B) which related to admission to skilled nursing facilities within 28 days after hospital discharge of an individual unable to be admitted to such facilities within 14 days because of a shortage of appropriate bed space, and redesignated former cl. (C) as (B).


Subsec. (k)(2)(A). Pub. L. 96-499, §951(b), inserted “of which at least two must be physicians described in subsection (r)(1) of this section)” after “two or more physicians”.

Subsec. (m)(4). Pub. L. 96-499, §930(l), inserted “who has successfully completed a training program approved by the Secretary” after “health aide”.

Subsec. (n). Pub. L. 96-499, §930(m), struck out subsec. (n) which defined “post-hospital home health services”.

Subsec. (o). Pub. L. 96-499, §930(n), in provisions following par. (7), struck out provision that “home health agency” was not to include a private organization which was not a nonprofit organization exempt from Federal income taxation under section 501 of title 26 unless it was licensed pursuant to State law and met such additional standards and requirements as prescribed by regulations.


Subsec. (q)(2). Pub. L. 96-499, §936(a), amended cl. (2) generally to expand definition of “physician” to include doctors of dental surgery or dental medicine acting within the scope of their licenses.

Subsec. (r)(3). Pub. L. 96-499, §931(a), substituted provisions relating to doctors of podiatric medicine for provisions relating to doctors of podiatry and surgical chirropy.

Subsec. (s)(4). Pub. L. 96-499, §937(a), substituted “services related to the condition of aphakia” for “establishing the necessity for prosthetic lenses”.


Subsec. (s)(10) to (14). Pub. L. 96-611, §1(a)(1), added par. (10) and redesignated former pars. (10) to (13) as (11) to (14), respectively.

Subsec. (u). Pub. L. 96-499, §933(c), inserted “comprehensive outpatient rehabilitation facility,” after “nursing facility”.

Pub. L. 96-499, §931(c), inserted “detoxification facility”.

1395x(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. (e)(8). Pub. L. 92–603, § 253(a), inserted “including colostomy bags and supplies directly related to colostomy care” after “organ”.

Subsec. (u), Pub. L. 92–603, §§ 227(d)(1), 278(a)(12), substituted “skilled nursing facility, or home health agency, or, for purposes of section 1395(g) and 1395(m)(6) 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 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), and substituted “skilled nursing facilities” for “extended care facilities”.


Subsec. (v)(6). Pub. L. 92–603, §§ 223(f), 251(c), redesignated former par. (4) as (6).


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

Subsec. (2). Pub. L. 92–603, §§ 234(b), 278(b)(6), added subsec. (C) and substituted “skilled nursing facility” for “extended care facility”.

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

1968—Subsec. (e). Pub. L. 90–248, § 129(c)(9)(C), inserted reference to section 1395a(b) in first and third sentences and deleted “or diagnostic services” after “hospital services” in third sentence.

Pub. L. 90–248, § 144(a), inserted in second sentence after par. (8), changed definition of hospitals for purposes of making payments for emergency hospital services by deleting provision that hospital meet requirements of pars. (1) to (4), by requiring that such hospitals have full-time nursing services, be licensed as a hospital, and be primarily engaged in providing not nursing care and related services but medical or rehabilitative care by or under the supervision of a doctor of medicine or osteopathy.

Subsec. (p). Pub. L. 90–248, §§ 129(c)(9)(C), 133(b), struck out definition of “outpatient hospital diagnostic services” and inserted definition of “outpatient physical therapy services”, respectively.


Subsec. (s). Pub. L. 90–248, § 144(a)–(c), struck out “unless they would otherwise constitute inpatient hospital services, extended care services, or home health services” after “items or services” in text preceding par. (1), inserted after “hospital” in sentence following par. (9) “which, for purposes of this section, means an institution considered a hospital for purposes of section 1395(c) 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 definitions 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, § 129(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 institutions that meet the requirements of subsection (e)(1) or (j)(1) of this section”.

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

Subsec. (y)(3). Pub. L. 90–248, § 132(a)(11), substituted “before” for “after”.

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 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. 108–173, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–152, title I, § 1301(c), Mar. 30, 2010, 124 Stat. 1057, provided that: “The amendments made by this section [amending this section] shall apply to items and services furnished on or after the first day of the first calendar quarter that begins at least 12 months after the date of the enactment of this Act [Mar. 30, 2010].”

Amendment by section 4103(a), (b) of Pub. L. 111–148 applicable to 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 subscriptions 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. 110–365, § 7(b), Oct. 8, 2008, 122 Stat. 3965, provided that: “The amendment made by subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Oct. 8, 2008].”

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Amendment by section 101(a)(1), (b)(1) of Pub. L. 110–275 applicable to services furnished on or after Jan. 1, 2009, see section 101(c) of Pub. L. 110–275, set out as a note under section 1395f of this title.

Amendment by section 125(b)(2) of Pub. L. 110–275 applicable with respect to accreditations of hospitals granted on or after the date that is 24 months after July 15, 2008, with transition rule, see section 125(c) of Pub. L. 110–275, set out as an Effective Date of 2008 Amendment; Transition Rule note under section 1395fb of this title.

Amendment by section 143(a), (b)(5), (6) of Pub. L. 110–275 applicable to services furnished on or after July 1, 2009, see section 143(c) of Pub. L. 110–275, set out as a note under section 1395s of this title.

Amendment by section 144(a)(1) of Pub. L. 110–275 applicable to items and services furnished on or after Jan. 1, 2010, see section 144(a)(3) of Pub. L. 110–275, set out as a note under section 1395w–4 of this title.

Amendment by section 152(b)(1)(A), (B) of Pub. L. 110–275 applicable to services furnished on or after Jan. 1, 2010, see section 152(b)(2) of Pub. L. 110–275, set out as a note under section 1395w–4 of this title.

Amendment by section 1512(b)(1)(A), (B) of Pub. L. 110–275 applicable to items and services furnished on or after Jan. 1, 2005, see section 1512(b)(2) of Pub. L. 110–275, set out as a note under section 1395y of this title.

Amendment by section 1512(b)(1)(A), (B) of Pub. L. 110–275 applicable to services furnished on or after Jan. 1, 2005, see section 1512(b)(2) of Pub. L. 110–275, set out as a note under section 1395y of this title.

Amendment by section 1512(b)(1)(A), (B) of Pub. L. 110–275 applicable to services furnished on or after Jan. 1, 2005, see section 1512(b)(2) of Pub. L. 110–275, set out as a note under section 1395y of this title.

Effective date of 2006 Amendment

Amendment by section 512(a), (b) of Pub. L. 109–171 applicable to services furnished on or after Jan. 1, 2006, see section 512(f) of Pub. L. 109–171, set out as a note under section 1395f of this title.

Amendment by section 511(a)(1), (b) of Pub. L. 109–171 applicable to services furnished on or after Jan. 1, 2006, see section 511(c) of Pub. L. 109–171, set out as a note under section 1395s of this title.


Effective date of 2003 Amendment

Amendment by section 415(b) of Pub. L. 108–173 applicable to services furnished on or after Jan. 1, 2005, see section 415(c) of Pub. L. 108–173, set out as a note under section 1395m of this title.

Amendment by section 512(c) of Pub. L. 108–173 applicable to services provided by a hospice program on or after Jan. 1, 2005, see section 512(d) of Pub. L. 108–173, set out as a note under section 1395d of this title.

Amendment by section 611(a), (b), (d)(2) of Pub. L. 108–173 applicable to services furnished on or after Jan. 1, 2005, but only for individuals whose coverage period under this part begins on or after such date, see section 611(e) of Pub. L. 108–173, set out as a note under section 1395w–4 of this title.

Section 101 of Pub. L. 109–171, title VI, § 612(d), Dec. 8, 2003, 117 Stat. 2305, provided that: "The amendments made by this section [amending this section and section 1395f of this title] shall apply to tests furnished on or after January 1, 2005."

Pub. L. 108–173, title VI, § 613(d), Dec. 8, 2003, 117 Stat. 2305, provided that: "The amendments made by this section [amending this section and section 1395f of this title] shall apply to tests furnished on or after January 1, 2005."

Amendment by section 612(a) of Pub. L. 108–173 applicable to services furnished on or after Jan. 1, 2004, see section 612(c) of Pub. L. 108–173, set out as a note under section 1395f of this title.

Pub. L. 110–163, title IX, § 926(b)(2), Dec. 8, 2003, 117 Stat. 2305, provided that: "The amendments made by paragraph (1) [amending this section] shall apply to discharge plans made on or after such date as the Secretary of Health and Human Services shall specify, but not later than 6 months after the date the Secretary provides for availability of information under subsection (a) [amending provisions set out as a note under this section]."

Amendment by section 946(c) of Pub. L. 108–173 applicable to services furnished on or after Dec. 8, 2003, see section 946(c) of Pub. L. 108–173, set out as a note under section 1395f of this title.

Effective date of 2000 Amendment

Pub. L. 110–554, § 1(a)(6) [title I, § 101(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–468, provided that: "The amendments made by subsection (a) [amending this section] shall apply to items and services furnished on or after July 1, 2001."
Effective Date of 1997 Amendment
Amendment by section 4102(a), (c) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4102(e) of Pub. L. 105–33, set out as a note under section 1395f of this title.
Amendment by section 4103(a) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 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(a)(1) of Pub. L. 105–33 applicable to items and services furnished on or after Jan. 1, 1998, see section 4104(e) of Pub. L. 105–33, set out as a note under section 1395f of this title.
Amendment by section 4105(a)(1), (b)(1) of Pub. L. 105–33 applicable to items and services furnished on or after July 1, 1998, see section 4105(d)(1) of Pub. L. 105–33, set out as a note under section 1395f of this title.
Section 4106(d) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section and sections 1395w–4, 1395aa, 1396a, and 1396n of this title] shall apply to bone mass measurements performed on or after July 1, 1998."
Amendment by section 4202(c)(1), (2) of Pub. L. 105–33 applicable to services furnished on or after Oct. 1, 1997, see section 4202(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.
Section 4203(b)(2) of Pub. L. 105–33 provided that: "The amendments made by paragraph (1) [amending this section] shall take effect on January 1, 1998."
Section 4205(c)(2) of Pub. L. 105–33 provided that: "The amendment made by paragraph (1) [amending this section] applies to waiver requests made on or after January 1, 1998."
Section 4206(d)(4) of Pub. L. 105–33 provided that:

"(A) IN GENERAL.—Except as otherwise provided, the amendments made by the preceding paragraphs [amending this section and section 1395s of this title] take effect on the date of the enactment of this Act [Jan. 1, 1997]."

"(B) CURRENT RURAL HEALTH CLINICS.—The amendments made by the preceding paragraphs take effect, with respect to entities that are rural health clinics under title XVII of the Social Security Act (42 U.S.C. 1395 et seq.), on the date of enactment of this Act, on the date of the enactment of this Act [sic]."

"(C) GRANDFATHERED CLINICS.—"

"(i) IN GENERAL.—The amendment made by paragraph (3)(A) [amending this section] shall take effect on the effective date of regulations issued by the Secretary under clause (ii)."

"(ii) REGULATIONS.—The Secretary shall issue final regulations implementing paragraph (3)(A) that shall take effect no later than January 1, 1999."

Amendment by section 4312(d), (e) of Pub. L. 105–33 effective Aug. 5, 1997, and may be applied with respect to items and services furnished on or after Jan. 1, 1998, see section 4312(f) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Section 4313(f)(3) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Section 4315(a)(1)–(2)(B), (d) of Pub. L. 105–33 applicable to services furnished and supplies provided on and after Jan. 1, 1998, see section 4315(e) of Pub. L. 105–33, set out as a note under section 1395k of this title.

Amendment by section 4512(a) of Pub. L. 105–33 applicable to services furnished and supplies provided on and after Jan. 1, 1998, see section 4512(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Section 4513(b) of Pub. L. 105–33 provided that: "The amendments made by subsection (a) [amending this section] applies to services furnished on or before January 1, 2000."

Section 4557(b) of Pub. L. 105–33 provided that: "The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1998."

Section 4606(c) of Pub. L. 105–33 provided that: "The amendments made by this section [amending this section and section 1395b(bb) of this title] apply to cost reporting periods beginning on or after October 1, 1997."

Amendment by section 4611(b) of Pub. L. 105–33 applicable to services furnished on or after Jan. 1, 1998, and for purposes of applying such amendment to a 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 1395k of this title.

Section 4612(b) of Pub. L. 105–33 provided that: "The amendment made by subsection (a) [amending this section] applies to services furnished on or after October 1, 1997."

Effective Date of 1996 Amendment

Effective Date of 1994 Amendment
Section 107(b) of Pub. L. 103–432 provided that: "The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after the first day of the first month beginning more than one year after the date of the enactment of this Act [Oct. 31, 1994]."

Amendment by section 145(b) of Pub. L. 103–432 applicable to mammography furnished by the facility on and after the first date that the certificate requirements of section 263(b) of this title apply to such mammography conducted by such facility, see section 145(d) of Pub. L. 103–432, set out as a note under section 1395m of this title.

Section 146(c) of Pub. L. 103–432 provided that: "The amendments made by this section [amending this section] shall take effect on January 1, 1999."

Section 147(e)(11), (14), (15), (16)(A), (6)(A), (B), (E) of Pub. L. 103–432 effective as if included in the enactment of Pub. L. 101–508, see section 147(g) of Pub. L. 103–432, set out as a note under section 1328a–3a of this title.

Section 158(a)(2) of Pub. L. 103–432 provided that: "The amendment made by paragraph (1) [amending this section after July 1, 1998, see section 4432(d) of Pub. L. 105–33, set out as a note under section 1395l–3 of this title.

Section 444(b) of Pub. L. 105–33 provided that: "The amendment made by subsection (a) [amending this section] shall apply with respect to items or services furnished on or after April 1, 1998."

Amendment by sections 4445 and 4446 of Pub. L. 105–33 applicable to benefits provided on or after Aug. 5, 1997, except as otherwise provided, see section 4449 of Pub. L. 105–33, set out as a note under section 1395d of this title.

Amendment by section 454(a)(1) of Pub. L. 105–33 effective Aug. 5, 1997, and applicable to items and services furnished on or after such date, with provision that Secretary of Health and Human Services issue regulations to carry out such amendment by not later than July 1, 1998, see section 454(d) of Pub. L. 105–33, set out as an Effective Date note under section 1395i–5 of this title.

Section 4511(a)(1)–(2)(B), (d) of Pub. L. 105–33 applicable to services furnished and supplies provided on and after Jan. 1, 1998, see section 4511(e) of Pub. L. 105–33, set out as a note under section 1395k of this title.

Amendment by section 4512(a) of Pub. L. 105–33 applicable to services furnished and supplies provided on and after Jan. 1, 1998, see section 4512(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Amendment by section 4454(a)(1) of Pub. L. 105–33 applicable to services furnished and supplies provided on and after Jan. 1, 1998, see section 4454(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Amendment by section 4455(a) of Pub. L. 105–33 effective Aug. 5, 1997, and applicable to items and services furnished on or after such date, with provision that Secretary of Health and Human Services issue regulations to carry out such amendment by not later than July 1, 1998, see section 4455(d) of Pub. L. 105–33, set out as an Effective Date note under section 1395i–5 of this title.

Amendment by section 4511(a)(1)–(2)(B), (d) of Pub. L. 105–33 applicable to services furnished and supplies provided on and after Jan. 1, 1998, see section 4511(e) of Pub. L. 105–33, set out as a note under section 1395k of this title.
section] shall apply with respect to cost reporting periods beginning on or after July 1, 1996.

**Effective Date of 1993 Amendment**

Section 1353(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 1355(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 1355(d) 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 1356(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 OBRA–1990 [Pub. L. 101–508]."

Section 1364(b)(2) of Pub. L. 101–66 provided that: "The amendment made by paragraph (1) [amending this section] shall apply to items furnished on or after January 1, 1994."

**Effective Date of 1990 Amendment**


Amendment by section 4124(a)(3) of Pub. L. 101–508 applicable to items furnished on or after Jan. 1, 1994, see section 4124(a)(3) of Pub. L. 101–508, set out as a note under section 1395m of this title.

Amendment by section 4131(b)(5) of Pub. L. 101–508 provided that: "The amendments made by subsections (A) and (B) [amending this section and section 1395y of this title] shall apply to items furnished on or after January 1, 1994."

Amendment by section 4155(a), (d) of Pub. L. 101–508 applicable to services furnished on or after Jan. 1, 1994, see section 4155(e) of Pub. L. 101–508, set out as a note under section 1395k of this title.

Amendment by section 4157(d) of Pub. L. 101–508 applicable to services furnished on or after Jan. 1, 1994, see section 4157(d) of Pub. L. 101–508, set out as a note under section 1395k of this title.

Amendment by section 4161(a)(1), (2), (5) of Pub. L. 101–508 applicable to services furnished on or after Oct. 1, 1994, see section 4161(a)(8) of Pub. L. 101–508, set out as a note under section 1395k of this title.

Amendment by section 4163(c)(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, 1994, 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, 1995, 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)(I) 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, 1994."


**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 1395a of this title.

Amendment by section 6115 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 Screening pap smears performed on or after July 1, 1990."

Amendment by section 6131(a)(2) of Pub. L. 101–239 applicable with respect to therapeutic shoes and inserts furnished on or after July 1, 1989, with additional provisions regarding applicability of the increase under section 1395(c)(2)(C) of this title, see section 6131(c) of Pub. L. 101–239, set out as a note under section 1395f of this title.

Section 6141(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 1320a–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 8424(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, set out as a note under section 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) of Pub. L. 100–360, set out as a note under section 1395a of this title.

Amendment by section 203(b), (e)(1) of Pub. L. 100–360 applicable to items and services furnished on or after January 1, 1989, see section 203(b), (e)(1) of Pub. L. 100–360, set out as a note under section 1395a 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 applied to 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 applied 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. 1861.

As excepted as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(d)(5)(A), (C)(iii), (4)(D), (5)–(7)(A), (E), (F), (I)(O), (3)(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 1395bb 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 4046(c)(2) of Pub. L. 100–203 provided that: “The amendment made by paragraph (1) [amending this section] shall apply to diagnostic tests performed on or after January 1, 1990.”

Section 4046(c) of Pub. L. 100–203 provided that: “The amendments made by this section [amending the sections and section 1395r of this title] shall become effective on the first day of the first month to begin after the effective date provided in section 402(c) of OBRA [Pub. L. 100–203, set out below].”

“(A) The amendments made by subsection (b) [amending this section and sections 1395l and 1395n of this title] shall become effective on the date of enactment of this Act [Dec. 22, 1987].”

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

Section 4071(b) of Pub. L. 100–203 provided that:

“(1) The provisions of subsection (e) of section 4072 of this Act [amending this section] shall apply to screening mammography performed on or after January 1, 1990, see section 4072(e) of Pub. L. 100–203, set out as a note under section 1395k of this title.

“(2) In conducting the demonstration project pursuant to paragraph (1), in order to determine the cost effectiveness of including influenza vaccine in the medicare program, the Secretary of Health and Human Services is required to conduct a demonstration of the provision of influenza vaccine as a service for medicare beneficiaries and to expend $25,000,000 each year of the demonstration project for this purpose. In conducting this demonstration, the Secretary is authorized to purchase in bulk influenza vaccine and to distribute it in a manner to make it widely available to medicare beneficiaries, to develop projects to provide vaccine in the same manner as other covered medicare services, to engage in other appropriate use of monies 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 4072 of Pub. L. 100–203 provided that:

“(1) The amendments made by this section [amending this section and sections 1395l, 1395m, 1395aa, 1395bb, 1396a, and 1396n of this title] shall become effective (if at all) in accordance with paragraph (2).

“(2)(A) The Secretary of Health and Human Services (in this paragraph referred to as the ‘Secretary’), shall establish a demonstration project to begin on or after January 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) The demonstration project under subparagraph (A) shall be conducted for an initial period of 24 months. Not later than October 1, 1990, the Secretary shall report to the Congress on the results of such project. If the Secretary finds, on the basis of existing data, that furnishing therapeutic shoes under the medicare program to the extent provided under the amendments made by this section is cost-effective, the Secretary shall include such finding in such report, such project shall be discontinued, and the amendments made by this section shall become effective on November 1, 1990.

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


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

Amendment by section 4073(a) 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 4075(b) of Pub. L. 100–203 provided that: “The amendment made by section 4075 of Pub. L. 100–203 shall be effective with respect to services furnished on or after January 1, 1988.”

Section 4076(b) of Pub. L. 100–203 provided that: “The amendment made by section 4076 of Pub. L. 100–203 shall be effective with respect to services performed on or after January 1, 1988.”

Section 4077(a)(2) of Pub. L. 100–203 provided that: “The amendment made by section 4077 of Pub. L. 100–203 shall be effective with respect to services performed on or after January 1, 1988.”

Section 4078(b) of Pub. L. 100–203 provided that: “The amendment made by section 4078 of Pub. L. 100–203 shall be effective with respect to services furnished on or after January 1, 1988.”

Section 4079(a)(2) of Pub. L. 100–203 provided that: “The amendment made by paragraph (1) [amending this section] shall be effective with respect to services fur-
lished on or after the date of enactment of this Act [Dec. 22, 1987]."

Amendment by section 4077(b)(1), (4) of Pub. L. 100–203 effective with respect to services performed on or after July 1, 1988, see section 4077(b)(5) of Pub. L. 100–203, as amended, set out as a note under section 1395s of this title.

Amendment by section 4804(c)(1) of Pub. L. 100–203 applicable to services furnished after Dec. 31, 1988, see section 4804(c)(3) of Pub. L. 100–203, as added, set out as a note under section 1395f of this title.

Amendments by section 4201(a)(1), (b)(1), (d)(1), (2), (5) of Pub. L. 100–203 applicable to services furnished on or after Sept. 1, 1984, see section 4201(a), (b), (c), (f) of Pub. L. 100–203 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(j), (k) of Pub. L. 100–203, as amended, set out as notes under section 1395k of this title.

Section 9335(c)(2) of Pub. L. 99–509 provided that: "The amendments made by subsection (a) [amending this section and section 1395ff of this title] take effect on the date of the enactment of this Act [Oct. 21, 1986]."

Section 9335(c)(2) of Pub. L. 99–509 provided that: "The amendments made by this paragraph [probably meaning "this subsection", which amended this section and section 1395ff of this title] take effect on the date of the enactment of this Act [Oct. 21, 1986]."

Section 9335(c) of Pub. L. 99–509 provided that: "The amendments made by subsection (a) [amending this section] shall be effective with respect to items and services furnished on or after Jan. 1, 1989, for hospitals located in rural areas which meet certain requirements related to certified registered nurse anesthetists, see section 9320(j), (k) of Pub. L. 99–509, as amended, set out as notes under section 1395k of this title.

Section 9335(c)(2) of Pub. L. 99–509 provided that: "The amendments made by subsection (a) [amending this section] shall apply to immunosuppressive drugs furnished on or after January 1, 1987."

Section 9335(c) of Pub. L. 99–509 provided that: "The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after April 1, 1987."

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 1395f of this title.

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 9107(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(a)(1) 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 June 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(a)(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 (iii) of section 1861(v)(1)(O) of such Act [subsec. (v)(1)(O)(iii) of this section] shall apply to costs incurred on or after the date of the enactment of this Act."

Section 2314(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 1395s of this title.

Amendment by section 2321(e) of Pub. L. 98–369 applicable to items and services furnished on or after July 18, 1984, see section 2321(g) of Pub. L. 98–369, set out as a note under section 1395f of this title.

Amendment by section 2321(b) of Pub. L. 98–369 applicable to items and services furnished on or after Sept. 1, 1984, see section 2321(d) of Pub. L. 98–369, set out as a note under section 1395s of this title.

Section 2321(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(a) of Pub. L. 98–369 applicable to services furnished on or after Sept. 1, 1984, see section 2323(g) of Pub. L. 98–369, set out as a note under section 1395f of this title.

Amendment by section 2323(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 1395m of this title.

Amendment by 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 2354(b)(18)–(29) of Pub. L. 98–369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2354(e)(1) of Pub. L. 98–369, set out as a note under section 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 602(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 cost reporting periods ending after September 30, 1982, but in the case of any cost reporting period beginning before October 1, 1982, any reduction in payments under title XVIII of the Social Security Act [this subchapter] to a hospital or skilled nursing facility resulting from such amendment shall be imposed only in proportion to the part of the period which occurs after September 30, 1982.”

Section 105(b) of Pub. L. 97–248 provided that: “The amendment made by subsection (a) [amending this section] shall be effective with respect to cost reporting periods beginning on or after the date of the enactment of this Act [Sept. 3, 1982].”

Section 106(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 under title XVIII of the Social Security Act [this subchapter], except that it shall not apply to costs which have been allowed prior to the date of the enactment of this Act [Sept. 3, 1982] pursuant to the final court order affirmed by a United States Court of Appeals.”

Section 107(b) of Pub. L. 97–248 provided that: “The amendment made by subsection (a) [amending this section] shall be effective with respect to costs incurred after the date of the enactment of this Act [Sept. 3, 1982].”


Section 109(c)(3) of Pub. L. 97–248 provided that: “The amendment made by subsection (b)(1) [amending this section] shall not apply to contracts entered into before the date of the enactment of this Act [Sept. 3, 1982].”

Amendment by section 122(d) of Pub. L. 97–248 applicable to hospice care provided on or after Nov. 1, 1983, see section 122(h)(1) of Pub. L. 97–248, as amended, set out as a note under section 1396c of this title.


“(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 1395y, 1395cc, and 1395uu of this title and section 162 of Title 26] shall be effective as if it had been originally included as a part of that provision of the Social Security Act or Internal Revenue Code of 1986 to which it relates, as such provision of such Act or Code was amended by the Omnibus Budget Reconciliation [Reconciliation] Act of 1981 [Pub. L. 97–35].

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

Amendment by section 148(b) of Pub. L. 97–248 effective with respect to contracts entered into or after Oct. 1, 1982, see section 149 of Pub. L. 97–248, set out as an Effective Date note under section 1323c of this title.

**Effective Date of 1981 Amendment**

Section 2102(b)(1) of Pub. L. 97–35 provided that: “The amendments made by subsection (a) [amending this section], shall apply to services provided on or after the first day of the first month beginning after the date of the enactment of this Act [Aug. 13, 1981].”

Amendment by section 2121(c), (d) of Pub. L. 97–35 applicable to services furnished in detoxification facilities for inpatient stays beginning on or after the tenth day after Aug. 13, 1981, see section 2121(d) of Pub. L. 97–35, set out as a note under section 1396d of this title.

Section 2141(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 2143(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 2183 of Pub. L. 97–35, see section 2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

**Effective Date of 1980 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 1396d of this title.

Section 902(c) of Pub. L. 96–499 provided that: “The amendments made by this section [amending this section and sections 1332, 1333, 1335, 1336, 1337, 1338, 1339g, 1339h, 1339i, and 1339j 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 903(s) of Pub. L. 96–499 provided that: “(1) the amendments made by this section [amending this section, sections 426, 1395cc, 1395f, 1395k, 1395l, 1395n, and 1395gg of this title], and section 231 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 1395gg 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-
provisions, in accordance with the amendment made by subsection (n)(1) [amending this section], will be made not later than June 30, 1981.

Amendment by section 933(c)(4) of Pub. L. 96-499 effective Apr. 1, 1981, see section 935(e) of Pub. L. 96-499, set out as a note under section 1395d of this title.

Amendment by section 933(c)-(e) of Pub. L. 96-499 effective with respect to a comprehensive outpatient rehabilitation facility's first accounting period beginning on or after July 1, 1981, see section 933(h) of Pub. L. 96-499, set out as a note under section 1395k of this title.

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

Section 937(c) of Pub. L. 96-499, as amended by Pub. L. 98-369, div. B, title III, §2354(c)(1)(B), July 18, 1984, 98 Stat. 1102, provided that: "The amendment made by subsection (a) [amending this section] shall apply to services furnished on or after July 1, 1981."

Section 938(b) of Pub. L. 96-499 provided that: "The amendments made by subsection (a) [amending this section] shall apply to services furnished on or after January 1, 1981."

Section 948(c)(1) of Pub. L. 96-499 provided that: "The amendments made by subsection (a) [amending this section and section 1395e 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] as administered in accordance with section 15 of Public Law 93-233] as of September 30, 1978, shall constitute such hospital's election under such section (as amended by subsection (a)(1)) on and after October 1, 1978, until otherwise provided by the hospital."

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 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 501(c) of Pub. L. 95-216 provided that: "The amendments made by this section [amending this section and section 1385a 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. 25, 1977, see section 937(e) of Pub. L. 95-142, set out as an Effective Date note under section 1320a-3 of this title.

Amendment by section 19(b)(1) of Pub. L. 95-142 effective with respect to operation of a hospital, skilled nursing facility, or intermediate care facility on and after the first day of its first fiscal year which begins after the end of the six-month period beginning on the date a uniform reporting and utilization 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, 1977]."

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]."

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 December 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, and 1395bb of this title] shall apply with respect to any provider of services for fiscal years (of such provider) beginning after the fifth month following the month in which this Act is enacted [October 1972]."

Section 246(c) of Pub. L. 92-603 provided that: "The amendments made by this section [amending this section and section 1396c 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 sections 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)(5) of the Social Security Act [subsec. (v)(5) of this section]."

Section 253(b) of Pub. L. 92-603 provided that: "The amendments made by subsection (a) [amending this section] shall only apply with respect to items furnished on or after the date of the enactment of this Act [Oct. 30, 1972]."
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.

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

Section 278(a) of Pub. L. 92–603 to apply with respect to services rendered after Dec. 31, 1972, see section 278(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 1395e of this title] shall apply with respect to services furnished after December 31, 1967.’’

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

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

Amendment by section 134(b) of Pub. L. 90–248 applicable with respect to services furnished after Mar. 31, 1968, see section 134(c) 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 1395d 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


Construction of 2008 Amendment


Conforming References to Previous Part D

Pub. L. 108–173, title I, §101(ex)(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(i) 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) Specification of Codes.—The Secretary shall determine the appropriate life-safety codes for such clinics that treat patients for needs referred to in subsection (b)(2).

‘‘(d) Funding.—

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

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

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

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

‘‘(g) Definitions.—In this section, the terms ‘hospital’ and ‘critical access hospital’ have the meanings given such terms in subsections (e) and (mm), respectively, of section 1861 of the Social Security Act (42 U.S.C. 1395x).’’

MEDPAC Study of Coverage of Surgical First 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 low vision therapist.

“(b) REPORT ON APPROPRIATENESS OF A DEMONSTRATION PROJECT To Test Feasibility of Using FP0 Networks To Reduce Costs of Acquiring Eye Glasses 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 to reduce the per-patient cost of providing eye glasses to Medicare beneficiaries after cataract surgery by using FP0 networks.

“(c) 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.

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

“(2) IMPLEMENTATION; DURATION.—

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

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

“(4) EVALUATION AND REPORT.—

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

“(A) to determine whether eligible beneficiaries who use chiropractic services use a lesser overall...
amount of items and services for which payment is made under the medicare program than eligible beneficiaries who do not use such services; 

"(b) To determine the costs 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 conduct a 2-year demonstration project under which medicare beneficiaries shall conduct a 2-year demonstration project under which medicare beneficiaries that is directly attributable to such clarification. 

"(2) The specific data evidencing the amount of any increase in expenditures in expenditures that is directly attributable to 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. 

"(k) Waiver Authority.—The Secretary shall waive compliance with the requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) to such extent and for such period as the Secretary determines is necessary to conduct demonstration projects. 

"(l) Construction.—Nothing in this section shall be construed as waiving any applicable civil monetary penalty, criminal penalty, or other remedy available to the Secretary under title XVIII of the Social Security Act (this subchapter and subchapter XI of this chapter) for acts prohibited under such titles, including penalties for false certifications for purposes of receipt of items or services under the medicare program. 

"(m) Authorization of Appropriations.—Payments for the costs of carrying out the demonstration project under this section shall be made from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t). 

"(n) 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

Pub. L. 108–173, title IX, §926(a), Dec. 8, 2003, 117 Stat. 2396, provided that: ‘‘The Secretary [of Health and

"(5) the beneficiary requires technological assistance or the assistance of another person to leave the home; and 

"(6) the beneficiary does not regularly work in a paid position full-time or part-time outside the home. 

"(c) Demonstration Project Sites.—The demonstration project established under this section shall be conducted in 3 States selected by the Secretary to represent the Northeast, Midwest, and Western regions of the United States. 

"(d) Limitation on Number of Participants.—The aggregate number of such beneficiaries that may participate in the project may not exceed 15,000. 

"(e) Data.—The Secretary shall collect such data on the demonstration project with respect to the provision of home health services to medicare beneficiaries that relates to quality of care, patient outcomes, and additional costs, if any, to the medicare program. 

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

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

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

"(B) Has directly caused an increase in 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. 

"(4) Authorization of Appropriations.—Payments for the costs of carrying out the demonstration project under this section shall be made from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t). 

"(5) 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

Pub. L. 108–173, title IX, §926(a), Dec. 8, 2003, 117 Stat. 2396, provided that: ‘‘The Secretary [of Health and
Human Services) shall publicly provide information that enables hospital discharge planners, medicare beneficiaries, and the public to identify skilled nursing facilities that are participating in the medicare program.

IMPLEMENTATION OF AMENDMENTS BY PUB. L. 105–277


“(1) IN GENERAL.—The Secretary of Health and Human Services shall promptly issue (without regard to chapter 8 of title 5, United States Code) such regulations or program memoranda as may be necessary to effect the amendments made by this section (amending this section, sections 1395r and 1395fff of this title, and provisions set out as notes under section 1395ff of this title) for cost reporting periods beginning during fiscal year 1999.

“(2) USE OF PAYMENT AMOUNTS AND LIMITS FROM PUBLISHED TABLES.—

“(A) PER BENEFICIARY LIMITS.—In effecting the amendments made by subsection (a) [amending this section] for cost reporting periods beginning in fiscal year 1999, the ‘median’ referred to in section 1861(v)(1)(L)(v)(I) of the Social Security Act [subsec. (v)(1)(L)(v)(I) of this section] for such periods shall be the national standardized per beneficiary limitation specified in Table 3C published in the Federal Register on August 11, 1998 (63 FR 42926) and the ‘standardized regional average of such costs’ referred to in section 1861(v)(1)(L)(v)(I) of such Act [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)(v)(V) of such Act [subsec. (v)(1)(L)(v)(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 IV, § 433], Dec. 21, 2000, 114 Stat. 2783, 2783A–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 education and training requirements for certified registered nurse first assistants who furnish such first assisting services.

“(3) Appropriate rates of payment under the program to such certified registered nurse first assistants for furnishing such services, taking into account the costs of compensating, hiring, 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 MEDI-CARE COVERAGE OF SERVICES PROVIDED BY CERTAIN NONPHYSICIAN PROVIDERS

Pub. L. 106–554, § 1(a)(6) [title IV, § 435], Dec. 21, 2000, 114 Stat. 2783, 2783A–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 some or all medicare beneficiaries. In conducting the study, the Commission shall consider the short-term and long-term benefits, and costs to the medicare program, of such addition.

“(b) REPORT.—Not later than 2 years after the date of the enactment of this Act [Dec. 21, 2000], the Medicare Payment Advisory Commission 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."

STUDY ON MEDICARE COVERAGE OF ROUTINE THYROID SCREENING

Pub. L. 106–554, § 1(a)(6) [title I, § 123], Dec. 21, 2000, 114 Stat. 2783, 2783A–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 of routine thyroid screening using a thyroid stimulating hormone test as a preventive benefit provided to medicare beneficiaries under title XVIII of the Social Security Act [this subchapter] for some or all medicare beneficiaries. In conducting the study, the Academy shall consider the short-term and long-term benefits, and costs to the medicare program, of such addition.

“(b) REPORT.—Not later than 2 years after the date of the enactment of this Act [Dec. 21, 2000], the Secretary of Health and Human Services shall submit to the Committee on Ways and Means and the
Committee on Commerce [now Committee on Energy and Commerce] of the House of Representatives and the Committee on Finance of the Senate a report on the development of standard instruments for the assessment of the health and functional status of patients, for whom items and services described in subsection (b) are furnished, and include in the report a recommendation on the use of such standard instruments for payment purposes.

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

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

"(B) only elements necessary to meet program objectives are collected; and

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

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

"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 C of this subchapter] is deemed a reference to part D of 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."

"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(p)(p) of the Social Security Act (42 U.S.C. 1395x(p)), as added by paragraph (1), on the coverage of a screening barium enema as a colorectal cancer screening test under such section."

"Establishment of Outcome Measures for Beneficiaries With Diabete mellitus Section 4109(e) 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 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 paragraph (1), the Secretary shall from time to time submit recommendations to Congress regarding modifications to the coverage of services for such beneficiaries under the medicare program."

"Vaccines Outreach Expansion Section 4107 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 Appropriations.—There are hereby authorized to be appropriated for each of fiscal years 1998 through 2002, $8,000,000 for the Campaign described in subsection (a). Of the amount so authorized to be appropriated in each fiscal year, 60 percent of the amount so appropriated shall be payable from the Federal Hospital Insurance Trust Fund, and 40 percent shall be payable from the Federal Supplementary Medical Insurance Trust Fund."

"Study on Preventive and Enhanced Benefits Section 4106 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 of the analysis to Congress.

"Utilization Guidelines Section 453(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."

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

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

"(2) The volunteer ambulance service involved—

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

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

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

"(3) The entity supplying the ALS intercept service is:

"(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, 1992 (57 Fed. Reg. 6725)).

Section 601(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)(i) of the Social Security Act (42 U.S.C. 1395x(v)(1)(L)(i)).’’

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 of items and services for individuals with post-menopausal osteoporosis as the Secretary considered appropriate.

PRODUCTIVITY SCREENING GUIDELINES APPLICATION TO STAFF IN RURAL HEALTH CLINICS

Section 4611(b)(3) of Pub. L. 101–508 provided that: ‘‘In employing any screening guideline in determining the productivity of physicians, physician assistants, nurse practitioners, and certified nurse-midwives in a rural health clinic, the Secretary of Health and Human Services shall provide that the productivity guideline shall not account the combined services of such staff (and not merely the service within each class of practitioner).’’

DEVELOPMENT OF PROSPECTIVE PAYMENT SYSTEM FOR HOME HEALTH SERVICES

Section 4207(c), formerly 4027(c), of Pub. L. 101–508, as renumbered and amended by Pub. L. 103–432, title I, §160(d)(4), (9), Oct. 31, 1994, 108 Stat. 4444, Pub. L. 105–362, title VI, §601(b)(2), Nov. 10, 1998, 112 Stat. 3286, directed Secretary of Health and Human Services to develop a proposal to modify the current system under which payment is made for home health services. This subchapter or a proposal to replace such system with a system under which such payments would be made on the basis of prospectively determined rates, with Secretary to submit to Congress by not later than Apr. 1, 1993, the research findings upon which the proposal was to be based, and directed Prospective Payment Assessment Commission to submit to Congress by not later than Mar. 1, 1994, an analysis of and comments on the proposal.

APPLICATION OF BUDGET-NEUTRAL BASIS

Section 4207(d)(2), formerly 4027(d)(2), of Pub. L. 101–508, as renumbered by Pub. L. 103–432, title I, §160(d)(4), Oct. 31, 1994, 108 Stat. 4444, provided that: ‘‘In updating the wage index for establishing limits under section 1861(v)(1)(L)(iii) of the Social Security Act [subsec. (v)(1)(L)(iii) of this section], the Secretary shall ensure that aggregate payments to home health agencies under title XVIII of such Act (this subchapter) will be no greater or lesser than such payments would have been without regard to such update.’’

TRANSITION PROVISIONS FOR DETERMINING REASONABLE COSTS FOR HOME HEALTH AGENCY SERVICES

Section 4207(d)(3), formerly 4027(d)(3), of Pub. L. 101–508, as renumbered by Pub. L. 103–432, title I, §160(d)(4), Oct. 31, 1994, 108 Stat. 4444, provided that, notwithstanding subsec. (v)(1)(L)(iii) of this section, the Secretary of Health and Human Services was to, in determining the limits of reasonable costs under this subchapter with respect to services furnished by a home health agency, utilize a wage index equal to (1) for cost reporting periods beginning on or after July 1, 1991, and on or before June 30, 1992, a combined area wage index consisting of 67 percent of the area wage index applicable to such home health agency, determined using the survey of the 1982 wages and wage-related costs of hospitals in the United States, and 33 percent of the area wage index applicable to hospitals located in the geographic area in which the home health agency was located, determined using the survey of the 1988 wages and wage-related costs of hospitals in the United States, and 67 percent of the area wage index applicable to hospitals located in the geographic area in which the home health agency was located, determined using the survey of the 1988 wages and wage-related costs of hospitals in the United States.

PERMITTING DENTIST TO SERVE AS HOSPITAL MEDICAL DIRECTOR

Section 6025 of Pub. L. 101–239 provided that: ‘‘Notwithstanding the requirement that the responsibility
for organization and conduct of the medical staff of an institution be assigned only to a doctor of medicine or osteopathy in order for the institution to participate as a hospital under the 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 permit a doctor of dental surgery or of dental medicine to serve as the medical staff director of a hospital."

RECOGNITION OF COSTS OF CERTAIN HOSPITAL-BASED NURSING SCHOOLS

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, a 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 cost reporting periods beginning on or after the date of enactment of this Act [Dec. 19, 1989] and on or before the date on which the Secretary issues regulations pursuant to subsection (b)(2)(A) [set out as a note under section 1395ww of this title]."

DISSEMINATION OF RURAL HEALTH CLINIC INFORMATION

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 any land 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."

CONTINUOUS USE OF HOSPITAL 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)(ii)(I) of the Social Security Act [subsection (v)(1)(L)(ii)(I) 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 8427 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 [subsection (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(l)(2)(E) of Pub. L. 100-300 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-1 of this title], section 1861(i) of the Social Security Act [subsection (i) of this section] is deemed to include the requirement described in section 1819(c)(3)(A) of such Act [section 1395a(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 4039(e) of Pub. L. 100-203 provided that: "The Secretary of Health and Human Services shall not implement any voluntary or mandatory program of prior authorization for home health services, extended care services, or post-hospital extended care services under part A or B of title XVIII of the Social Security Act [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 DEEMING OF ENTITIES

Section 4039(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 [subsection (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 the 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-
suits 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, 1988.

**Considerations in Establishing Limits on Payment for Home Health Services**

Section 931(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 931(c) of Pub. L. 99–509 directed Comptroller General to study and report to Congress, not later than Feb. 1, 1988, on appropriateness and impact on medicare beneficiaries of applying the per visit cost limits for home health services under subsec. (v)(1)(L) of this section on a discipline-specific basis, rather than on an aggregate basis, for all home health services furnished by an agency, and appropriateness of the percentage limits so established.

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

Section 933(b) of Pub. L. 99–509 directed Secretary of Health and Human Services to reduce the amount of duplicate payments that may be for cost reporting periods beginning no earlier than October 1, 1983, and on or after July 1, 1986, otherwise made to hospitals and skilled nursing facilities under this subchapter to eliminate estimated duplicate payments for historical or current costs attributable to services furnished by physicians after the date on which final regulations of the Secretary are first published.’’

**Study and Report on Payments for Physician Assistants**

Section 933(e) of Pub. L. 99–509 directed Secretary to report to Congress, by Apr. 1, 1988, concerning adjustments to amount of payment made, under part B for services described in subsec. (s)(2)(K) of this section, to ensure that amount of such payments reflects approximate cost of furnishing the services, taking into account compensation costs and overhead and supervision costs attributable to physician assistants.

**Cost Limits for Routine Services for Urban and Rural Hospital-Based Skilled Nursing Facilities; Cost Reporting Periods Beginning on or After October 1, 1982, and Prior to July 1, 1984**

Section 2319(d) of Pub. L. 98–21 directed Secretary of Health and Human Services to conduct a study of nec-

cessity and appropriateness of requirements that certain “core” services be furnished directly by a hospice, as required under subsec. (d)(2)(A)(ii)(I) of this section and report results of such study to Congress with the report required under section 122(i)(1) (122(j)(1)) of the Tax Equity and Fiscal Responsibility Act of 1982 (Pub. L. 97–248), set out as a note under section 1395f of this title.

**Report on Effect of 1982 Amendment on Hospital-Based Skilled Nursing Facilities**

Section 605(b) of Pub. L. 98–21 directed Secretary of Health and Human Services, prior to Dec. 31, 1983, to complete a study and report to Congress with respect to (1) effect which implementation of section 102 of the Tax Equity and Fiscal Responsibility Act of 1982, amending this section, would have on hospital-based skilled nursing facilities, given the differences (if any) in patient populations served by such facilities and by community-based skilled nursing facilities and (2) impact on skilled nursing facilities of hospital prospective payment systems, and recommendations concerning payment of skilled nursing facilities.

Section 2319(e) of Pub. L. 98–369 directed Secretary of Health and Human Services to submit to Congress, prior to Dec. 1, 1984, the report required under section 605(b) of the Social Security Amendments of 1983 (Pub. L. 97–21), set out above.

**Elimination of Private Room Subsidy**

Section 111 of Pub. L. 98–248 provided that:

’’(a) The Secretary of Health and Human Services shall, pursuant to section 1861(v)(2) of the Social Security Act [subsec. (v)(2) of this section], not allow as a subsidy 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 first issue such final regulations (whether on an interim or other basis) as may be necessary to implement subsection (a) by October 1, 1982. If such regulations are promulgated on an interim final basis, the Secretary shall take such steps as may be necessary to provide opportunity for public comment, and appropriate revision based thereon, so as to provide that such regulations are not on an interim basis later than January 31, 1983.”

**Regulations Regarding Access to Books and Records**

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 only apply to books, documents, and records relating to services furnished (pursuant to contract or subcontract) on or after the date on which final regulations of the Secretary are first published.’’

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

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(j)(13) of the Social Security Act [subsec. (j)(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), with or without waivers of specific provisions, or by
meeting the applicable provisions of a fire and safety code by State law as provided for in such section 1861(j)(13), as it is amended by subsection (a) of this section.

Section 196(c) of Pub. L. 94-192 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), 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 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 196(f) of the Social Security Act [section 1396d(1) of this title], except for clause (1) 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."

PROCLAMATION OF REGULATIONS DEFINING COSTS CHARGEABLE 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 [section 1861(aa)(2) of this section], 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)."

HOME HEALTH SERVICES; GRANTS FOR ESTABLISHMENT, OPERATION, STAFFING, ETC., OF PUBLIC AND NONPROFIT PRIVATE AGENCIES AND ENTITIES; PROCEDURES; PAYMENTS; AUTHORIZATION OF APPROPRIATIONS


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. 93-586, §7, Aug. 7, 1974, 88 Stat. 422; Pub. L. 94-948, July 16, 1976, 90 Stat. 2952, §15(a)(1), (b)-(d), July 16, 1976, 90 Stat. 2952, §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, subsection (b) of this section will be administered as if paragraph (7) of subsection (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 such Act [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, and to 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 of Health, Education, and Welfare [now Health and Human Services], final regulations implementing the provisions of section 1861(v)(5) of the Social Security Act [subsec. (v)(5)] of this title.

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(s)(6) of the Social Security Act [subsec. (s)(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 1395f 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. 25611, provided:

Memorandum for the Secretary of Health and Human Services

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

Yet every day, all across America, patients are denied the kindnesses and caring of a loved one at their sides—whether in a sudden medical emergency or a prolonged hospital stay. Often, a widow or widower with no children is denied the support and comfort of a good friend. Members of religious orders are sometimes unable to choose someone other than an immediate family member to visit them and make medical decisions on their behalf. Also uniquely affected are gay and lesbian Americans who are often barred from the 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 visiting 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.

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. 1395ccc and other relevant provisions of law, and provide technical assistance on how hospitals participating in Medicare or Medicaid can best comply with the regulations and take any additional appropriate measures to fully enforce the regulations.

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

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

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

Barack Obama.

§ 1395y. Exclusions from coverage and medicare as secondary payer

(a) Items or services specifically excluded

Notwithstanding any other provision of this subchapter, no payment may be made under part A or part B 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(sx)(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 1320c–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

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

(G) in the case of prostate cancer screening tests (as defined in section 1395x(yy)(9) of this title), which are performed more frequently than is covered under such section,

(H) in the case of colorectal cancer screening tests, which are performed more frequently than is covered under section 1395m(d) of this title,

(I) the frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation,

(J) in the case of a drug or biological specified in section 1395w–3a(c)(6)(C) of this title for which payment is made under part B 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(xx)(1) of this title), which are performed more frequently than is covered under section 1395x(xx)(2) of this title,

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

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

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

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

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

(3) which are paid for directly or indirectly by a governmental entity (other than under this chapter and other than under a health benefits or insurance plan established for employees of such an entity), except in the case of rural health clinic services, as defined in section 1395x(aa)(1) of this title, in the case of Federally qualified health center services, as defined in section 1395x(aa)(3) of this title, in the case of services for which payment may be made under section 1395q(e) of this title, and in such other cases as the Secretary may specify;

(4) which are not provided within the United States (except for inpatient hospital services furnished outside the United States under the conditions described in section 1395f(f) of this title and, subject to such conditions, limitations, and requirements as are provided under or pursuant to this subchapter, physicians’ services and ambulance services furnished an individual in conjunction with such inpatient hospital services but only for the period during which such inpatient hospital services were furnished);

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

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

(7) where such expenses are for routine physical checkups, eyeglasses (other than eyewear 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 hygiene 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(i)(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) which are covered 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(z)(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(z)(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 (h)(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 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
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 subparagraph, 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 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:

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TITLE 42—THE PUBLIC HEALTH AND WELFARE

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(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 workers’ 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 workers’ 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 of the Secretary of the Treasury applicable to charges for late payments).

(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.
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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 accordance with subparagraphs (1) and (2)(A).

(B) Reference to excise tax with respect to nonconforming group health plans

For provision imposing an excise tax with respect to nonconforming group health plans, see section 5000 of the Internal Revenue Code of 1986.

(C) Prohibition of financial incentives not to enroll in a group health plan or a large group health plan

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–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.

(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) in the case of an item or service payment for which is determined under this subchapter on the basis of reasonable cost (or other cost-related basis) or under section 1395ww of this title, the amount which would be payable under this subchapter on such basis, and

(ii) in the case of an item or service for which payment is authorized under this subchapter on another basis—

(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(l)(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-
administration 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 such an inquiry as to the determinations described in subparagraph (A) that should have been submitted.

(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
(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); and

(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 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 time the item or service was ordered or furnished to the person.

(e) Item or service by excluded individual or entity; 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) 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 Internet website of the Centers for 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.
(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 1395f(i)(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 405.201(b) of title 42, Code of Federal Regulations (as in effect as of September 1, 2003));

(B) the trial meets criteria established by the Secretary to ensure that the trial conforms to appropriate scientific and ethical standards; and

(C) in the case of a trial initiated before January 1, 2010, the device involved in the trial has been determined by the Secretary to be intended for use in the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition.

(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.

Subsec. (a)(7). Pub. L. 108–173, § 611(d)(1)(B), substituted “(H), or (K)” for “or (H)”.
Subsec. (b)(2)(A). Pub. L. 108–173, § 301(b)(1), inserted at end of “and” appears “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 in whole or in part.”
Subsec. (b)(2)(A)(ii). Pub. L. 108–173, § 301(a)(1), struck out “promptly (as determined in accordance with regulations)” after “be expected to be made”.
Subsec. (b)(3). Pub. L. 108–173, § 301(b)(3), substituted “In order to recover payment made under this subchapter for an item or service, the United States may recover under this clause from any entity that has received 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.” for “Any payment under this subchapter with respect to any item or service to which subparagraph (A) applies shall be conditioned on reimbursement to the appropriate Trust Fund established by this subchapter when notice or other information is received that payment for such item or service has been or could be made under such subparagraph,” and “on the date notice of, or information related to, a primary plan’s responsibility for such payment or other information is received” for “on the date such notice or other information is received”.
Subsec. (b)(2)(B)(iii). Pub. L. 108–173, § 301(b)(3), substituted “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 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 or from the proceeds of a primary plan’s payment to any entity.” for “In order to recover payment made by a primary plan, the United States may bring an action against any entity which is required or responsible (directly, as a third-party administrator, or otherwise) to make payment with respect to such item or service (or any portion thereof) under a primary plan (and may, in accordance with paragraph (3)(A) collect double damages against that entity), or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service, and may join or intervene in any action related to the events that gave rise to the need for the item or service. The United States may, in accordance with paragraph (3)(A) collect double damages against any entity. If it is demonstrated that the United States was not provided with such information, it may bring an action against any or all entities that are or were required or responsible to make payment with respect to such 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 or from the proceeds of a primary plan’s payment to any entity.”

Subsec. (c). Pub. L. 101–239 repealed Pub. L. 100–360, §204(d)(2), and provided that the provisions of law amended or repealed by such section are restored or revived if as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (d). 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 room of a hospital’’.

Subsec. (e). 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. (f)(1). Pub. L. 100–203, §4039(c)(1)(B), inserted ‘‘in determining the amount subject to repayment under paragraph (2)(C),’’ after ‘‘(3),’’.


Subsec. (h). Pub. L. 100–93, §8(b)(3), substituted ‘‘sections (c), (f), and (g) of section 1320a–7a of this title’’ for ‘‘paragraphs (2) and (3) of subsection (d) of this section’’.

Subsec. (i)(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),’’.


Subsec. (b)(3)(A)(i). Pub. L. 99–272, §9201(a)(1), substituted ‘‘(to the spouse of such individual)’’ for ‘‘(to the spouse of such individual)’’.

Subsec. (b)(3)(A)(ii). 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 428(a) of this title’’.


Subsec. (b)(1). Pub. L. 98–369, §2344(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. 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 law, policy, plan, or insurance.’’
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. (c). Pub. L. 98–369, § 2313(c), added subsec. (c). 1980—Subsec. (a)(1). Pub. L. 96–611, § 1(a)(3)(A), inserted "policy, plan, or insurance" after "law or policy", and inserted provision authorizing the Secretary to waive the provisions of this subsection in the case of an individual claim if he determined that the probability of recovery or amount involved did not warrant the pursuit of the claim.


Subsec. (e). Pub. L. 96–499, § 933(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 this subchapter upon determining that such physician or practitioner had been convicted of a criminal offense related to such physician’s or practitioner’s involvement in the programs under this subchapter or the program under subchapter XIX of this chapter.

Subsec. (f). Pub. L. 97–248, § 122(g)(1), substituted "paragraph (1)(A)" for "paragraph (1)".


Subsec. (i). Pub. L. 97–35, § 2103(a), added subsec. (i). 1980—Subsec. (a)(1). Pub. L. 96–611, § 1(a)(3)(A), inserted "", or, 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" after "of a malformed body member".

Subsec. (a)(7). Pub. L. 96–611, § 1(a)(3)(B), inserted "except as otherwise allowed under section 1395x(s)(10) of this title and paragraph (1)" after "immunizations".

Subsec. (a)(12). Pub. L. 96–499, § 936(c), inserted "or because of the severity of the dental procedure," after "and clinical status".


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 "policy, plan, or insurance" after "law or policy" and inserted provision authorizing the Secretary to waive the provisions of this subsection in the case of an individual claim if he determined that the probability of recovery or amount involved did not warrant the pursuit of the claim.


Subsec. (e). Pub. L. 96–499, § 933(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 this subchapter upon determining that such physician or practitioner had been convicted of a criminal offense related to such physician’s or practitioner’s involvement in the programs under this subchapter or the program under subchapter XIX of this chapter.

Subsec. (f). Pub. L. 97–248, § 122(g)(1), substituted "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 1395c–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.


1975—Subsec. (c). Pub. L. 94–182 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 benefits plan under chapter 89 of Title 5 was made which would allow a Federal employee benefits under part A or B of this subchapter.


1973—Subsec. (a)(12). Pub. L. 93–283 substituted "the provision of such dental services if the individual, because of his underlying medical condition or status, requires hospitalization in connection with the provision of such services" for "a dental procedure
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 references 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 under part A in the case of inpatient hospital services furnished an individual in conjunction with emergency inpatient hospital services.


1968—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 1395f of this title.

Effective Date of 2008 Amendment

Amendment by section 101(a)(3), (b)(3), (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 1395f of this title.

Pub. L. 110–275, title VII, § 731(b)(2), Dec. 8, 2003, 117 Stat. 2427, provided that: ‘‘The amendments 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 411.15(c) of title 42, Code of Federal Regulations, is superseded to the extent inconsistent with section 1862(m) of the Social Security Act [subsec. (m) of this section], as added by such paragraph.’’

Pub. L. 110–275, title IX, § 948(a)(2), Dec. 8, 2003, 117 Stat. 2423, provided that: ‘‘The amendment made by paragraph (1) [amending this section] shall apply to local coverage determinations made on or after January 1, 2004.’’

Amendment by section 948(a) of Pub. L. 108–173 effective, except as otherwise provided, as if included in the enactment of BIPA [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 amendments 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. 1077, 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 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 request for a national or local coverage determination filed, a request to make such a determination, 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 section 1(a)(6) (title V, § 522(b)) of Pub. L. 106–554 applicable with respect to a request for a national or local coverage determination filed, a request to make such a determination, 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.
services provided on or after such date, subject to being applicable with respect to contracts entered into, renewed, or extended after Apr. 30, 1997, as well as contracts entered into before April 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 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 1395b-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 cost reporting periods beginning 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 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 4432(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 1395f-3 of this title.

Amendment by section 4507(c)(2)(D) 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 1395f-5 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 4614(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.

Amendment by section 4632(b) 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.

Amendment by section 4746(e)(6) of Pub. L. 105-33 effective as if included in the enactment of Pub. L. 101-508, see section 4746(g) of Pub. L. 105-33, set out as a note under section 13936a-3a of this title.

Section 151(a)(2)(B) of Pub. L. 103-432 provided that: "The amendment made by subparagraph (A) [amending this section] shall apply with respect to items and services furnished on or after the expiration of the 120-day period beginning on the date of the enactment of this Act [Oct. 31, 1994]."

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. 104-66.

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. 104-66.

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. 101-239.

Amendment by section 156(a)(2)(D) 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.

Section 157(b)(6) of Pub. L. 103-432 provided that: "The amendments made by this subsection [amending this section, section 1395mm of this title, and provisions set out as notes under section 1395mm 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 15661(c)(6) 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]."

Amendment by section 15661(d)(1) of Pub. L. 103-66 effective 90 days after Aug. 10, 1993, see section 15661(d)(3) of Pub. L. 103-66, set out as a note under section 5000 of Title 26, Internal Revenue Code.


Section 1583(d)(4) of Pub. L. 103-66 provided that: "The amendments made by this section [enacting section 1320b-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)(B) 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(c)(1) 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)(4) of Pub. L. 101-508, set out as a note under section 1396x of this title.

Amendment by section 4163(d)(2)(A) of Pub. L. 101-508, as added, set out as a note under section 1396v 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]."
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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)(9) of Pub. L. 101–239, set out as a note under section 152 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.”

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 201 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 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 not apply to items or 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.

The amendments made by this section [amending this section] shall take effect on January 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 4034(b) of Pub. L. 100–203 provided that: “The amendment made by subsection (a) [amending this section] shall be effective with respect to changes made after the date of the enactment of this Act [July 18, 1988].”

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 shall be effective with respect to items and services furnished on or after Jan. 1, 1986.”

For effective date of amendment by section 4972(c) 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.

Amendment by Pub. L. 100–93 effective at end of four-teen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 15(a) of Pub. L. 100–93, set out as a note under section 1320a–7 of this title.

Effective Date of 1985 Amendments

Amendment by Pub. L. 99–509 applicable to items dispensed on or after Jan. 1, 1990, see section 6202(b) of Pub. L. 99–509, set out as a note under section 1395k of this title.

The amendment made by subsection (c) [amending this section] shall become effective on the date of the enactment of this Act [July 18, 1984].”

Amendment by section 2344(d) of Pub. L. 98–369 provided that: “The amendments made by this section [amending this section] shall take effect on 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 1395xx 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. 97–364, see section 309(c)(2) of Pub. L. 97–448, set out as a note under section 1320a–1 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–1 of Title 29, Labor.

Amendment by section 122(f), (g)(1) of Pub. L. 97–248 applicable to hospice care provided on or after Nov. 1,
1983, see section 122(h)(1) of Pub. L. 97–248, as amended, set out as a note under section 1395c of this title.

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(e)(2) of Pub. L. 97–248, set out as a note under section 1395x of this title.

Amendment by sections 142 and 148(a) of Pub. L. 97–248 effective with respect to contracts entered into on or after July 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 1395f 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 1395f of this title.

Section 936(b) of Pub. L. 96–499 provided that: "The amendments made by subsection (a) [amending this section] shall apply with respect to services furnished with respect to admissions occurring after Dec. 31, 1973, see section 18(2–3)(2) of Pub. L. 93–238, set out as a note under section 1395f of this title.

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. 92–603, set out as a note under section 1395f of this title.

Effective Date of 1972 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 1395x of this title.

Construction 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.

Notwithstanding section 303(a)(1) 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.


Pub. L. 108–173, title IX, §943, Dec. 8, 2003, 117 Stat. 2422, provided that: "(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 1882(b) of the Social Security Act [subsec. (b) of this section] (relating to Medicare secondary payor 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 A 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 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 I, §111(b), Dec. 29, 2007, 121 Stat. 2499, 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 461(a)(2) of Pub. L. 103–33 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 [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))."

RETROSPECTIVE EXEMPTION FOR CERTAIN SITUATIONS INVOLVING RELIGIOUS ORDERS

Section 1358(f)(1) of Pub. L. 103–66 provided that: "Section 1862(b)(1)(C) of the Social Security Act [subsec. (b)(1)(C) 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 had not identified as the 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 by not later than 14 days after the date of the enactment of this Act [Dec. 19, 1989]."

IGHT OF CERTIFICATION AS HEART TRANSPLANT FACILITY

Section 4009(b) of Pub. L. 100–203 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 1165(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. 1395f(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)(15) of the Social Security Act [subsec. (a)(1)(C) of this section], apply (under section 1862(b)(1)(A) of such Act [section 1395f(a)(15)] added by section 9305(f) of Pub. L. 99–509, set out above, and section 9126(c) of Pub. L. 99–272, set out below) 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 10008(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 MEMBERS RELATING TO LARGE GROUP HEALTH PLANS AND MEDI-CAIRE AS SECONDARY PROVIDER

Section 9315(e) of Pub. L. 100–599 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 1395r 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.

REINSTATEMENT OF WAIVER OF LIABILITY PRESUMPTION

Section 9126(c) of Pub. L. 99–272, as amended by Pub. L. 100–365, 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 1862(b)(1)(A) of the Social Security Act [enacting section 5000 of Title 26, Internal Revenue Code, and amending this section and sections 1395p and 1395r of this title] on access of disabled individuals and family members."

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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


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 circling other surgical procedures for which an assistant at consultation, develop recommendations and guidelines respecting other surgical procedures for which an assistant at surgery was generally not medically necessary and circling other surgical procedures for which an assistant at consultation, develop recommendations and guidelines respecting other surgical procedures for which an assistant at surgery was generally not medically necessary. For the implementation of, the guidelines described in subsection (a) of this section, the Secretary shall provide, pursuant to section 1862(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 services (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 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(c)(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(c)(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]."]"

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 1395 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 or removed 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 1862(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 services (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 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(c)(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(c)(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, enacted 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(c)(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(c)(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]."]"

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.
§ 1395z. 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),1 (o)(6), (cc)(2)(I), and 2/dd)(2), and (mm)(1) of section 1395x of this title, or by ambulatory surgical centers under section 1395k(a)(2)(F)(i) 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 (j)(3)”.

1989—Pub. L. 101–239 substituted “(jj)(3)”, and (mm)(1)” for “and (jj)(3)”.

1 See References in Text note below.

2 So in original. The word “and” probably should not appear.
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.

Amendment by Pub. L. 92–665 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. 92–463, set out as a note under section 1395k of this title.

AMENDMENT

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. 770, 776, 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 1395k(2)(B) of this title, or whether an ambulatory surgical center meets the standards specified under section 1395k(a)(2)(P)(i) of this title. To the extent that the Secretary finds it appropriate, an institution or agency which has such an agreement may (subject to approval of the Secretary) furnish to a skilled nursing facility, after proper request by such facility, such specialized consultative services (which such agency is able and willing to furnish in a manner satisfactory to the Secretary) as such facility may need to meet one or more of the conditions specified in section 1395l–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, clinic, 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 or services 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 this 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, whether corrective actions have been taken or are planned, and the sanctions, if any, imposed under this subchapter with respect to the agency) 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...
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(c)(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).


1996—Subsec. (a). Pub. L. 104–134, in first sentence, substituted “or whether screening mammography meets the standards established under section 1395m(c)(3) of this title” after “section 1395cc of this title” for “whether screening mammography satisfies the standards established under section 1395m(c)(3) of this title”.

1990—Subsec. (a). Pub. L. 101–508, § 4207(g), formerly § 4027(g), as renumbered by Pub. L. 103–432, § 145(c)(3), substituted “section 1395m(c)(3) of this title” for “section 1395m(c)(3) of this title” in first sentence.

1989—Subsec. (a). Pub. L. 101–239, § 6113(c), substituted “paragraphs (15) and (16)” for “paragraphs (14) and (15)”.

1987—Subsec. (a). Pub. L. 100–342, § 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 1395cc of this title” first sentence.

1986—Subsec. (c). Pub. L. 100–203, title IV, § 4027(g), as added Pub. L. 100–342, § 160(a)(1)(B), substituted “section 1395cc of this title” for “section 1395m(c)(3) of this title” in first sentence.

1984—Subsec. (a). Pub. L. 98–369, div. B, title III, § 2354(b)(17), struck out “of a significant deficiency or deficiencies which would, if found to be present, adversely affect health and safety of patients,” after “such facility or entity with any requirement of this subchapter (other than any fee relating to section 263a of this title)”.


1981—Subsec. (a). Pub. L. 97–248, title I, § 122(g)(3), July 1, 1988, 102 Stat. 728, 729, 774, substituted at end “or whether screening mammography meets the standards established under section 1395m(c)(3) of this title” for “whether screening mammography satisfies the standards established under section 1395m(c)(3) of this title”.


References in Text

Part A of this subchapter, referred to in subsec. (b), is classified to section 1395cc et seq. of this title.

Amendments


Subsec. (e). Pub. L. 101–508, § 4166(c)(2), inserted before period at end of first sentence “of any fee relating to section 263a of this title”.

1990—Subsec. (a). Pub. L. 101–508, § 4163(c)(2), inserted before period at end of first sentence “or whether screening mammography meets the standards established under section 1395m(c)(3) of this title” after “section 1395cc of this title”.


1989—Subsec. (a). Pub. L. 101–239, § 6113(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(m)(1)(C) of this title,” after “section 1395m(a)(1)” in first sentence.

Pub. L. 101–234 repealed Pub. L. 100–360, §§ 203(a)(3), 209(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.


Pub. L. 100–360, §411(d)(4)(A)(ii), as added by Pub. L. 100–485, §608(d)(20)(B)(ii), substituted “utilized by the Secretary under section 1395bb of this title” for “such agency to maintain a unit”.

Pub. L. 100–360, §411(d)(4)(A)(i)(I), as added by Pub. L. 100–485, §608(d)(20)(C), substituted “such State or local agency to maintain a unit” for “such agency to maintain a unit”.

Pub. L. 100–360, §411(d)(4)(A)(i)(II), as added by Pub. L. 100–485, §608(d)(20)(D), substituted “utilized by the Secretary under section 1395bb of this title” for “pursuant to an agreement with the Secretary under this subchapter”.

Pub. L. 100–360, §204(d)(3), substituted “paragraphs (14) and (15)” for “paragraphs (13) and (14)”.

Pub. L. 100–360, §204(c)(2), inserted, or whether sequential mammmography meets the standards established under section 1395m(e)(3) of this title” after “section 1395a(a)(2)(F) of this title”.

Pub. L. 100–360, §203(e)(3), inserted, or whether an intravenous drug therapy provider, after “hospice program” and substituted “hospice program, or home intravenous drug therapy provider” for “or hospice program”.

1987—Subsec. (a). Pub. L. 100–203, §422(b), directed an amendment of subsec. (a) identical to Pub. L. 100–203, §422(c), was amended generally by Pub. L. 100–360, §204(d)(3), so that it does not amend this section but rather section 1396b of this title.

Pub. L. 100–203, §4202(c), inserted, or whether in the case of skilled nursing facilities the posting in a physical readily accessible to patients (and patients’ representatives) after “place” in fifth sentence.

Pub. L. 100–203, §4201(d)(4), as added by Pub. L. 100–360, §411(l)(1)(C), as added by Pub. L. 100–485, §608(d)(27)(B), substituted “conditions specified in section 1395x–3(a) of this title” for “conditions specified in section 1395x–3(a) of this title”.

Pub. L. 100–203, §4072(d), substituted “paragraphs (13) and (14)” for “paragraphs (12) and (13)” in first sentence.

Pub. L. 100–203, §4025(a), inserted at end “Any agreement under this subchapter 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 this subchapter (which information shall include any significant deficiencies found with respect to patient care in the most recent certification survey conducted with respect to the agency), when that survey was completed, whether corrective actions have been taken or are planned, and the sanctions, if any, imposed under this subchapter with respect to the agency 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 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 pursuant to an agreement with the Secretary under this section, and consumer medical records (but only with the consent of the consumer or his or her legal representative).”

Subsec. (d). Pub. L. 100–203, §4203(a)(1), inserted before period at end “and the establishment of remedies under sections 1395l–3(h)(1) and 1395l–3(h)(2)(C) of this title (relating to establishment and application of remedies)”.

Pub. L. 100–203, §4202(a)(1), inserted “and section 1395i–3(g)(1) of this title” before period at end.


1988—Subsec. (a). Pub. L. 99–599 substituted “paragraphs (12) and (13)” for “paragraphs (11) and (12)”.

1984—Subsec. (a). Pub. L. 98–599 struck out “the” after “Joint Commission on”.

1982—Subsec. (a). Pub. L. 97–248 inserted “or whether an agency is a hospice program” and substituted “home health agency, or hospice program” for “or 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”.

Pub. L. 96–499, §934(c)(2), substituted “or a comprehensive outpatient rehabilitation facility as defined in section 1395x(cc)(2) of this title” after “section 1395x(aa)(2) of this title” and “comprehensive outpatient rehabilitation facility” after “rural health clinic” in four places.

Pub. L. 96–499, §934(c)(2), inserted “or whether an ambulatory surgical center meets the standards specified under section 1395x(aa)(2)(F) of this title” after “section 1395x(p)(4) of this title” and “ambulatory surgical center” after “health care facility,” in three 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), 299A(d), 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”.


1968—Subsec. (a). Pub. L. 90–248, §133(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.

Pub. L. 90–248, §228(b), struck out last sentence providing for utilization of State facilities to provide consultative services to institutions furnishing medical care, covered in section 1396a(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(d) 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 1395x 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 1395x 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) 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 1395x of this title.

Effective Date of 1999 Amendment

Section 4154(d)(2) of Pub. L. 101–508 provided that: “The amendment made by paragraph (1) amending this

§1395aa
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 4165(c)(2) of Pub. L. 101–508 applicable to screening mammography performed on or after Jan. 1, 1991, see section 4165(e) of Pub. L. 101–508, set out as a note under section 1395f of this title.

**Effective Date of 1989 Amendments**

Amendment by section 6115(c) 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 Pub. L. 101–234 effective Jan. 1, 1990, see section 201(c) of Pub. L. 101–234, set out as a note under section 1393a–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 608(g)(1) of Pub. L. 100–485, set out as a note under section 704 of this title.

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

Amendment by section 204(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)(A), (B)(i), (C), (D) 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**

Section 4025(c), formerly §4025(b), of Pub. L. 100–203, as redesignated and amended by Pub. L. 100–360, title IV, §411(d)(4)(A), (B)(i), July 1, 1988, 102 Stat. 774, provided that: "The amendment made by this section [amending this section and section 1395b of this title] shall apply with respect to agreements entered into or renewed on or after the date of enactment of this Act [Dec. 22, 1987]."

For effective date of amendment by section 4027(d) of Pub. L. 100–203, see section 4027(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 4202a(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 1385–3 of this title, see section 4203a(j) of Pub. L. 100–203, as amended, set out as an Effective Date note under section 1385–3 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 1385–3 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 1395–3(b), (c), or (d) of this title is deemed a reference to section 1395x(i)(1) of this title, see section 4203b of Pub. L. 100–203, as added by Pub. L. 100–485, set out as an Effective Date note under section 1395–3 of this title.

**Effective Date of 1986 Amendment**

Amendment by Pub. L. 99–508 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(1), (c) of Pub. L. 99–508, 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(e)(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. 96–611 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 1395f of this title.

For effective date of amendment by section 933(g) of Pub. L. 96–499, see section 933(h) of Pub. L. 96–499, set out as a note under section 1395k of this title.

**Effective Date of 1977 Amendment**

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**

Section 299(c) of Pub. L. 92–603 provided that: "The provisions of this section [amending this section and section 1396a of this title] shall be effective beginning January 1, 1973, or within 6 months following the enactment of this Act (Oct. 30, 1972), whichever is later.''

**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(c)(2)(A) of such Act [section 1819(c)(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 (4)) by the American Osteopathic Association or any other national accreditation body demonstrates that all of the applicable conditions or requirements of this subchapter (other than the 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 shall 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 approve 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 accreditation determinations made on or after such effective date (which may not be later than the date of publication of the approval) as the Secretary specifies in the publication notice.

(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 1395aa(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. (b). Pub. L. 110–275, § 125(a), (b)(1)(B), redesignated subsec. (c) as (b), substituted “Secretary” for “Secretary by”. Former subsec. (a) 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. (c) as (d).

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 section 1395x(aa)(2)(F)(1), 1395x(e)(3), 1395x(f), 1395x(g), 1395x(p)(4)(A), or (B), paragraphs (15) and (16) of section 1395x(s), section 1395aa(a)(2), 1395x(cc)(2), 1395x(dd)(2), or 1395x(mm)(1) of this title, as the case may be, are met, he may, to the extent he deems it appropriate, treat such survey as meeting the condition or conditions with respect to which he made such finding,” and redesignated fourth sentence as subsec. (c).


Subsec. (c). Pub. L. 104–134, §101(d) [title V, §516(c)(2)], redesignated fourth sentence of subsec. (a) as subsec. (c).

Subsec. (d). Pub. L. 104–134, §101(d) [title V, §516(b)(1), (c)(2)(A)], redesignated subsec. (b) as (d) and subsec. (d) as (c)(2)(A), and provided that the provisions of law amended or repealed by such section are restored or revived as the case may be, met, he may, to the extent he deems it appropriate, treat such survey as meeting the condition or conditions with respect to which he made such finding,” and redesignated fourth sentence as subsec. (c).


1989—Subsec. (a). Pub. L. 101–239, §6115(c), substituted “paragraphs (15) and (16)’’ for “paragraphs (14) and (15)’’.

Pub. L. 101–239, §6101(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, §111(d)(4)(B)(iv)(I), substituted “1395x(dd)(2), or 1395x(mm)(1) of this title” for “or 1395x(dd)(2) of this title” in third sentence.

Pub. L. 101–234 repealed Pub. L. 100–360, §290(c)(3), (d)(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 and 1989 Amendment notes.

Subsec. (a)(2). Pub. L. 103–423, §6010(a), designated existing provisions as subpar. (A), struck out “(if it is included within a survey described in section 1395aa(c) of this title)” after “institution,” inserted “together with any other information directly related to the survey as the Secretary may require (including corrective action plans)” after “by such Commission,” and added subpar. (B).

Subsec. (b). Pub. L. 101–239, §6019(c), struck out “following a survey made pursuant to section 1395aa(c) of this title” after “If the Secretary finds”.


Pub. L. 100–360, §290(d)(3), substituted “paragraphs (14) and (15)” for “paragraphs (13 and (14))” in third sentence.

Pub. L. 101–203, §4027(d), substituted “paragraphs (13 and (14)” for “paragraphs (12 and (13)” in penultimate sentence.


1986—Subsec. (a). Pub. L. 99–509, §9305(c)(3), inserted “requires a discharge planning process (or imposes another requirement which serves substantially the same purpose)” after “the same purpose),” and “clause (A) or (B) of” after “comply also with” in second sentence.


1984—Subsec. (a). Pub. L. 98–369, §2246(a), in provisions following par. (4), substituted “section 1395x(aa)(2)(F)(1), 1395x(e), 1395x(f), 1395x(g), 1395x(p)(4)(A) or (B), paragraphs (15) and (16) of section 1395x(s), section 1395aa(a)(2), 1395x(cc)(2), or 1395x(dd)(2)” for “section 1395x(e), (j), (o), or (dd) of this title,” and substituted “entity” for “institution or agency” in two places.

Pub. L. 98–369, §2345(a), struck out “on a confidential basis” after “release to the Secretary” in par. (2), and inserted provision that the Secretary may not disclose any accreditation survey made and released to him by the Joint Commission on Accreditation of Hospitals, the American Osteopathic Association, or any other national accreditation body, of an entity accredited by such body, in provisions following par. (4).

1982—Subsec. (a). Pub. L. 97–298, §122(g)(4), substituted “(o)” for “(or o)”.

Subsec. (b). Pub. L. 97–298, §128(d)(3), substituted “a hospital” for “an institution” and “the hospital” for “such institution”.

1972—Pub. L. 92–603 designated existing provisions as subsec. (a), inserted reference to subsec. (b) of this section in opening provisions, redesignated existing provisions as pars. (1) and (3) and added pars. (2) and (4) and in provisions following par. (4) inserted provisions for the imposition of a standard which the Secretary determines is at least equivalent to a survey conducted by the Secretary as described in par. (4), and added subsec. (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, 1396x, 1395aa, and 1396I 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 the hospital has been treated as substantially equivalent to the standards set by 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 263b(b) of this title apply to such mammography conducted by such facility, see section 145(d) of Pub. L. 103–432, set out as a note under section 1395m of this title.

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 1395m 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 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 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(l), (k) of Pub. L. 99–509, as amended, set out as notes under section 1395x of this title.

**Effective Date of 1984 Amendment**

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], 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)(1) 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(c) 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 1395(g) 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 and shall be eligible for payments under this subchapter if it files with the Secretary an agreement—

(A)(ii) not to impose any charge that is prohibited under section 1396a(n)(3) of this title,

(B) not to charge any individual or any other person for items or services for which such individual is not entitled to have payment made 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 1395y(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 who 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 validity of diagnostic information provided by such hospital, the completeness, adequacy, and quality of care provided, the appropriateness of admissions and discharges, and the appropriateness of care provided for which additional payments are sought under section 1395ww(d)(5) of this title, with respect to inpatient hospital services 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 which provide covered skilled nursing facility services—

(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 1395yy(e)(2)(A)(ii) of this title) furnished by the skilled nursing facility or otherwise under arrangements (as defined in section 1395w(w)(1) of this title) made by the skilled nursing facility.

(I) in the case of a hospital or critical access hospital—

(i) 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—

(i) the individual’s rights to benefits for inpatient hospital services and for post-hospital services under this subchapter,

(ii) the circumstances under which such an individual will and will not be liable for charges for continuous stay in the hospital,

(iii) the individual’s right to appeal denials of benefits for continued inpatient hospital services, including the practical steps to initiate such an appeal, and

(iv) 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—

(i) to make available to its patients the directory or directories of participating physicians (published under section 1395w(h)(4) of this title) for the area served by the hospital or critical access hospital,

(ii) 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,

(iii) 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

(iv) to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital participates in the medicare 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 (i) 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)(i) 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—

(i) the nature of such financial interest,

(ii) the number of individuals who were discharged from the hospital and who were identified as requiring home health services, and

(iii) 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—

(i) under the contract health services program funded by the Indian Health Service
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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) of such Act [29 U.S.C. 697(b)], to comply with the Bloodborne Pathogens standard under section 1910.1039 of title 29 of the Code of Federal Regulations (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) 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 requirements 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(f)(b), or section 1395x(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 an individual eligible for such 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 such 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 1395(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 1395(t)(5) 1 of this title. In the case of items and services described in section 1395(a)(8) of this title or section 1395(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 also 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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2 So in original. The comma probably should be preceded by a closing parenthesis.
3 So in original. Probably should be preceded by “section”.
4 So 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 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 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 be made under this subchapter, such provider, notwithstanding the preceding provisions of this subchapter, the cost of such an agreement to the hospital, critical access hospital, facility, or agency involved, for which payment may be made under this subchapter.

(C) Such payments—

(i) shall be transferred in appropriate proportions from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical 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

(ii) shall not be less in the aggregate for a fiscal year—

(I) in the case of hospitals, than the amount specified in paragraph (1)(F)(i)(III), and

(II) in the case of facilities, critical access hospitals, and agencies, than the amounts the Secretary determines to be sufficient to cover the costs of such organizations’ conducting the activities described in subparagraph (A) with respect to such facilities, critical access hospitals, or agencies under part B of subchapter XI of this chapter.

(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—

(A) 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,

(B) has determined that the provider fails substantially to meet the applicable provisions of section 1395x 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 subsection (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. 661 et seq.] for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(U)5 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.

(c) 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

5So in original. Probably should be subsection "(a)(1)(V)".
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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 reason therefor has 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)(1)(A) of this title (or meets the requirements of such section through the operation of subsection (g) or (h)(2) of section 1396x 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 (h)(2) of section 1396x of this title)

(2) a community mental health center (as defined in section 1395x(ff)(3)(B) of this title), or

(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(I), 1395mm(c)(8), and 1395bbb(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 each 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 medical record whether or not the individual has executed an advance directive;

(C) not to condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive;

(D) to ensure compliance with requirements of State law (whether statutory or as recognized by the courts of the State) respecting advance directives at facilities of the provider or organization; and

(E) to provide (individually or with others) for education for staff and the community on issues concerning advance directives.

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 coming under the care of the agency;

(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) and relating to the provision of such care when the individual is incapacitated.

(4) For construction relating to this subsection, see section 14406 of this title (relating to clarification respecting assisted suicide, euthanasia, and mercy killing).

(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(a) 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(j) 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—

(A) a criminal background check;

(B) fingerprinting;

(C) unscheduled and unannounced site visits, including preenrollment site visits;

(D) database checks (including such checks across States); and

(E) 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 pre-payment review and payment caps, under the program under this subchapter, the Medicaid program under subchapter XIX,6 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–7(h)(f) of this title), has been excluded from participation under the program under this subchapter, the Medicaid 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 the program 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 as the obligated provider of services or supplier under such subchapter, 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) 7 Compliance programs

(A) In general

On or after the date of implementation determined by the Secretary under subpara-

6 So in original. Probably should be a comma.

7 So in original. Two pars. (8) have been enacted.
Quality reporting by cancer hospitals

§1395cc

§ 1395cc

(1) Quality measures

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 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 that is dissatisfied with a determination by the Secretary.

(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 1395aaa(a) of this title 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.

(B) 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.


Subsec. (h)(1). Pub. L. 108–173, § 932(b), (c)(1), designated existing provisions as subpar. (A) and added subpars. (B) and (C).


2000—Subsec. (a)(1)(H)(11)(I). Pub. L. 106–554 inserted "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) after "skilled nursing facility""


Subsec. (a)(2)(D). Pub. L. 105–33, § 4541(a)(3), which directed the amendment of subsec. (a)(2)(A)(ii) by inserting the following at the end "In the case of services described in section 1395x(a)(8) of this title or section 1395x(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, the applicable copayment amount established under section 1395l(t)(5) of this title," was executed by inserting the material in the end of subpar. (A) to reflect the probable intent of Congress.


Subsec. (f)(1)(B). Pub. L. 105–33, § 4391(a), substituted "in a prominent part of the individual's current medical record" for "in the individual's medical record".


Subsec. (d). Pub. L. 103–432, § 106(b)(1)(B), substituted "long-stay cases in a hospital" for "long-stay cases in a hospital or skilled nursing facility", "such hospital" for "such hospital or facility" in two places, "period of such services" for "period of such services or for post-hospital extended care services after such day of a continuous period of such care as is prescribed in or pursuant to regulations, as the case may be", and "notice to the hospital" for "notice to the hospital, or (in the case of a skilled nursing facility) to the facility and the hospital or hospitals with which it has a transfer agreement".


1993—Subsec. (h)(1). Pub. L. 103–296 inserted before period at end "; except that, in so applying such sections and in applying section 406(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".

"In the case of services described in section 1395x(a)(8) of this title or section 1395x(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, the applicable copayment amount established under section 1395l(t)(5) of this title," was executed by inserting the material in the end of subpar. (A) to reflect the probable intent of Congress.


Pub. L. 102–54 substituted “Secretary of Veterans Affairs” for “Administrator of Veterans Affairs”.


(a)(1)(H). Pub. L. 101–508, § 4157(c)(2), inserted “services delivered by section 1395a(s)(2)(K)(1) of this title, certified nurse-midwife services, qualified psychologist services, and” after “and other”.

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, § 4122(b), substituted “includes” and pars. (1) and (2) for “includes” and paragraphs (1) and (2) for “includes” and paragraphs (1) and (2) for “includes” and paragraphs (1) and (2) for “includes” and paragraphs (1) and (2) for “includes” and paragraphs (1) and (2) for “includes”.


Pub. L. 102–54 substituted “Secretary of Veterans Affairs” for “Administrator of Veterans Affairs”.


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


Pub. L. 100–203, § 4097(b), see 1987 Amendment note below.


Subsec. (a)(1)(O), Pub. L. 100–360, § 411(c)(2)(A)(ii), substituted “(a)” for “(a)”.

Pub. L. 100–89, § 608(f)(1), struck out subsec. (f) which provided for termination or decertification and alternatives thereto.
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managing employee (as defined in section 1320a–5(b) of this title) of such provider, is a person described in section 1320a–5(a) of this title.”

Subsec. (a)(3)(C)(II). Pub. L. 100–203, § 4107(b), amended subsec. (b) generally, substituting pars. (1) to (3) for former part (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 the 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 1396l(a) 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”.


Subsec. (b). Pub. L. 98–369, § 2335(d)(2), substituted “for ‘(including inpatient psychiatric hospital services)’” for “for ‘(including inpatient hospital services)’”.

Subsec. (d). Pub. L. 98–369, § 2335(d)(1), substituted “more than 30 days after such effective date” for “after the calendar year in which such termination is effective”.

Subsec. (a)(1). Pub. L. 98–99, § 2436(b)(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 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.

Subsec. (a)(1)(F). Pub. L. 98–21, § 602(c)(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. 98–21, § 1247(a)(2), 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)(i). Pub. L. 98–21, § 602(c)(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 subcl. (I).


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. (b)(4)(A). Pub. L. 97–248, § 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 (i) of the first sentence of this subparagraph with respect to items and services described in section 1395ww(d) of this title for which payment is made under part A as “reasonable cost”.

Subsec. (c). Pub. L. 92–603, § 249A(c)(4), redesignated subsec. (a)(3) as (2a), redesignated existing provisions as subcl. (i) and added subcl. (ii).

Subsec. (b)(2)(F). Pub. L. 95–292, §§ 227(b)(2), redesignated “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 1396d(a) of this title” for “section 1396d of this title”.

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 1395sw 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 and section 1395f of this title] 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 1395i–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(j)(1) of the Social Security Act [subsec. (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(j)(2) of the Social Security Act [former subsec. (j)(2), now subsec. (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(j)(3) of the Social Security Act [former subsec. (j)(3), now subsec. (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."

Pub. L. 108–173, title IX, §947(b), Dec. 8, 2003, 117 Stat. 2425, provided that: "The amendments made by this section [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 effective as if included in the enactment of Pub. L. 103–432, set out as a note under section 1330a–3a 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 Amendments**

Section 4008(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)(3) 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 1396k 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.

Amendment by section 4206(a) 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(c)(1) of Pub. L. 101–508, set out as a note under section 1395i–3 of this title.

**Effective Date of 1989 Amendments**

Section 6018(b) of Pub. L. 101–239 provided that: "The amendments made by subsection (a) [amending this
Section 4214(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-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 4214(a), (b)(2) of Pub. L. 100–203, set out as a note under section 1320a–7 of this title.

**Effective Date of 1988 Amendments**

Amendment by section 202(h)(1) of Pub. L. 100–360 applicable to items dispensed on or after Jan. 1, 1990, set out as a note under section 1395u of this title.


Amendment by section 104(d)(5) of Pub. L. 100–360 effective Apr. 1, 1988, except as otherwise provided, as if included in the enactment of Pub. L. 100–360, set out as a note under section 1395m of this title.

Section 1396a(a)(1)(M) of this section not later than six months after the date of enactment of Pub. L. 100–360, as amended, set out as a note under section 1395l of this title.

Amendment by section 202(h)(1) of Pub. L. 100–360 applicable to items dispensed on or after Jan. 1, 1990, set out as a note under section 1395l of this title.

Amendment by section 402(a) of Pub. L. 100–203 applicable to admissions occurring on or after Apr. 1, 1988, or, if later, the earliest date the Secretary can provide the information required under section 4012(c) of Pub. L. 100–203 (42 U.S.C. 1395mm note) in machine readable form, see section 4012(d) of Pub. L. 100–203, set out as a note under section 1395mm of this title.

Amendment by section 4062(d)(4) of Pub. L. 100–203 applicable to covered items (other than oxygen and oxygen equipment) furnished on or after Jan. 1, 1990, and to oxygen and oxygen equipment furnished on or after June 1, 1989, see section 4062(e) of Pub. L. 100–203, as amended, set out as a note under section 1395f of this title.

Section 4965(c)(1) of Pub. L. 100–203 provided that the amendment made by such section 4965(c)(1) is effective as if included in the enactment of Pub. L. 100–509.

Section 4965(c)(1) of Pub. L. 100–203 provided that: "The amendments made by this section [amending this title] 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 4214(a), (b)(2) of Pub. L. 100–203, as amended, set out as an Effective Date note under section 1396r of this title.
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 1395x of this title.

Amendment by section 309(c)(1) of Pub. L. 97–248, set out as a note under section 1395w 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 1395w 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 eleventh 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 1396a, 1396d, and 1396l 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), 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 the accounting periods beginning after Dec. 31, 1972, see section 223(h) of Pub. L. 92–603, set out as a note under section 1395x 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 1396x 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 1866 of the Social Security Act [this section] by skilled nursing facilities (as defined in section 1861(i) of such Act [section 1382i(x) 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 1395gg of this title.

**Effective Date of 1968 Amendment**

Amendment by section 128(c)(2) of Pub. L. 90–248 applicable with respect to services furnished after Mar. 31, 1968, see section 128(d) of Pub. L. 90–248, set out as a note under section 1395d 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 1395k 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 1395c of this title.

**Regulations**

Pub. L. 108–173, title VI, § 650(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. 111–114, title VI, §6401(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. 1397aa 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 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**


(a) Report.—Not later than two years after the date of the enactment of this Act [July 15, 2008], the Inspector General of the Department of Health and Human Services shall prepare and publish a report on—

"(1) the extent to which Medicare providers and plans are complying with the Office of Civil Rights' Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons and the Office's Culturally and Linguistically Appropriate Services Standards in health care; and

"(2) a description of the costs associated with or savings related to the provision of language services. Such report shall include recommendations on improving compliance with CLAS Standards and recommendations on improving enforcement of CLAS Standards.

(b) Implementation.—Not later than one year after the date of publication of the report under subsection (a), the Secretary of Health and Human Services shall implement changes responsive to any deficiencies identified in the report."

**GAO Study and Report on the Propagation of Concierge Care**


(a) Study.—

"(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. 1395u 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(l)(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 1395d and 1395m 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 1886 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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paragraph (1) for the reasons described in that 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 the 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. 98–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance.] Section 9122(d) of Pub. L. 98–21 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 the 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. 101–66, 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], 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 agreement, filed by a skilled nursing facility (as defined in section 1861(j) of the Social Security Act [section 1395(j) of this title]) with the Secretary under section 1866 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 furnishing 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 would be expended if the demonstration projects under this section were not implemented.


REFERENCES IN TEXT

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–515, 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-
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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(e)(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 1395u 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-
ties 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 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) of the Public Health Service Act.

(d) Limitations on judicial review

The following actions and determinations with respect to the demonstration program shall not
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.

(e) 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 subsections (a)(1) and (e), are classified to sections 1395c et seq., 1395d et seq., and 1395w–21 et seq., respectively, of this title.

Section 2702 of the Public Health Service Act, referred to in subsection (c)(3), is section 2702 of act July 1, 1944, which was classified to section 300gg–1 of this title, was amended by Pub. L. 111–148, title I, § 1201(3), Mar. 23, 2010, 124 Stat. 154, and was transferred to subsection (d) to (f) of section 300gg–4 of this title, effective for plan years beginning on or after Jan. 1, 2014. A new section 2702 of act July 1, 1944, related to guaranteed availability of coverage, was added by Pub. L. 111–148, title I, § 1201(4), Mar. 23, 2010, 124 Stat. 156, effective for plan years beginning on or after Jan. 1, 2014, and is classified to section 300gg–1 of this title.

CODIFICATION

In subsection (b)(4)(B), “section 4191 of title 41” was substituted for “section 5 of title 41, United States Code” on an authority of Pub. L. 111–350, 16(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted ‘‘Title 41, Public Contracts.”
(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 ethically 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

(i) 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.

(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.

(b) 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.

(c) 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

\(^1\) So in original. Probably should be "sections".
under this subparagraph shall be furnished or directed by the entity which is participating in the pilot program.

(D) Payment for post-acute care services after the episode of care

The Secretary shall establish procedures, in the case where an applicable beneficiary requires continued post-acute care services after the last day of the episode of care, under which payment for such services shall be made.

(4) Quality measures

(A) 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:

(i) Functional status improvement.

(ii) Reducing rates of avoidable hospital readmissions.

(iii) Rates of discharge to the community.

(iv) Rates of admission to an emergency room after a hospitalization.

(v) Incidence of health care acquired infections.

(vi) Efficiency measures.

(vii) Measures of patient-centeredness of care.

(viii) Measures of patient perception of care.

(ix) 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), including 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.
§ 1395cc–5. Independence at home medical practice demonstration program

(a) Establishment

(1) In general

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 reduce expenditures and improve health outcomes in the provision of items and services under this subchapter to applicable beneficiaries (as defined in subsection (d)).

(2) Requirement

The demonstration program shall test whether a model described in paragraph (1), which is accountable for providing comprehensive, coordinated, continuous, and accessible care to high-need populations at home and coordinating health care across all treatment settings, results in—

(A) reducing preventable hospitalizations;

(B) preventing hospital readmissions;

(C) reducing emergency room visits;

(D) improving health outcomes commensurate with the beneficiaries’ stage of chronic illness;

(E) improving the efficiency of care, such as by reducing duplicative diagnostic and laboratory tests;

(F) reducing the cost of health care services covered under this subchapter; and

(G) achieving beneficiary and family caregiver satisfaction.

(b) Independence at home medical practice

(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).

(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;
§ 1395cc–5

(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 1395jjj 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 non elective 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 to assess whether the practice achieved the results described in subsection (a).

(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 1395i 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.

References in Text

Parts A, B, and C, referred to in subsecs. (c) and (d)(1)(A), (B), are classified to sections 1395c et seq., 1395j et seq., and 1395w–21 et seq., respectively, of this title.

§ 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—

1So in original. Probably should be followed by a comma.

(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 (described in subsection (d)(1)(C) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment;

(D) in which the transfer is effected through qualified personnel and transportation equipment, 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 direction of any person employed by (or affiliated with or associated with 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(mm)(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 personnel described in subsection (c)(1)(A) 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.


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 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.”


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 comply with the requirements 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)(B). Pub. L. 101–508, §207(a)(2), (3), formerly §4027(a)(2), (3), as renumbered by Pub. L. 103–432, §160(d)(4), which directed amendment of this section, was executed by making the substitution for “knowingly” and “is gross and flagrant or is repeated” for “knowing and willful or negligent”, was executed by making the substitution for “knowingly” and “is gross and flagrant or is repeated” for “knowing and willful or negligent”, was executed by making the substitution for “knowingly” and “is gross and flagrant or is repeated” for “knowing and willful or negligent”, was executed by making the substitution for “knowingly” and “is gross and flagrant or is repeated” for “knowing and willful or negligent”.

“(or not more than $25,000 in the case of a hospital with less than 100 beds)” after “$50,000”.

Subsec. (e)(4)(B). Pub. L. 101–239, § 6211(h)(1)(D), inserted “described in paragraph (1)(A)” after “emergency medical condition”, “or occur during” after “to result in”, and “, and”, or “, 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 (l). Pub. L. 101–239, § 6211(f), added subsecs. (g) to (l).


1987—Subsec. (d)(1). Pub. L. 100–203, § 4009(a)(2), which directed insertion of a provision related to imposing the sanctions described in section 1395u(a)(2)(A) of this title, was amended generally by Pub. L. 100–360, § 411(b)(8)(A)(i), which 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 Act”, redesignated former subpars. (A) and (B) as (A) and (B) respectively, and designated former subpars. (A) and (B) as (A) and (B) respectively, see 1990 Amendment note below.

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 1395cc of this Act”.

Effective Date of 2003 Amendment
Pub. L. 108–173, 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 4201(d) of Pub. L. 105–33, set out as a note under section 1395d of this title.

Effective Date of 1990 Amendment
Amendment by section 4008(b)(1)–(3)(A) of Pub. L. 101–508 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 1395cc of this title.

Amendment by section 4207(a)(1)(A) of Pub. L. 101–508 effective on the first day of the first month beginning more than 60 days after Nov. 5, 1990, see section 4207(a)(1)(C) of Pub. L. 101–508, 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 renumbered and amended by Pub. L. 103–432, title I, § 140(h)(4), (5)(B), Oct. 31, 1994, 108 Stat. 4444, provided that: “(1) 3 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, ob-
sterics-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 investiga-
tions 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 para-
graph (4).

In selecting members described in paragraphs (1) through (3), the Secretary shall consider qualified indi-
viduals nominated by organizations representing prov-
iders 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 termin-
ate 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 (with-
in the Department of Health and Human Services or otherwise).


“(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 to eligible providers in States described in paragraph (1) or (2) of subsection (b).

“(2) AVAILABILITY.—Funds appropriated under para-
graph (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 Immigration and Naturalization Service, as of January 2003, based on the 2000 decennial census.

“(2) BASED ON NUMBER OF UNDOCUMENTED ALIEN AP-
prehension STATES.—

“(A) IN GENERAL.—Out of the amount appropriated under subsection (a) for a fiscal year, the Secretary shall use $83,000,000 of such amount to make allotments, in addition to amounts allotted under paragraph (1), for such fiscal year for each of the 6 States with the highest number of undocu-
mented 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) USE OF FUNDS.—

“(1) AUTHORITY TO MAKE PAYMENTS.—From the allot-
ments made for a State under subsection (b) for a fiscal year, the Secretary shall pay the amount (sub-
ject to the total amount available from such allot-
ments) determined under paragraph (2) directly to el-
igible 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 other-
wise) 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 para-
graph shall be an amount determined by the Secre-
tary 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 eligi-
ble provider in that State is paid 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.

“(C) METHODOLOGY.—In establishing a methodology under paragraph (2)(A)(ii), 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 physi-
cians; 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 serv-
ces 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).

(5) 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)).

"(6) APPLICATIONS; ADVANCE PAYMENTS.—

"(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.

"(2) ADVANCE PAYMENT; RETROSPECTIVE ADJUSTMENT.—The process established under paragraph (1) may provide for making payments under this section for each quarter of a fiscal year on the basis of advance estimates of expenditures submitted by applicants for such payments and such other investigation as the Secretary may find necessary, and for making reductions or increases in the payments as necessary to adjust for any overpayment or underpayment for prior quarters of such fiscal year.

"(c) DEFINITIONS.—In this section:

"(1) ELIGIBLE PROVIDER.—The term ‘eligible provider’ means a hospital, physician, or provider of ambulances services (including an Indian Health Service facility whether operated by the Indian Health Service or by an Indian tribe or tribal organization).

"(2) ELIGIBLE SERVICES.—The term ‘eligible services’ means health care services required by the application of section 1867 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. 1395x(e)), except that such term shall include a critical access hospital (as defined in section 1861(mm)(1) of such Act (42 U.S.C. 1395x(mm)(1)).

"(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. 1390d)."

"(6) STATE.—The term ‘State’ means the 50 States and the District of Columbia.


(b) Council for Technology and Innovation

(1) Establishment

The Secretary shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as ‘‘CMS’’).

(2) Composition

The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (4)).

(3) Duties

The Council shall coordinate the activities of coverage, coding, and payment processes under this subchapter with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

(4) Executive Coordinator for Technology and Innovation

The Secretary shall appoint (or designate) a noncareer appointee (as defined in section 3123(a)(7) of title 5) who shall serve as the Executive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under this subchapter.


Prior Provisions


Amendments


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 subsecs. (b) and (c) as pars. (2) and (3), respectively.


§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 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) Filing for redetermination

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.

(B) Limitations

(i) Appeal rights

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 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—

(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) 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 sub-
chapter or enrolled under part B of this sub-
chapter, 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 individu-
ual 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 paragraph (2), to judicial review of the Secretary’s final decision after such hearing as is provided in section 405(g) of this title. For purposes of the preceding sentence, any reference to the “Commissioner of Social Secu-
rity” or the “Social Security Administra-
tion” in subsection (g) or (l) of section 405 of this title shall be considered a reference to the “Secretary” or the “Department of Health and Human Services”, respectively.

(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,
(2) Expedited access to judicial review under which a provider of services or supplier that furnishes an item or service or an
entity (described in subparagraph (D)), obtains access to judicial review when a re-
view by the appropriate review entity shall
be made in a year after 2004, the dollar
amounts specified in clause (i) shall be
rounded to the nearest multiple of $10.

(iii) Adjustment of dollar amounts
For requests for hearings or judicial re-
view made in a year after 2004, the dollar
amounts specified in clause (i) shall be
rounded to the nearest multiple of $10.

(F) Expedited proceedings
(i) Expedited determination
In the case of an individual who has re-
ceived 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 individ-
ual’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 de-
termination made under subsection (a)(1)
of this section, as the case may be, and the
Secretary shall provide such expedited de-
termination or expedited reconsideration.

(ii) Reference to expedited access to judi-
cial review
For the provision relating to expedited
access to judicial review, see paragraph (2).

(G) Reopening and revision of determina-
tions
The Secretary may reopen or revise any
initial determination or reconsidered deter-
termination 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 sup-
plier 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)(i)) may
obtain access to judicial review when a re-
view entity (described in subparagraph (D)),
on its own motion or at the request of the
appellant, determines that the Depart-
mental Appeals Board does not have the au-
thority to decide the question of law or regu-
lation relevant to the matters in contro-
versy and that there is no material issue of
fact in dispute. The appellant may make
such request only once with respect to a ques-
tion 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 hear-
ing, 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 contro-
versy and that there is no material issue of
fact in dispute, and if such request
is accompanied by the documents and mate-
rials as the appropriate review entity shall
require for purposes of making such deter-
mination, such review entity shall make a
determination on the request in writing
within 60 days after the date such review en-
tity receives the request and such accom-
panying 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 mate-
rial 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 sub-
paragraph (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 de-
scribed 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 sub-
paragraph (B) for the determination.

(iii) Venue
Such action shall be brought in the dis-
trict court of the United States for the ju-
dicial district in which the appellant is lo-
cated (or, in the case of an action brought
jointly by more than one applicant, the ju-
dicial district in which the greatest num-
ber of applicants are located) or in the Dis-
trict 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 be-
ginning 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 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.

(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

(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.

(H) 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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1 So in original.
2 So in original. The word “and” probably should not appear.
3 So in original. A comma probably should appear.
sion made, 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 or both, continuing education activities by qualified independent contractors and administrative law judges. The continuing education activities shall be necessary to inform qualified independent contractors and administrative law judges about the requirements of this subchapter, the manner in which each state has satisfies the requirement contained in section 1395z-2(e) of this title, and the manner in which the appeals process is conducted.

(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 action, 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 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.

(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.
§ 1395ff

(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—

(I) shall review the record and shall permit discovery and the taking of evidence to evaluate the reasonableness of the determination, if the administrative law judge 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.

(ii) Upon the filing of a complaint by an aggrieved party, a decision of an administrative law judge under clause (i) shall be reviewed by the Departmental Appeals Board of the Department of Health and Human Services.

(iii) The Secretary shall implement a decision of the administrative law judge or the Departmental Appeals Board within 30 days of receipt of such decision.

(iv) A decision of the Departmental Appeals Board constitutes a final agency action and is subject to judicial review.

(B) Definition of local coverage determination

For purposes of this section, the term “local coverage determination” means a determination by a fiscal intermediary or a carrier under part A of this subchapter or part B of this subchapter, as applicable, respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with section 1395y(a)(1)(A) of this title.

(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).

(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"), each 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 credentialed 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 to be 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 1385y(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 (1)(B)(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;

(ii) the physicians' service is not so covered; or

(iii) the contractor lacks sufficient information to make a coverage determination with respect to the physicians' service.

(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)(2)(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—

(I) 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 et seq. of this title.

AMENDMENTS


Subsec. (a)(4), (5). Pub. L. 108-173, §938(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. (b)(1)(F)(ii). Pub. L. 108-173, §932(a)(2), amended heading and text of cl. (ii) generally. Prior to amendment, text read as follows: “In a hearing by the Secretary under this section, in which the moving party alleges that no material issues of fact are in dispute, the Secretary shall make an expedited determination as to whether any such facts are in dispute and, if not, shall render a decision expeditiously.”


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)(B)(i). Pub. L. 108-173, §933(b), inserted “(including the medical records of the individual involved)” after “clinical experience”.


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.”.
Subsec. (c)(3)(J). 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 “decision of the contractor”.
Subsec. (c)(4). Pub. L. 108–173, § 933(d)(3), substituted “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” for “not fewer than 12 qualified independent contractors under this subsection”.
Subsec. (f)(4)(A)(IV). Pub. L. 108–173, § 948(c)(1), substituted “clause (I), (II), or (III)” for “subclause (I), (II), or (III)”.
2009—Pub. L. 106–554, § 1(a)(6) [title V, § 522(a)], amended section generally, completely revising and expanding provisions relating to determinations with respect to benefits under part A or part B of this subchapter, changing the structure of the section from two subsecs. lettered (a) and (b) to five subsecs. lettered (a) to (e).
1994—Subsec. (b)(1). Pub. L. 103–296 inserted “, except that, in so applying such sections and in applying section 1395g 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” after “administration” in closing provisions.
1987—Subsec. (a). Pub. L. 100–203, § 4085(b)(18), inserted “a claim for benefits with respect to home health services under part B of this subchapter” before “shall”.
Subsec. (b)(2). Pub. L. 100–203, § 4085(b)(19), inserted “and (1)(D)” after “subparagraph (1)(C)” in two places.
Subsec. (b)(3)(B). Pub. L. 100–203, § 4082(a), substituted “section 553” for “chapter 5”.
Subsec. (b)(5). Pub. L. 100–203, § 4082(b), added par. (5).
Subsec. (c). Pub. L. 100–93 struck out subsec. (c) which read as follows: “Any institution or agency dissatisfied with any determination by the Secretary that it is not a provider of services, or with any determination described in section 1395cc(b)(2) of this title, shall be entitled to a hearing thereon by the Secretary (after reasonable notice and opportunity for hearing) 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.”
Amendment by subsection (a). Pub. L. 99–509, § 9313(b)(1)(A), inserted “or part B” after “amount of benefits under part A”.
Pub. L. 99–509, § 9313(b)(1)(A), inserted “and any other determination with respect to a claim for benefits under part A of this subchapter” before “shall”.
Pub. L. 99–509, § 9313(a)(1), in concluding provisions, inserted at end “Sections 406(a), 1302, and 1395h 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 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. 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.”
Pub. L. 99–509, § 9313(b)(1)(B), inserted “or part B”.
Pub. L. 99–509, § 9313(b)(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 1395i–1 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 1395w–21 of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 932(a) of Pub. L. 108–173 applicable to appeals filed on or after Oct. 1, 2004, see section 932(c) of Pub. L. 108–173, set out as a note under section 1395i–2 of this title.


Pub. L. 108–173, title IX, § 933(b), Dec. 8, 2003, 117 Stat. 2415, provided that: “(1) EFFECTIVE DATE.—The Secretary [of Health and Human Services] shall establish the prior determination process under the amendment made by subsection (a) [amending this section] in such a manner as to provide for the acceptance of requests for determinations
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 1395kk-1 of this title] with Medicare administrative contractors, any reference in section 1869(g) [probably should be 1869(h)] of such Act [subsection (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 SUBP.—For purposes of applying section 1846(c)(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 be 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 BIPA [the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2003, 117 Stat. 2396–2398, provided that:

"(1) The provisions of subparagraphs (A) and (B) of section 1869(b)(1) of the Social Security Act [subsection (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 [subsection (b)(2)(C) 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) on 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) [subsection (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 broad legal issues binding, precedential authority.
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"(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 should 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.

(5) 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).

(7) ADDITIONAL 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. 1395i), and the Federal Supplementary Medical Insurance Trust Fund, established under section 1841 of such Act (42 U.S.C. 1395t)) 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);

(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 1880(g) of the Social Security Act [section 1395zz(g) of this title], as inserted by section 301(a)(1) of this Act), and representatives of providers of services and suppliers, a process whereby, in the case of minor errors or omissions (as defined by the Secretary) that are detected in the submission of claims under the programs under title XVIII of such 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 CLAIMS 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-
peals 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 405(f) 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 1395(g) of this title, and section 1395t(f) 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 is made 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 or subchapter XVIII of this chapter 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 negotiated 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 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 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 person or persons, and

(5) if there is no person who meets the requirements of paragraph (1), (2) or (3), or (4), or if each person who meets such requirements dies before the payment due him under this subchapter is completed, determined by the Secretary to be 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 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


AMENDMENTS


1988—Pub. L. 100–360, §411(e)(3), added Pub. L. 100–203, §4039(h)(7), set out as a note under this subchapter relating to services furnished (or deemed to have been furnished) after 1968. The provisions of subsections (e) and (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. 92–603, §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.

1968—Subsec. (b). 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 December 30, 1971, and reports of actions considered 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 subsections (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, 1985, and ending on March 31, 1986, 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 sub-section (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 sub-section.

(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 noncompliance 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 1395 et seq., respectively, of this title.

Amendments


1986—Subsec. (a). Pub. L. 99–509, §4035(b), designated existing provisions as par. (1) and added par. (2).

Subsec. (c). Pub. L. 100–203, §4035(c), added subsec. (c).

1985—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(b)(2), Dec. 8, 2003, 117 Stat. 2375, 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]."

So in original. No subsec. (d) has been enacted.
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 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, statement, or representation 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. 301 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;

(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 290b–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-
cian 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.


REFERENCES IN TEXT

The Railroad Retirement Act of 1974, referred to in subsec. (a), is act Aug. 29, 1935, ch. 812, as amended generally by Pub. L. 93–445, title I, §101, Oct. 16, 1974, 88 Stat. 1359, which is classified generally to subchapter IV (§231 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 231t of Title 45, and Tables.

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

Parts A and B, referred to in subsecs. (d)(1) and (e)(3), are classified to sections 1395c et seq. and 1395 et seq., respectively, of this title.

July 15, 2008, referred to in subsec. (d)(1)(A) and (B), was in the original “the date of the enactment of this section” and “such date”, which were translated as meaning the date of enactment of Pub. L. 110–275, which enacted subsec. (d), to reflect the probable intent of Congress.

Part D, referred to in subsec. (e)(3), is classified to section 1395w–101 et seq. of this title.

Amendments


Effective Date of 2010 Amendment


Effective Date of 2008 Amendment

Amendment by Pub. L. 110–275 effective July 15, 2008, see section 188(c) of Pub. L. 110–275, set out as a note under section 3716 of Title 31, Money and Finance.

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 conflict 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).
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(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.

(c) 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 directly 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 such functions under this subchapter, the Secretary may, to the extent the Secretary determines to be appropriate and as specified in the contract with the contractor, reimburse the contractor 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 paragraphs (2)(D)(i), (5)(A), and (5)(B) of such section).

(2) Independent audits

(A) Performance of annual evaluations

Each year 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 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(8) 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 ensure that each Medicare administrative contractor shall provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, concerning the programs under this subchapter within 45 business days of the date of receipt of such inquiries.

(3) Response to toll-free lines

The Secretary shall ensure that each Medicare administrative contractor shall provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter, or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals, providers of services, and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under this subchapter.

(4) 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.

(C) Direct monitoring

Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.

(5) Authorization of appropriations

There are authorized to be appropriated such sums as are necessary to carry out this subsection.

REFERENCES IN TEXT
Parts A and B of this subchapter, referred to in subsecs. (a)(3)(B), (4), (5)(A) and (g)(1)–(3), (4)(B)(ii), are classified to sections 1395c et seq. and 1395d et seq., respectively, of this title.

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 availabilty 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) DIRECTION 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 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 MIP 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 1869(d)(2) of the Social Security Act (42 U.S.C. 1395ddd(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(a)(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(c)(2) of such Act [section 1395h(f)(2) of this title] (relating to timely processing of reconsiderations and applications for exemptions) and section 1812(c)(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 or 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


"(1) IN GENERAL.—The provisions of section 1874A(e)(2) of the Social Security Act [subsec. (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 [subsec. (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, §921(b)(2), Dec. 8, 2003, 117 Stat. 2389, provided that: "The provisions of section 1874A(f) of the Social Security Act [subsec. (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, §921(c)(3), Dec. 8, 2003, 117 Stat. 2390, provided that: "The provisions of section 1874A(h) of the Social Security Act [subsec. (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(c), Dec. 8, 2003, 117 Stat. 2407, 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
paragraph (2), the Secretary shall consider require-
1§ 1395f. 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) and the operation and administration of health maintenance organizations 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 402 of the Social Security Amendments of 1972 [42 U.S.C. 1395b–1 note], and shall transmit to the Congress annually a report concerning the operation of such programs.


1So 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 1395c et seq. and 1395d 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, 1395g, and 1395h 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 402 of the Social Security Amendments of 1972, referred to in subsec. (b), is section 402 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 1395(h)(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 1967 and $5,000,000 for each of fiscal years 1968 and 1969, and

“(B) from the Federal Supplementary Medical Insurance Trust Fund $2,000,000 for fiscal year 1967 and $2,500,000 for each of fiscal years 1968 and 1969.”


1984—Subsec. (b). Pub. L. 98–369 struck out “the” after “Joint Commission on”.


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 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 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 2354(e)(1) of Pub. L. 98–369, set out as a note under section 1509(a)–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. 1395–b).
“(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 jurisdiction 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

“(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) GENERAL.—The Comptroller General of the United States shall conduct a study on access of medicare beneficiaries to physicians’ services under the medicare program for such services under part B of the medicare program [part B of this subchapter], and 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].

“(b) 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.

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 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
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) MEDICARE 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 9313(d) of Pub. L. 99–509, as amended by Pub. L. 100–203, title IV, § 4085(i)(21)(A), Dec. 22, 1987, 101 Stat. 1330–133, 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.

SPECIAL 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 292(c) of Pub. L. 99–208, as amended, set out as a note under section 1395 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 SHOES, RESPIRATORY THERAPY SERVICES, AND FOOT CONDITIONS; GRANTS, PAYMENTS, AND EXPENDITURES

Pub. L. 96–499, title IX, § 938, 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 retard 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 as 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 1395 of this title, and the Federal Supplementary Medical Insurance Trust Fund established by section 1395 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. 92–142, §18, Oct. 25, 1977, 91 Stat. 1202, directed Secretary of Health, Education, and Welfare, not later than the second 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.

(C) The annual per capita rate of payment for each such class shall be equal to 95 percent of the adjusted average per capita cost (as defined in paragraph (4)) for that class.

(D) In the case of an eligible organization with a risk-sharing contract, the Secretary shall make monthly payments in advance and in accordance with the rate determined under subparagraph (g) of this section, and except as provided in subsection (C) of this section, to the organization for each individual enrolled with the organization under this section.

(E)(i) The amount of payment under this paragraph may be retroactively adjusted to take into account any difference between the actual number of individuals enrolled in the plan under this section and the number of such individuals estimated to be so enrolled in determining the amount of the advance payment.

(ii) Subject to subsection (II), 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 subparagraph (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 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)(i) 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(h) 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 1395f 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 exceed 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,

1 See References in Text note below.
except that (I) the organization may provide such members with such additional health care services as the members may elect, at their option, to have covered, and (II) in the case of an organization with a risk-sharing contract, the organization may provide such members with such additional health care services as the Secretary may approve. The Secretary shall approve any such additional health care services which the organization proposes to offer to such members, unless the Secretary determines that including such additional services will substantially discourage enrollment by covered individuals with the organization.

(B) If there is a national coverage determination made in the period beginning on the date of an announcement under subsection (a)(3)(A) of this section and ending on the date of the next announcement under such subsection that the Secretary projects will result in a significant change in the costs to the organization of providing the benefits that are the subject of such national coverage determination and that was not incorporated in the determination of the per capita rate of payment included in the announcement made at the beginning of such period—

(i) such determination shall not apply to risk-sharing contracts under this section until the first contract year that begins after the end of such period; and

(ii) if such coverage determination provides for coverage of additional benefits or under additional circumstances, subsection (a)(3)(A) of this section shall not apply to payment for such additional benefits or benefits provided under such additional circumstances until the first contract year that begins after the end of such period,

unless otherwise required by law.

(3)(A)(i) Each eligible organization must have an open enrollment period, for the enrollment of individuals under this section, of at least 30 days duration every year and including the period or periods specified under clause (ii), and must provide that at any time during which enrollments are accepted, the organization will accept up to the limits of its capacity (as determined by the Secretary) and without restrictions, except as may be authorized in regulations, individuals who are eligible to enroll under subsection (d) of this section in the order in which they apply for enrollment, unless to do so would result in failure to meet the requirements of subsection (f) of this section or would result in the enrollment of enrollees substantially nonrepresentative, as determined in accordance with regulations of the Secretary, of the population in the geographic area served by the organization.

(ii)(I) If a risk-sharing contract under this section is not renewed or is otherwise terminated, eligible organizations with risk-sharing contracts under this section and serving a part of the same service area as under the terminated contract are required to have an open enrollment period for individuals who were enrolled under the terminated contract as of the date of notice of such termination. If a risk-sharing contract under this section is renewed in a manner that discontinues coverage for individuals residing in part of the service area, eligible 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 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 related 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)(1) 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.

(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 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(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. The provisions of section 1395ff(b)(1)(E)(iii) 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 during 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.
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(8) A contract under this section shall provide that the eligible organization shall meet the requirement of section 1395ccc(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 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 only, respectively, if they were not members of an eligible organization.

(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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organization consists of individuals who are entitled to benefits under this subchapter or under a State plan approved under subchapter XIX of this chapter, or

(B) in the case of an eligible organization that is owned and operated by a governmental entity, only with respect to a period of three years beginning on the date the organization first enters into a contract under this section, and only if the organization has taken and is making reasonable efforts to enroll individuals who are not entitled to benefits under this subchapter or under a State plan approved under subchapter XIX of this chapter.

(3) If the Secretary determines that an eligible organization has failed to comply with the requirements of this subsection, the Secretary may provide for the suspension of enrollment of individuals under this section or of payment to the organization under this section for individuals newly enrolled with the organization, after the date the Secretary notifies the organization of such noncompliance.

(4) Effective for contract periods beginning after December 31, 1996, the Secretary may waive or modify the requirement imposed by paragraph (1) to the extent the Secretary finds that it is in the public interest.

(g) Risk-sharing contract

(1) The Secretary may enter a risk-sharing contract with any eligible organization, as defined in subsection (b) of this section, which has at least 5,000 members, except that the Secretary may enter into such a contract with an eligible organization that has fewer members if the organization primarily serves members residing outside of urbanized areas.

(2) Each risk-sharing contract shall provide that—

(A) if the adjusted community rate, as defined in subsection (e)(3) of this section, for services under parts A and B of this subchapter (as reduced for the actuarial value of the coinsurance and deductibles under those parts) for members enrolled under this section with the organization and entitled to benefits under part A of this subchapter and enrolled in part B of this subchapter, or

(B) if the adjusted community rate for services under part B of this subchapter (as reduced for the actuarial value of the coinsurance and deductibles under that part) for members enrolled under this section with the organization and entitled to benefits under part B of this subchapter only

is less than the average of the per capita rates of payment to be made under subsection (a)(1) of this section at the beginning of an annual contract period for members enrolled under this section with the organization and entitled to benefits under part A of this subchapter or enrolled in part B of this subchapter, or enrolled in part B of this subchapter only, respectively, the additional benefits described in paragraph (3) 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) 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 provided 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 period, the Secretary may determine such an average based on the enrollment experience of other contracts entered into under this section.

(3) The additional benefits referred to in paragraph (2) are—

(A) the reduction of the premium rate or other charges made with respect to services furnished by the organization to members enrolled under this section, or

(B) the provision of additional health benefits, or both.


(5) An organization having a risk-sharing contract under this section may (with the approval of the Secretary) provide 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 Supplementary 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 subsequent periods by the organization in accordance with paragraph (3). Any of such value of additional benefits which is not provided to members 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 section 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 organization 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 providers and suppliers for such covered services furnished to individuals enrolled under this section under the contract. If the Secretary provides for
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)(1) 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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not offered by the same Medicare Advantage organization.

(iii) A plan described in this clause for a year for a service area is a plan described in section 1395w-2(1)(A)(i) of this title if the service area for the year meets the following minimum enrollment requirements:

(I) With respect to any portion of the area involved that is within a Metropolitan Statistical Area with a population of more than 250,000 and counties contiguous to such Metropolitan Statistical Area that are not in another Metropolitan Statistical Area with a population of more than 250,000, 5,000 individuals. If the service area includes a portion in more than 1 Metropolitan Statistical Area with a population of more than 250,000, the minimum enrollment determination under the preceding sentence shall be made with respect to each such Metropolitan Statistical Area (and such applicable contiguous counties to such Metropolitan Statistical Area).

(II) With respect to any other portion of the area for the year meets the following minimum enrollment requirements:

(i) Duration, termination, effective date, and terms of contract; powers and duties of Secretary

(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, 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)(b) 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)(ii) 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
subparagraph (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
entity that is excluded from participation
under this subchapter under section 1320a–7 or
1320a–7a of this title for the provision of health
care, utilization review, medical social work,
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)(I) of such subpara-
graph, of not more than $100,000 for each such
determination, plus, with respect to a deter-
mination 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-
nization of a determination under subpara-
graph (A) and until the Secretary is satisfied
that the basis for such determination has been
notified 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
section (other than subsections (a) and (b)) shall
apply to a civil money penalty under subpara-
graph (B)(i) or (C)(i) in the same manner as such
provisions apply to a civil money penalty under
proceeding under section 1320a–7a(a) 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
organization 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-
fractions 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-
ion 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-
jization 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)(A) 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 from 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)(3)(B) 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 section (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.
(B) Restrictions on imposition of premium taxes under section 1395w-24(g) of this title in relating to payments to such organizations under this section.

(C) The requirement to accept enrollment of new enrollees during November 1998 under section 1395w-21(e)(6) of this title.

(D) Payments under section 1395w-27(e)(2) of this title.


REFERENCES IN TEXT

Parts A and B of this subchapter, referred to in text, are classified to sections 1385c et seq. and 1395 et seq., respectively, of this title.

Section 300e-9(d) of this title, referred to in subsection (b)(1), was redesignated section 300e-3(c) of this title by Pub. L. 100-517, §7(b), Oct. 24, 1988, 102 Stat. 2579.

Part C of this subchapter, referred to in subsection (k)(4), is classified to section 1395w-21 et seq. of this title.

AMENDMENTS


Subsec. (h)(5)(C)(i)(I), (II). Pub. L. 110-275, §167(b), inserted “provided that all such plans are not offered by the same Medicare Advantage organization” after “clause (III)”.

Subsec. (h)(5)(C)(iii). Pub. L. 110-275, §167(c), inserted “that are not in another Metropolitan Statistical Area with a population of more than 250,000” after “such Metropolitan Statistical Area” and inserted “or” for “and” in clause (III).
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. (j)(6)(B). Pub. L. 101–194, § 215(a)(4), struck out concluding provisions which read as follows: "The provisions of section 1320a–7a of this title (other than subpar. (F)) shall apply to a civil money penalty or proceeding under section 1320a–7a(a) of this title."


Subsec. (j)(7)(A). Pub. L. 101–194, § 215(b), substituted "a written agreement" for "an agreement".


Subsec. (a)(3). Pub. L. 103–432, § 157(b)(1), substituted "subsections (c)(2)(B)(ii) and (c)(7)" for "subsection (c)(7) of this section".

Subsec. (c)(5)(B). Pub. L. 101–206 inserted at end "In applying sections 405(b) and 406(g) of this title as provided in this subparagraph, and in applying section 405(f) 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 existing provisions as subpar. (A), redesignated former subpars. (A) and (B) and former cls. (1) and (2) as cls. (1) and (2), respectively, and added subpar. (B).

Subsec. (a)(6). Pub. L. 101–508, § 4204(c)(2), substituted "subsections (c)(2)(B)(ii) and (c)(7)" for "subsection (c)(7)".

Subsec. (c)(2). Pub. L. 101–508, § 4204(c)(1), designated existing provisions as subpar. (A), redesignated former subpars. (A) and (B) and former cls. (1) and (2) as cls. (1) and (2), respectively, and added subpar. (B).


Subsec. (c)(4)(A)(i). 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", "physician or provider of services or renal dialysis facility" for "physician" in three places, and "applicable participation agreement" for "participation agreement under section 1395u(h)(1) of this title".

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 "which are furnished to an enrollee of an eligible organization under this section [sic] by a physician, provider of services, or renal dialysis facility who is not under a contract with the organization," for "which—" and subpars. (A) and (B) which read as follows:

"(A) are emergency services or out-of-area coverage (described in clauses (iii) and (iv) of subsection (b)(2)(A) of this section), and

"(B) are furnished to an enrollee of an eligible organization under this section by a person who is not under a contract with the organization,".


Subsec. (a)(5). Pub. L. 101–234, § 202(a), repealed Pub. L. 100–360, § 211(c)(3)(A), and provided that the provisions of law amended or repealed by such section are restored or revised as if such section had not been enacted, see 1988 Amendment note below.

Subsec. (c)(3)(A)(i). Pub. L. 101–239, § 6206(b)(1)(B), added cl. (ii) and struck out former cl. (i) 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 appropriate consistent with this section."

Subsec. (e)(1), (g)(3)(A). Pub. L. 101–234, § 201(a), repealed Pub. L. 100–360, § 202(f), 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. (g)(5). Pub. L. 101–239, § 6212(c)(2), struck out "and during a period of not longer than four years" after first reference to "Secretary."


1988—Subsec. (a)(5). Pub. L. 100–360, § 211(c)(3)(B), amended second sentence generally. Prior to amendment, second sentence read as follows: "The portion of that 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 supplemental medical insurance for the month as determined under section 1395(e)(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 supplemental medical insurance for the month as determined under section 1395(e)(4) of this title."


Subsec. (e)(1). Pub. L. 100–360, § 202(f), 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 1395m(a)(2)(B)(iii) of this title; and

"(ii) has members who have a collectively bargained contractual right to obtain health benefits through the organization; and

"(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; 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. (f)(3)(A). Pub. L. 100–360, § 411(c)(6), amended Pub. L. 100–360, § 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. (g)(3)(A). Pub. L. 100–360, § 2029(c)(2), substituted "rates" for "rate".


Subsec. (g)(6). Pub. L. 100–360, § 411(c)(4)(A), inserted "in addition to any other remedies authorized by law", after "the Secretary may provide in concluding negotiations provisions.".

Subsec. (i)(6)(B). Pub. L. 100–360, § 411(c)(4)(C), former § 411(c)(4)(B), as redesignated by Pub. L. 100–485, § 608(d)(19)(B)(ii), substituted "or proceeding under section 1320a–7a(a) of this title" for "under that section" in last sentence.


Pub. L. 100–360, § 224, inserted at end "plus, with respect to a determination 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 returned to the individual concerned)", and plus, with respect to a determination under subparagraph (A)(iv), "$15,000 for each individual not enrolled as a result of the practice involved.".

Subsec. (i)(7)(A). Pub. L. 100–360, § 411(c)(5), added Pub. L. 100–203, § 4039(h)(8)(A), (B), as added by Pub. L. 100–360, § 411(c)(5), substituted "Each" for "Except as provided under section 1320a–3a(a)(4)(C) of this title, each", inserted "or with an entity selected by the Secretary under section 1320a–3a(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)(5), substituted the "review organization" for "the peer review organization".

1986—Subsec. (a)(1)(A). Pub. L. 99–514 substituted "announced in a manner intended to provide notice to interested parties" for "publish in introductory provisions".

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)(6). 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 subchapter 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 distribution of the material, and that 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.


Subsec. (f)(2). Pub. L. 99–509, § 8312(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 subchapter 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 enters
into an agreement with the Secretary pursuant to
section (i) of this section, as the Secretary might per-
mit.

Subsec. (1)(B). Pub. L. 94–460, § 201(c), substituted
“other than costs 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 pur-
suant to paragraph (2)(A), the cost of providing any mem-
ber 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)”.

struck out “, with the apportionment of savings being
proportional to the losses absorbed and not yet offset”
at end.

Subsec. (g)(2). Pub. L. 93–233, § 18(n), substituted “por-
tion of its premium rate or other charges” for “por-
tion” 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
cobuttons”, respectively.

“skilled nursing facility” for “extended care facility”
and “skilled nursing facilities” for “extended care fac-
ilities”.

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.

effectiveness Date of 1996 Amendment

Section 215(c) of Pub. L. 104–191 provided that: “The amendments made by this section [amending this sec-
tion] shall apply with respect to contract years begin-
ing on or after January 1, 1997.”

Amendment by section 231(g) of Pub. L. 104–191 applic-
able 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.

Amendment by Pub. L. 103–296 effective Mar. 31, 1995,
see section 110(a) of Pub. L. 103–296, set out as a note
under section 401 of this title.

effectiveness Date of 1990 Amendment

Section 1204 effective Date of 1990 Amendment

Section 420(a)(4) of Pub. L. 101–508 provided that:
“The amendments made by paragraphs (1) and (2)
amending this section] shall apply with respect to con-
tact years beginning on or after January 1, 1992, and
the amendments made by paragraph (3) [amending sec-
tion 1320a–7a of this title] shall take effect on the date
of the enactment of this Act [Nov. 5, 1990].”

Section 420(c)(3) of Pub. L. 101–508, as amended by
442, provided that: “The amendments made by this
subsection [amending this section] shall apply with re-
spect to national coverage determinations that are not
incorporated in the determination of the per capita
rate of payment for individuals enrolled for years be-
ginning with 1991 with an eligible organization which
has entered into a risk-sharing contract under section
1976 of the Social Security Act”.

Section 420(d)(2) of Pub. L. 101–508, as amended by
section and repealing provisions set out as notes under section 106 of Title 1, General Provisions.

The amendments made by this subsection (amending this section and section 1395cc this title) shall apply to contracts entered into or renewed on or after the date of enactment of this Act [Dec. 22, 1987].

Section 401(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 401(d) of Pub. L. 100–203 provided that: "The amendments made by subsections (a) and (b) [amending this section and section 1396a 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 401(b) of Pub. L. 100–203, which provided the effective date for amendment made by section 401(b) of Pub. L. 100–203, was omitted in the general amendment of section 413 of Pub. L. 100–360, title IV, §411(c)(3), July 1, 1988, 102 Stat. 773.

Effective Date of 1986 Amendments

Section 1995(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."

Section 9312(b)(2) of Pub. L. 99–509 provided that: "The amendment made by paragraph (1) [amending this section] shall take effect on January 1, 1987, and shall apply to enrollments effected on or after such date."


"(A) New restriction.—The amendment made by paragraph (1) [amending this section] shall apply to modifications and waivers granted after the date of the enactment of this Act [Oct. 21, 1986]."

"(B) Sanctions for Noncompliance.—The amendments made by paragraph (2) [amending this section] shall take effect on the date of the enactment of this Act."

"(C) Treatment of Current 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 requirement imposed by paragraph (1) of that section, but

(ii) does not meet the requirement 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 is described in clauses (i) and (ii) of subparagraph (c) and that received a grant or grants totaling at least $3,000,000 in fiscal year 1987 under section 320(b)(1)(A) or 330(b)(1) of the Public Health Service Act [42 U.S.C. 294b(d)(1)(A), 254(d)(1)]—

(i) before January 1, 1996, section 1876(f) of the Social Security Act [subsec. (f) of this section] shall not apply to the organization;

(ii) beginning on January 1, 1990, the Secretary of Health and Human Services shall conduct an annual enforcement action with respect to the organization; and

(iii) before December 31, 1989, the Secretary shall make written findings, explain the basis for such findings, and inform the organization of such findings."

Effective Date of 1987 Amendment

Section 401(i)(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]."
review of the organization to determine the organiza-
tion's compliance with the quality assurance require-
ments of section 1876(c)(6) of such Act [subsec. (c)(6) of this section]; and

"(iii) After January 1, 1990, if the organization re-
ceives an unfavorable review under clause (ii), the
Secretary, after notice to the organization of the un-
favorable 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 re-
spect to individuals enrolling with the organization
after the date the Secretary notifies the organization
that it is not in compliance with the require-
ments 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]
with respect to services furnished on or after January
1, 1987." 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 9533(e)(3)(B) of Pub. L. 99–509, as amended by
Pub. L. 100–203, title IV, § 403(b)(9)(C), as added by Pub.
L. 100–360, 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 con-
tracts with eligible organizations, under section 1876
of the Social Security Act [this section], as of April 1,
1987 and for such changes in the risk-sharing con-
tracts in effect under section 1876 of such Act (as in
effect before the date of the enactment of Public Law
97–248 [Sept. 3, 1982]) in the same manner as it applies to eligible organizations
with risk-sharing contracts in effect under section 1876
of such Act (as in effect on or after the date of the enactment
of this Act [Dec. 22, 1987])."

Section 9211(e) of Pub. L. 99–272 provided that:

"(1) FINANCIAL RESPONSIBILITY.—The amendments
made by subsection (a) [amending this section] shall apply
to enrollments and disenrollments that become
effective on or after the date of the enactment of this
Act [Apr. 7, 1986].

"(2) DISENROLLMENTS.—The amendments made
by subsection (b) [amending this section] shall apply to re-
terms for termination of enrollment submitted on or
after May 1, 1986.

"(3) MATERIAL REVIEW.—(A) The amendment made
by subsection (c) [amending this section] shall not apply
to material which has been distributed before July 1,
1986.

"(B) Such amendment also shall not apply so as to re-
quire the submission of material which is distributed
before July 1, 1986.

"(C) Such amendment shall also not apply to mate-
rial which the Secretary determines has been prepared
before the date of the enactment of this Act [Apr. 7,
1986] and for which a commitment for distribution has
been made, if the application of such amendment would
constitute a hardship for the organization involved.

"(4) PUBLICATION.—The amendment made by sub-
section (d) [amending this section] shall apply to deter-
minations of per capita rates of payment for 1987 and
subsequent years.

"(5) NECESSARY MODIFICATION OF CONTRACTS.—The
Secretary of Health and Human Services shall provide
for such changes in the risk-sharing contracts which
have been entered into under section 1876 of the Social
Security Act [this section] as may be necessary to con-
form to the requirements imposed by the amendments
made by this section [amending this section] on a time-
ly basis."
“(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 the 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 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.

Individually 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], and

“(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

“(ii) 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, or reimbursement on a reasonable cost basis under section 1833(a)(1)(A) of such Act [section 1833(a)(1)(A) of this title], and which is not an existing risk-sharing contract or an existing demonstration project.

“(B) The term ‘existing risk-sharing contract’ means a contract entered into under section 1876(i)(2)(A) of the Social Security Act [subsec. (i)(2)(A) of this section], as in effect before the initial effective date.

“(C) 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].

“(D) 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].

“(E) 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 1833(a)(1)(A) of this title].

“(F) As used in this section, the term ‘initial effective date’ means—

“(A) the first day of the thirteenth month which begins after the date of the enactment of this Act [Sept. 3, 1982], or

“(B) the first day of the first month [Feb. 1, 1985] after the month in which the Secretary of Health and Human Services notifies the Committee on Finance of the Senate and the Committee on Ways and Means and on Energy and Commerce of the House of Representatives that he is reasonably certain that the methodology to make appropriate adjustments (referred to in 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 section, 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) and after the first 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(z–3)(3) of Pub. L. 92–233 provided that: “The amendments made by this section (amending this section) shall be effective with respect to services provided after June 30, 1973.”

**Effective Date**

Section 226(f) of Pub. L. 92–603 provided that: “The amendments made by this section (enacting this section, amending sections 1395f, 1395i, 1395j, and 1396b of this title, and enacting provisions set out as notes
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 PSO 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 EQUIVALENCE 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, could not be executed, because section 4204(b) of Pub. L. 101–508 did not contain pars. (4) and (5) subsequent to amendment 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, 1993, and before Jan. 1, 1999, with Secretary to issue a report to Congress on results of the study not later than Jan. 1, 1999, 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.

Section 4206(a)(2) of Pub. L. 101–239 provided that: "Before January 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 1990."

ADJUSTMENT OF CONTRACTS WITH PREPAID HEALTH PLANS

Section 2204(b) of Pub. L. 101–234 provided that: "Notwithstanding any other provision of this Act [see Table] for classification, 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 1395(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(i)(2)(A) of such Act [subsec. (i)(2)(A) of this section] (as in effect before February 1, 1985), under section 402(a) of the Social Security Amendments of 1987 [section 1395(b–1)(a) of this title], or under section 222(a) of the Social Security Amendment of 1972 [Pub. L. 92–603, set out as a note under section 1395b–1 of this title]."

ADJUSTMENT OF CONTRACTS WITH PREPAID 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 1395 of this title]; and

"(2) require such organizations and organizations paid under section 1395(a)(1)(A) of such Act [section 1395(b–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(i)(2)(A) of the Social Security Act [subsec. (i)(2)(A) of this section] (as in effect before February 1, 1985), under section 402(a) of the Social Security Amendments of 1967 [section 1395(b–1a) 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 4112(c) of Pub. L. 100–203, as amended by Pub. L. 100–360, title IV, § 4112(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**


(1) The Secretary of Health and Human Services (in this subsection referred to as the ‘Secretary’) may provide for 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 meets the requirements and requirements of subsection (a) [amending section 1395cc of this title] and

(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), of section 1876 of the Social Security Act [this section] shall apply to a project in the same manner as they apply to eligible organizations with risk-sharing contracts under such section.

(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.

**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 1876(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.

**APPLICATION OF PROVISIONS.**—The provisions of subsection (a)(2) and the first sentence of subsection (b) of section 492 of the Social Security Amendments of 1967 [section 1385(b)(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,

الحلقة الاحترافية، أو أي رحلة تقريرية عادية في أقسام العضوية 103–7 (فيما ينطوي على الطلب لتقديم تقرير مبكر لـ 540، 100–203، توضع في صفحة 9، بمراجع 3003 من Pin. L. 1994–66، كما تم تعيينه كمixin under section 1113 من Title 31، Money and Finance.)

**GAO STUDY AND REPORTS ON MEDICARE CAPITATION**

Portion of Pub. L. 1999–203، بتوجيه Comptroller General to conduct a study on medicare capitiation 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 establishing 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 utilization of services and improvements in the definition of geographic areas، the extent to which individuals enrolled 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 in rates through group experience rating or other means: approaches for limiting the liability of the contracting organization under section 1876 of such Act in catastrophic cases: ways of establishing capitiation 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 underserved areas، while maintaining cost savings: and directed 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**


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(a) EXTENSION.—Notwithstanding any other provision of law، any demonstration project conducted under section 4017 of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100–123 [Pub. L. 1999–203؛ 42 U.S.C. 1395mm note] and conducted for the additional period of 2 years as provided for under section 4019 of BBA [Pub. L. 1999–33، set out as a note below]، shall be conducted for an additional period of 2 years.
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(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 demonstration under 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 demonstration during 1999، except that the following modifications shall apply:

(A) BASIC CAPITATION RATE.—The basic capitiation rate paid for services covered under the project (other than case management services) per enrollee per month and furnished during—

(1) the period beginning with October 1، 2000، and ending with December 31، 2000، shall be determined by actuarially adjusting the actual capitiation rate paid for such services in 1999 for inflation، utilization، and other changes to the CNO service package، and by reducing such adjusted capitiation rate by 10 percent in the case of the demonstration sites located in Arizona، Minnesota، and Illinois، and 15 percent for the demonstration site located in New York; and

(ii) 2001 shall be determined by actuarially adjusting the amount determined under subclause (I) for inflation; and

(ii) such case management fee shall be paid only for enrollees who are classified as moderately frail or frail pursuant to criteria established by the Secretary.

(C) GREATER UNIFORMITY IN CLINICAL FEATURES AMONG SITES.—Each project shall implement for each site—

(1) 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 planning approaches;

(2) disease management programs for targeted diseases (such as congestive heart failure، arthritis، diabetes، and hypertension) that are highly prevalent in the enrolled populations;

(3) systems and protocols to track enrollees through hospitalizations، including pre-admission planning، concurrent management during inpatient hospital stays، and post-discharge assessment، planning، and follow-up; and

(4) standardized patient educational materials for specified diseases and health conditions.

(D) QUALITY IMPROVEMENT.—Each project shall implement at each site once during the 15-month period—

(1) enrollee satisfaction surveys؛ and

(2) reporting on specified quality indicators for the enrolled population.

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(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 Finance of the Senate a preliminary report that—

(A) evaluates such demonstration projects for the period beginning July 1، 1997، and ending December 31، 1999، on a site-specific basis with respect to the impact on per beneficiary spending، specific health utilization measures، and enrollee satisfaction؛ and

(B) includes a similar evaluation of such projects for the portion of the extension period that occurs after September 30، 2000.

(2) FINAL REPORT.—The Secretary shall submit a final report to such Committees on such demonstration 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.—Another 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 a demonstration project as of the first day of the period under evaluation؛ and

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“(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 1393(a)(1)(A) of such Act (section 1395mm(a)(1)(A) of this title).”

Section 1000(a)(6) of Pub. L. 106–113, set out above, provided that: "The Secretary shall enter into an agreement with not less than four eligible organizations submitting applications to conduct demonstration projects conducted under section 4079 of the Omnibus Budget Reconciliation Act of 1987 (Pub. L. 100–203, set out as a note below) may be conducted for a additional period of 2 years, and the deadline for any report required relating to the results of such projects shall be not later than 6 months before the end of such additional period."

Section 4079 of Pub. L. 100–203, as amended by Pub. L. 100–366, title IV, §411(b)(3), July 1, 1989, 102 Stat. 797, 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 and not enrolled with the organization under this section, within the geographic area served by the organization and enrolled with such organization in accordance with subsection (c)(3).”

“(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 1861(s) of the Social Security Act [section 1395mm(aa)(2)(H)(ii), (5)–(9) of this title].

(G) Rural health clinic services described in section 1861(aa)(1)(C) of such Act [section 1395mm(aa)(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, directly or through arrangements with other qualified personnel, the services described in paragraph (1).

(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.

(3) The requirements of subparagraphs (B), (D), and (E) of section 1876(b)(2) of the Social Security Act (42 U.S.C. 1396mm(b)(2), (D), (E)).

(4) 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 (c) 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 XVIII 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, with 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 class of individuals who are enrolled with such organization 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 described in 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 of health and medical services, develop and disseminate guidelines for determination of payments for community nursing and ambulatory care, and such other data as the Secretary finds that adequate data are not available to determine that 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 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 subparagraphs (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 capta 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. (e)(3) of this section] which are selected by the eligible organization and which the Secretary finds are at least
Jan. 1, 1988, specific legislative recommendations constitute, and the adjusted community rate ("ACR", as defined in subsec. (g)(5) of this section). 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 conduct a study evaluating the extent of, and reasons for, the termination by Medicare beneficiaries of their membership in organizations with contracts under section 1876 of the Social Security Act (this section), with 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) 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(d) 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 membership in organizations with contracts under section 1876 of such Act [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


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 subsec. (g)(2) of this section, with 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.
organization to be provided by that organization, between such individuals and individuals who are enrolled with such organization pursuant to section 1395x(d) 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 1395x(c)(3) of such Act (subsec. (c)(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 1395x(c)(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 (a)(1) and (d) of this section, an ownership or investment interest in the entity, or

(B) except as provided in subsection (c)(3) 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)(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 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 300e–9(d) 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—
   (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,
(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.

(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 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 services performed personally by the physician (or an immediate family member of such physician).
(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), 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 physician or a physician group at substantial financial risk as determined by the Secretary pursuant to section 1395nn(1)(B)(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 or 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-
(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 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.

(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-
The term “fair market value” means the value in arms length transactions, consistent with 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 lessor.

(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)(v), 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.
(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-
subject to purchase 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.

(ii) 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)(i)) 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
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 (vi) 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)(i).

(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.

(1) Limitation on review
There shall be no administrative or judicial review under section 1395f of this title, section 1395cc 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 (1), 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 1395b–1 of this title.

Section 300e–9(d) of this title, referred to in subsec. (b)(3)(D), was redesignated section 300e–9(c) of this title by Pub. L. 100–517, §7(b), Oct. 24, 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 subsecs. (c) and (h)(2), is classified generally to Title 26, Internal Revenue Code. Part B of this subchapter, referred to in subsec. (c)(2)(C) and (h)(2), is classified generally to Title 26, Internal Revenue Code.

Part C of this subchapter, referred to in subsec. (h)(5)(A), is classified to section 1395c 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...
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 designated health services (as defined in section 1395x(d) of this title) who furnish such services in the area in which such individual resides.”


Subsec. (i)(2). Pub. L. 103–432, § 152(a)(2), (3), inserted “, or with a compensation arrangement (as described in subsection (a)(2)(B) of this section),” after “investment interest” (as described in subsection (a)(2)(A) of this section) and “interest or who have such a compensation relationship with the entity” before period at end.

Subsec. (b)(5). Pub. L. 103–432, § 152(b), in subpar. (D), substituted “services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services” for “or other diagnostic services”, and in subpars. (E), (F), and (H), inserted “and suppliers” before period at end.

1993—Subsecs. (a) to (e). Pub. L. 103–66, § 13562(a)(1), amended headings and text of subsections. (a) to (e) generally, substituting present provisions for provisions which related to: prohibition of certain referrals in subsection (a), general exceptions to both ownership and compensation arrangement prohibitions in subsection (b), general exception related only to ownership or investment prohibition for ownership in publicly-traded securities in subsection (c), additional exceptions related only to ownership or investment prohibition in subsection (d), and exceptions relating to other compensation arrangements in subsection (e).


Subsec. (d)(2). Pub. L. 108–173, § 507(a)(2), amended heading and text of par. (2) generally. Prior to amendment, text read as follows: “In the case of designated health services furnished in a rural area (as defined in section 1395ww(d)(2)(D) of this title) by a hospital described in subparagraph (F)” for “an applicable hospital (as defined in subparagraph (E))”. The Secretary may waive the requirements of this subsection (and the requirements of chapter 35 of title 44 with respect to information provided under this subsection (3) but which separately reports to a directory language services (as defined in section 1395x(a)(6)(B) of this title) who are interested investors or who are immediate relatives of interested investors.”


1994—Subsec. (f). Pub. L. 103–432, § 152(a)(1)(4), substituted “other compensation arrangements”, and in closing provisions, substituted “designated health services” for “covered items and services” and struck out “or at the end.”

The Secretary may waive the requirements of this subsection (and the requirements of chapter 35 of title 44 with respect to information provided under this subsection (3) but which separately reports to a directory language services (as defined in section 1395x(a)(6)(B) of this title) who are interested investors or who are immediate relatives of interested investors.”


Subsec. (b)(3)(E). Pub. L. 106–113, § 1000(a)(6) (title V, § 524(a)(5)), which directed addition of provisions at end of subsection (3) but which separately reports to a directory language services (as defined in section 1395x(a)(6)(B) of this title) who are interested investors or who are immediate relatives of interested investors.”

Subsec. (g)(5). Pub. L. 101–508, § 4207(k)(2), formerly § 4207(k)(1), struck out “as determined by the Secretary” after “The Secretary determines” and text of subsec. which related to: prohibition of certain referrals in subsection (a), general exceptions to both ownership and compensation arrangement prohibitions in subsection (b), general exception related only to ownership or investment prohibition for ownership in publicly-traded securities in subsection (c), additional exceptions related only to ownership or investment prohibition in subsection (d), and exceptions relating to other compensation arrangements in subsection (e).

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money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7(a)(a) of this title.


Pub. L. 101–508, §4207(e)(1)(A), (B), formerly §4207(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 title” for “in the case of an item or 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. 108–173, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT


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. 1356, 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, 1993.

“(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 1377 of the Social Security Act [subsects. (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 1377 (as amended by this Act);

“(B) section 1377(b)(4) of the Social Security Act [subsect. (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 1377(c)(2) of the Social Security Act [section 1377(c)(2) of this Act] (as amended by this Act) shall not apply to any arrangements that meets the requirements of section 1377(c)(2) of the Social Security Act (as in effect on the day before the date of the enactment of this Act);”

“(D) section 1377(e)(3) of the Social Security Act [subsection (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 (e)(2) or subsection (e)(3) of section 1377 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 1377(h)(4)(A), and of clause (i) of section 1377(h)(4)(B) of the Social Security Act [subsects. (h)(4)(A)(iv), (v), (B)(1) of this section] (as amended by this Act) shall not apply; and

“(F) section 1377(h)(4)(B) of the Social Security Act [subsection (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)(ii) of such Act (as amended by this Act).”

Section 152(d)(2) of Pub. L. 103–432 provided that: “The amendments made by this subsection [amending this section and provisions set out below] shall apply as if included in the enactment of OBRA–1993 [Pub. L. 103–66].”

EFFECTIVE DATE OF 1990 AMENDMENT


“(2) The reporting requirement of section 1877(f) of the Social Security Act [subsection (f) of this section] shall take effect on October 1, 1990.”

DEADLINE FOR CERTAIN REGULATIONS

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 1395v 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 [subsection (f) of this section] shall take effect on October 1, 1990.”

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. 1395mm(i)(1)] as added by subsection (a)(2), 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-REFERAL DISCLOSURE PROTOCOL
Pub. L. 111–146, title VI, §6409, Mar. 23, 2010, 124 Stat. 772, provided that:

“(1) 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 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) instructions on the implication of the SRDP on corporate integrity agreements and corporate compliance agreements.

“(2) Publication on the 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.

“(3) 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)).

“(b) Reduction in amounts 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.

“(c) 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

“(1) MedPAC study.—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 such hospitals and the extent to which 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;

“(B) 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

“(C) 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) Reports.—Not later than 15 months after the date of enactment of this Act [Dec. 8, 2003], 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

Statistical Summary of Comparative Utilization
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) 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 six months after the date of enactment of this subchapter for the period covered by such report. 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.

(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

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

(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.

(c) 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.
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 such 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 1395y(w)(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.

(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 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” for “the rate of return on equity capital established by regulation pursuant to section 1395w(v)(1)(B) of this title and in effect at the time”.


Subsec. (e). Pub. L. 98–369, §2354(b)(40), substituted “(e)” for “(e) 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. (l). Pub. L. 98–369, §2351(b)(1), inserted “or which have obtained a hearing under subsection (b) of this section” after “a common ownership or control” in last sentence.

1983—Subsec. (a). Pub. L. 98–21, §602(h)(1)(A), inserted provision in introductory text that, except as provided in subsec. (g) of this section, any hospital which receives payments in amounts computed under section 1395ww(b) or (d) of this title and which has submitted such reports within such time as Secretary may require in order to make payment under such section may obtain a hearing with respect to such payment by Board.

Subsec. (a)(1)(A). Pub. L. 98–21, §602(h)(1)(B), (C), designated existing provisions as cl. (i) and added cl. (ii).

Subsec. (a)(3). Pub. L. 98–21, §602(h)(1)(D), substituted “(1)(A)(i), or with respect to appeals under paragraph (1)(A)(ii)(1), 180 days after notice of the Secretary’s final determination,” for “(1)(A)”.

Subsec. (f)(1). Pub. L. 98–21, §602(h)(2), inserted “(or, in an action brought jointly by several providers, the judicial district in which the greatest number of such providers are located)” after “the judicial district in which the provider is located”, and “Any appeal to the Board or action for judicial review by providers which are under common ownership or control must be brought by such providers as a group with respect to any matter involving an issue common to such providers.”

Subsec. (g). Pub. L. 98–21, §602(h)(3), designated existing provisions as par. (1) and added par. (2).

Subsec. (h). Pub. L. 98–21, §602(h)(4), substituted “payment of providers of services” for “cost reimbursement”.

1980—Subsec. (f)(1). Pub. L. 96–499 inserted provision empowering providers of services to obtain judicial review of any action of a fiscal intermediary involving a
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 providing for judicial review of any affirmation by Secretary, and added pars. (2) and (3).

Effective Date of 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)(4) of Pub. L. 101–508, set out as a note under section 1395x of this title.

Effective Date of 1984 Amendment

Section 2351(c) of Pub. L. 98–369 provided that: “(1) the amendments made by section 602(b)(2)(A) of this 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(b)(2)(B) of this 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)(i) 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 for such items or services or reasonably comparable items or services. Any provider or other person furnishing items or services for which payment may not be made 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 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, pro-
vider or other person furnishing services, procedure, or test, with respect to which such pro-
vider or other person has been notified by the Secretary (including notification by a utiliza-
tion 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 pay-
ment could not be made; indemnification of 
individual

In any case in which the provisions of para-
graphs (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 ex-
pected 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, indem-
nify the individual (referred to in such para-
graphs) for any payments received from such in-
dividual by such provider or such other person, 
as the case may be, for such items or services. 
Any payments made by the Secretary as indem-
nification 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 pro-
visions 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 rea-
son 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 ac-
count 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 sub-
chapter 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 rea-
son of section 1395l(a)(1) or (a)(9) of this title or 
by reason of a coverage denial described in sub-
section (g) of this section.

(d) Exercise of rights

In any case arising under subsection (b) of this 
section (but without regard to whether pay-
mments 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 regula-
tions, be exercised by such provider or other per-
son 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 pro-
vider of services acting in good faith in accord-
ance with the advice of a utilization review com-
mittee, quality control and peer review organi-
sation, or fiscal intermediary, or on the basis of 
whether such individual has the same rights that an 
individual will not exercise such rights under 
such sections.

(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 re-
spect to specific services may be rebutted by ac-
tual 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 re-
specting timely submittal of bills for payment 
and medical documentation.

(B) The agency program has reasonable pro-
duced 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 cov-
erage 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 by reason 
of a coverage denial described in subsection (g) 
of this section does not exceed 2.5 percent, com-
cputed 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 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 1395n(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)—

(1) 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;

(2) furnishes an item or service to a beneficiary for which payment is denied in advance under section 1395m(a)(5) 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)(7)(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 remaining 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.


1987—Subsec. (b). Pub. L. 100–203 struck out "subject to the deductible and coinsurance provisions of this subchapter," after "referred to in such paragraphs" and inserted at end "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."

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, §9341(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, 1980]."

**Effective Date of 1987 Amendment**
Amendment by Pub. L. 100–203 applicable to services furnished on or after Jan. 1, 1988, see section 6096(d) of Pub. L. 100–203, set out as a note under section 1320c–3 of this title.

**Effective Date of 1986 Amendment**

**Effective Date**
Section 123(b) of Pub. L. 92–603 provided that: "(a) Eligibility for payments; conditions and requirements; twelve-month period [this subchapter]."

**Provisions Related to Advance Beneficiary Notices; Report on Prior Determination Process**
Pub. L. 108–173, title IX, § 938(c), Dec. 8, 2003, 117 Stat. 2415, provided that:

"(1) DATA COLLECTION.—The Secretary of Health and Human Services shall establish a process for the collection of information on the instances in which an advance beneficiary notice (as defined in paragraph (5)) has been provided and on instances in which a beneficiary indicates on such a notice that the beneficiary does not intend to seek to have the item or service that is the subject of the notice furnished.

"(2) OUTREACH AND EDUCATION.—The Secretary shall establish a program of outreach and education for beneficiaries and providers of services and other persons on the appropriate use of advance beneficiary notices and coverage policies under the medicare program.

"(3) GAO REPORT ON USE OF ADVANCE BENEFICIARY NOTICES.—Not later than 18 months after the date on which section 1869(h) of the Social Security Act [section 1395f(h) of this title] (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of advance beneficiary notices under title XVIII of such Act [this subchapter]. Such report shall include information concerning the providers of services and other persons that have provided such notices and the response of beneficiaries to such notices.

"(4) GAO REPORT ON USE OF PRIOR DETERMINATION PROCESS.—Not later than 30 months after the date on which section 1869(h) of the Social Security Act [section 1395f(h) of this title] (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of prior determination processes under such section. Such report shall include:

"(A) information concerning—
"(i) the number and types of procedures for which a prior determination has been sought;

"(ii) determinations made under the process;

"(iii) the percentage of beneficiaries prevailing;

"(iv) in those cases in which the beneficiaries do not prevail, the reasons why such beneficiaries did not prevail; and

"(v) changes in receipt of services resulting from the application of such process;

"(B) an evaluation of whether the process was useful for physicians (and other suppliers) and beneficiaries, whether it was timely, and whether the amount of information required was burdensome to physicians and beneficiaries; and

"(C) recommendations for improvements or continuation of such process.

"(5) ADVANCE BENEFICIARY NOTICE DEFINED.—In this subsection, the term 'advance beneficiary notice' means a written notice provided under section 1879(a) of the Social Security Act (42 U.S.C. 1395pp(a)) to an individual entitled to benefits under part A or enrolled under part B of title XVIII of such Act (part A and part B of this subchapter) before items or services are furnished under such part in cases where a provider of services or other person who would furnish the item or service believes that payment will not be made for some or all of such items or services under such title (this subchapter)."

**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 1395y(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 requirements (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 improvements 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 Secretary 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 nursing facilities of such Service which may be necessary to achieve compliance with the applicable conditions and requirements of this subchapter. The preceding sentence shall cease to apply when the Secretary determines and certifies that substantially all of the hospitals and skilled nursing facilities of such Service in the United States are in compliance with such conditions 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 in terms of their compliance with the applicable conditions and requirements of this subchapter and of the progress being made by such hospitals and facilities (under plans submitted under subsection (b) of this section and otherwise) toward the achievement of such compliance.

(e) Services provided by Indian Health Service, Indian tribe, or tribal organization

(1) (A) Notwithstanding section 1395q(d) of this title, subject to subparagraph (B), the Secretary shall make payment under part B of this subchapter to a hospital or an ambulatory care clinic (whether provider-based or freestanding) that is operated by the Indian Health Service or by an Indian tribe or tribal organization (as defined for purposes of subsection (a) of this section) for services described in paragraph (2) (and for items and services furnished on or after January 1, 2005, all items and services for which payment may be made under part B of this subchapter) furnished in or at the direction of the hospital or clinic under the same situations, terms, and conditions as would apply if the services 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 payment 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 subchapter is made under a fee schedule.

(C) Services furnished by a physical therapist 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 certain 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 payment may be made under this subchapter, see section 1645 of title 25.


REFERENCES IN TEXT

Part B of this subchapter, referred to in subsec. (e)(1)(A), (2)(B), (C), is classified to section 1385 et seq. of this title.

Section 1645 of title 25, referred to in subsec. (f), was amended generally by section 10221(a) of title X of Pub. L. 111–148, Mar. 23, 2010, 124 Stat. 935, and, as so amended, no longer contains provisions relating to direct billing of medicare, medicaid, and other third party payors.

AMENDMENTS

2010—Subsec. (e)(1)(A). Pub. L. 111–148, § 2902(a), substituted “on or after” for “during the 5-year period beginning on”.

2003—Subsec. (e)(1)(A). Pub. L. 108–173 inserted “(and for items and services furnished during the 5-year period beginning on January 1, 2005, all items and services for which payment may be made under part B of this subchapter)” after “for services described in paragraph (2)”.


1 See References in Text note below.
to reflect renumbering of corresponding section of original act.

Effective Date of 2010 Amendment

Amendment by 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. 106–417 effective Oct. 1, 2000, see section 3(c) of Pub. L. 106–417, set out as a note under section 1645 of Title 25, Indians.

Medicare Payments Not Considered in Determining Appropriations for Indian Health Care


MEDICARE PAYMENTS NOT CONSIDERED IN DETERMINING APPROPRIATIONS FOR INDIAN HEALTH CARE


MEDICARE PAYMENTS NOT CONSIDERED IN DETERMINING APPROPRIATIONS FOR INDIAN HEALTH CARE

Similar provisions are contained in section 401(a) of Pub. L. 94–437, which is classified to 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

Similar provisions are contained in section 401(b) of Pub. L. 94–437, which is classified to section 1641(b) of Title 25, Indians.

End stage renal disease program

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 benefits 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.

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-care dialysis services) in 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)(F) 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) 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 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 1395x(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.

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

1See 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 include, 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 renegotiated 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-
od (or methods) shall provide for the prospective determination of a rate (or rates) for each mode of care based on a single composite weighted formula (which takes into account the mix of patients who receive dialysis services at a facility or at home and the relative costs of providing such services in such settings) for hospital-based facilities and such a single composite weighted formula for other renal dialysis facilities, or based on such other method or combination of methods which differentiate between hospital-based facilities and other renal dialysis facilities and which the Secretary determines, after detailed analysis, will more effectively encourage the more efficient delivery of dialysis services and will provide greater incentives for increased use of home dialysis than through the single composite weighted formulas. The amount of a payment made under any method other than a method based on a single composite weighted formula may not exceed the amount (or, in the case of continuous cycling peritoneal dialysis, 130 percent of the amount) of the median payment that would have been made under the formula for hospital-based facilities. Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the Secretary shall provide for such exceptions to such methods as may be warranted by unusual circumstances (including the special circumstances of sole facilities located in isolated, rural areas and of pediatric facilities). Each application for such an exception shall be deemed to be approved unless the Secretary disapproves it by not later than 60 working days after the date the application is filed. The Secretary may provide that such method will serve in lieu of any target reimbursement rate that would otherwise be established under paragraph (6). The Secretary shall reduce the amount of each composite rate payment under this paragraph for each treatment by 50 cents (subject to such adjustments as may be required to reflect modes of dialysis other than hemodialysis) and provide for payment of such amount to the organizations (designated under subsection (c)(2) of this section to ensure equitable treatment of all such network organizations. The Secretary in distributing any such payments to network organizations shall take into account—
(A) the geographic size of the network area;
(B) the number of providers of end stage renal disease services in the network area;
(C) the number of individuals who are entitled to end stage renal disease services in the network area; and
(D) the proportion of the aggregate administrative funds collected in the network area.

The Secretary shall increase the amount of each composite rate payment for dialysis services furnished during 2000 by 1.2 percent above such composite rate payment amounts for such services furnished on December 31, 1999, for such services furnished on or after January 1, 2001, and before January 1, 2005, by 2.4 percent above such composite rate payment amounts for such services furnished on December 31, 2000, and for such services furnished on or after January 1, 2005, by 1.6 percent above such composite rate payment amounts for such services furnished on December 31, 2004.

(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.

(11)(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 1395f 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 1395f of this title; and
(ii) in the case of erythropoietin provided by a provider of services, renal dialysis facility, or other supplier of home dialysis supplies and equipment—

(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 or physician for the same 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 2006 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 2006 or 2007, 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 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 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
(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), as 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 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-
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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)—

(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) 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).

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.

(C) The Secretary shall, in regulations, prescribe requirements with respect to membership in network organizations by individuals (and the relatives of such individuals) (i) who have an ownership or control interest in a facility or provider which furnishes services referred to in section 1395(f) of this title, or (ii) who have received remuneration from any such facility or provider in excess of such amounts as constitute reasonable compensation for services (including time and effort relative to the provision of professional medical services) or goods supplied to such facility or provider; and such requirements shall provide for the definition, disclosure, and, to the maximum extent consistent with effective administration, prevention of potential or actual financial or professional conflicts of interest with respect to decisions concerning the appropriateness, nature, or site of patient care.

(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 assist network organizations in their development of or 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 expenses 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;

(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 dialyzer 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)) 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.


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(b)(5)(C), (D), Dec. 22, 1987, 101 Stat. 1330–80.

Amendments

2010—Subsec. (b)(14)(F)(1). Pub. L. 111–148, § 3401(b)(1), designated existing provisions as subcl. (1), (2), 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)(II). Pub. L. 111–148, § 3401(b)(2), substituted “Subject to clause (i)(II) the” for “The” and “and clause (i) minus 1.0 percentage point”.

2006—Subsec. (b)(12)(A). Pub. L. 110–275, § 153(a)(2), (b)(3)(A)(i)(I), substituted “Subject to paragraph (14), in concluding provisions, inserted “or paragraph (14)” after “this paragraph” and “or under the system under paragraph (14)” after subparagraph (B).


Subsec. (b)(13)(B). Pub. L. 110–275, § 153(b)(3)(A)(III)(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 1395w–3a of this title, section 1395w–3b of this title, or section 1395w–3c 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.”


Subsec. (b)(12)(G). Pub. L. 109–171 amended subpar. (G) generally. Prior to amendment by Pub. L. 109–171, § 13061, the last sentence of the second paragraph of this section, referred to in subsec. (b)(12)(F), was section 623(c) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, the Secretary” for “The Secretary”, and, in concluding provisions, struck out “and” before “for such services furnished on or after January 1, 2001,”, inserted “and before January 1, 2005,” after “April 1, 2007,” in cl. (ii) and added cls. (iii) and (iv).


rate payment amounts for such services furnished on December 31, 2004" before period at end.
Subsec. (b)(17). Pub. L. 106–554 substituted for "such services furnished on or after January 1, 2001, by 2.4 percent" for "for such services furnished on or after January 1, 2001, by 1.2 percent" in concluding proviso.

1994—Subsec. (b)(3). Pub. L. 103–296 inserted before period at end, "except that, in so applying such sections and in applying section 405(h) 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".
Pub. L. 101–508, § 4201(c)(1), designated existing provisos as subpar. (A) and added subpar. (B).
1989—Subsec. (b)(5)(A). Pub. L. 101–239, § 6102(c)(8), inserted "or, for services furnished on or after January 1, 1992, on the basis described in section 1395w–4 of this title after "comparable services".
Subsec. (b)(4). Pub. L. 101–239, § 6203(b)(2), designated existing provisos as subpar. (A) and added subpar. (B).
Subsec. (b)(7). Pub. L. 101–239, § 6218(a), substituted "organizations (designated under subsection (c)(1)(A) of this section) for such organizations' necessary and proper administrative costs incurred in carrying out the responsibilities described in subsection (c)(2) of this section. The Secretary shall provide that amounts paid under the previous sentence shall be distributed to the organizations described in subsection (c)(1)(A) of this section to ensure equitable treatment of all such network organizations. The Secretary in distributing any such payments to network organizations shall take into account—" and subpars. (A) to (D) for "network administrative organization (designated under subsection (c)(1)(A) of this section) for the network area in which the treatment is provided) for its necessary and proper administrative costs incurred in carrying out its responsibilities under subsection (c)(2) of this section.
"Each application for such an exception shall be deemed to be approved unless the Secretary disapproves it by not later than 60 working days after the date the application is filed.".
Subsec. (c)(1)(A). Pub. L. 99–509, § 9335(d)(1), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "For the purpose of assuring effective and efficient administration of the benefits provided under this section, the Secretary shall establish, in accordance with such criteria as he finds appropriate, renal disease network areas, such network organizations (including a coordinating council, an executive committee of such council, and a medical review board, for each network area) as he finds necessary to accomplish such purpose, and a national end stage renal disease medical information system. The Secretary may by regulations provide for such coordination of network planning and quality assurance activities and such exchange of data and information among agencies with responsibilities for health planning and quality assurance activities under Federal law as is consistent with the economical and efficient administration of this section and with the responsibilities established for network organizations under this section.
"Subsec. (c)(1)(B). Pub. L. 99–509, § 9335(e), amended subpar. (B) generally, substituting "network council and each medical review board for "coordinating council and executive committee".
Subsec. (c)(2)(A). Pub. L. 99–509, § 9335(f)(1), inserted "and the participation of patients, providers of services, and renal disease facilities in vocational rehabilitation programs" before the semicolon.
Subsec. (c)(2)(B). Pub. L. 99–509, § 9335(f)(2), inserted "and with respect to working with patients, facilities, and providers in encouraging participation in vocational rehabilitation programs" before first semicolon.
Subsec. (c)(2)(D) to (F). Pub. L. 99–509, § 9335(f)(5), added subpars. (D) to (F). Former subpars. (D) and (E) redesignated (G) and (H), respectively.
Subsec. (c)(2)(G). Pub. L. 99–509, § 9335(f)(3), (5), redesignated former subpar. (D) as (G) and inserted "and reporting to the Secretary on facilities and providers that are not providing appropriate medical care" before the semicolon.
Subsec. (c)(2)(H). Pub. L. 99–509, § 9335(f)(4), (5), redesignated former subpar. (E) as (H) and inserted "and encouraging participation in vocational rehabilitation programs" after "and transplantation".
Subsec. (c)(3). Pub. L. 99–509, § 9335(g), inserted "or to follow the recommendations of the medical review board" after "network plans and goals".
Subsec. (c)(6). Pub. L. 99–509, § 8335(h), 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. (f)(7). Pub. L. 99–509, § 8335(k)(1), 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."

Subsec. (a), (b)(1), (2)(A), (B), (3), (8). Pub. L. 96–369, § 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, § 2352(a), inserted provision 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.

Subsec. (b)(2)(A). Pub. L. 98–617, amended par. (7) to read as follows: "The amendments made by paragraph (1) [amending 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 2323(d)(4) of Pub. L. 101–508, set out as a note under section 1365x of this title.

Effective Date of 1989 Amendment

Section 2323(b)(3) of Pub. L. 101–239 provided that: "The amendments made by this subsection [amending this section] shall apply with respect to the furnishing of home dialysis services, supplies, and equipment furnished on or after February 1, 1990."

Effective Date of 1987 Amendments

Amendment by section 4065(b) of Pub. L. 100–203 effective Jan. 1, 1988, see section 4065(b)(1) of Pub. L. 100–203, set out as a note under section 1365x 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 15(a) of Pub. L. 100–93, set out as a note under section 1320a–7 of this title.

Effective Date of 1986 Amendment

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, § 4085(i)(21)(C), Dec. 22, 1987, 101 Stat. 1330–133, 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 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 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 2353(b) of Pub. L. 98–369 provided that: “The amendment made by this section [amending this section] apply to determinations made by the Secretary on or after the date of the enactment of this Act (July 18, 1984).” Amendment by section 2354(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. 98–369, set out as a note under section 1320a–1 of this title.

**Effective Date of 1981 Amendment**

Section 2145(b) of Pub. L. 97–35 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 first promulgate regulations to carry out section 1884(b)(7) of the Social Security Act [subsec. (b)(7) 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, § 153(b)(4), July 15, 2008, 122 Stat. 2515, 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 title XVIII of the Social Security Act (this subchapter) for such drugs and biologicals and the acquisition costs 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).”

**Demonstration of Bundled Case-Mix Adjusted Payment System for ESRD Services**

Pub. L. 108–173, title VI, § 623(e), 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. 6, 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, bundling 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 appropriate methodology for establishing a specific payment adjustment to account for additional costs incurred by rural facilities.
“(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, 2002, 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 rate payment (as determined taking into account the transitional percentage allowance equal to 0.39 percent (to account for the timing of implementation of the CPI update)).

“(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, 1531A–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 home and such services furnished in a hospital. 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,
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 RATIOS
Section 4202(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) RECOMMENDATIONS.—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 1993 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 1993) 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. 101–353, set out as a note under section 1395b–4 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 paragraph (1) 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—

"(1) 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 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(b)(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.

"(4) 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, 1995, 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 to 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 January 1, 2000, such base rate shall be equal to the respective 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).

"(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


"The amendment made by paragraph (1) (amending sec-
§ 1395rr-1. Medicare coverage for individuals exposed to environmental health hazards

(a) Deeming of individuals as eligible for Medicare benefits

(1) In general

For purposes of eligibility for benefits under this subchapter, an individual determined under subsection (c) to be an environmental exposure affected individual described in subsection (e)(2) shall be deemed to meet the conditions specified in section 426(a) of this title.

(2) Discretionary deeming

For purposes of eligibility for benefits under this subchapter, the Secretary may deem an individual determined under subsection (c) to be an environmental exposure affected individual described in subsection (e)(2) to meet the conditions specified in section 426(a) of this title.

(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 1 B 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 to individuals described in paragraph (2)(A) who reside in each such area.

(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—

(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, at 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 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 such sums 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);

(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.
§ 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)(c), (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, 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 (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 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 by subparagraph (H); and

(B) includes requirements equal to or more stringent than the requirements described in paragraphs (2) through (5) of subsection (c) of this section; and

(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 (or 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.

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 (s) 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—

(i) provides notice to such physician or supplier and the beneficiary of the payment determination under the policy, and

(ii) 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 returned 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) It is unlawful for a person to sell or issue to an individual entitled to benefits under part A of this chapter, or enrolled under part B of this chapter (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 under 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 under 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 under 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 (I) and fails to furnish the appropriate 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 111(m)(2) of the Social Security Act Amend-
ments of 1994 (Public Law 103–432) and as modi-
fied 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 state-
specification under subparagraph (D) of this para-
graph (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 sub-
clause (V), strike the boldface matter that be-
gins "This insurance" and all that follows up
to the next paragraph that begins "Medicare".
(IV) In each statement not described in sub-
clause (V), insert before the boxed matter
(that states "Before You Buy This Insurance")
the following: "This policy may pay benefits
without regard to other health benefit cov-
erage to which you may be entitled under
Medicare or other insurance.".
(V) In a statement relating to policies pro-
viding both nursing home and non-institu-
tional coverage, to policies providing nursing
home benefits only, or policies providing home
health benefits only, amend the sentence that
begins "Federal law" to read as follows: "Fed-
eral law requires us to inform you that in cer-
tain 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 poli-
cies, 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 supple-
mental policy) or rider to a policy 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 any medical assistance
under subchapter XIX of this chapter, whether
as a qualified medicare beneficiary or other-
wise, and
(II) the written statement is accompanied by
a written acknowledgment, signed by the sell-
er 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 eligi-
ble individual does not need more than one
medicare supplemental policy,
(II) states in substance that individuals may
be eligible for benefits under the State med-
icaid program under subchapter XIX of this
chapter and that such individuals who are ent-
titled 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 bene-
fits under such subchapter and may be re-
instated upon loss of such entitlement, and
(III) states that counseling services may be
available in the State to provide advice con-
cerning the purchase of medicare supple-
mental policies and enrollment under the med-
icaid 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 as-
sistance 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 pol-
icy and indicates an intent to terminate the pol-
icy 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 cov-
erage (taking into account any such replace-
ment).
(III) If the statement required by clause (i) is
obtained and indicates that the individual is en-
titled to any medical assistance under sub-
chapter XIX of this chapter, the sale of the pol-
icy is not in violation of clause (i) (insofar as
such clause relates to such medical assistance),
if (aa) a State medicaid plan under such sub-
chapter 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 pre-
scription drugs, or (cc) the only medical assist-
ance to which the individual is entitled under
the State plan is medicare cost sharing de-
scribed in section 1396d(p)(3)(A)(ii) of this title.
(iv) Whoever issues or sells a medicare supple-
mental 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.

(f) 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 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) or for members or former members (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 2355 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(aa)(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).

(i) 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 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 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, and

(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) by the date specified in paragraph (1)(B) or (2)(B) (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 remain 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 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 revised NAIC Model Regulation or the revised Federal model standards (as the case may be) before the date of the sale of the policy.

In this paragraph, the term “transition deadline” means 1 year after the date the Association 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, 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) by the date specified in paragraph (1)(B) or (2)(B) (as the case may be).
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(4)(A) The date specified in this paragraph for a policy issued in a State is—

(1) if 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, as 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-

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 "1991 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 (1)(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 (1)(A) in those States that on Novem-
(7) This subsection shall not be construed as preventing an issuer of a medicare supplemental policy who otherwise meets the requirements of this section 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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4So 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.

(D) 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 171(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 171(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.

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 171(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 171(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.

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 171(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 171(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 civil 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.

(6) Coverage for pre-existing conditions

(1) If a medicare supplemental policy replaces another medicare supplemental policy, the issuer of the replacing policy shall wait 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) 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 section 2701(c) 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 pre-existing 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 subparagraph (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 pre-existing condition under such policy.

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 to such Medicare supplemental policy. 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 Medicare+Choice plan 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.

(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 1395(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; or

(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 enrols, 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 Medicare+Choice plan under part C of this subchapter or in a PACE program under section 1395eee 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 “F” under the standards established under subsection (p)(2) of this section.

(ii) 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 medicare supplemental policy described in this subparagraph in which the individual was most recently previously enrolled as modified under 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)(6)(A) 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 comparable benefit packages other than under the classification referred to in clause (I), the references to comparable 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-
suers 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 subparagraph (B)(iv)(I), 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 in a 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)(B) 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 as the Secretary may determine, taking into account estimated savings under contracts with carriers and fiscal intermediaries and other factors 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 (B) applies

(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 medicare 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 medicare 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
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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 established under 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.

(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)(x)(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
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(2) Prohibition on collection of genetic information

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 such 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”.


REFERENCES IN TEXT

Parts A and B of this subchapter, referred to in subsecs. (d)(3)(A)(i), (vi)(I), (vii)(ID), (B)(i), (s)(2)(A), (3)(B)(vi), (w)(2)(A)(i), (iii), and (y)(1), are classified to sections 1395c et seq. and 1395d et seq., respectively, of this title.


Part D of this subchapter, referred to in subsecs. (g)(1) and (v)(2)(B)(i)(1), (ii), (6)(C), is classified to section 1395w–101 et seq. of this title.

Section 603(c) of the Social Security Amendments of 1963, referred to in subsec. (g)(1), is section 603(c) of Pub. L. 98–21, title VI, Apr. 29, 1983, 97 Stat. 188, which was not classified to the Code, and was repealed by Pub. L. 102–233, title IV, §4803(d), Aug. 5, 1997, 111 Stat. 550, subject to transition provisions.


Section 9412(b) of the Omnibus Budget Reconciliation Act of 1986, referred to in subsec. (g)(1), is section 9412(b) of Pub. L. 99–509, title IX, Oct. 21, 1986, 100 Stat. 2662, which was not classified to the Code, and was repealed by Pub. L. 100–203, title IV, §4081(b), Aug. 4, 1988, 102 Stat. 742–746, as amended.

For complete classification of this Act to the Code, see Short Title of 1988 Amendment note set out under section 1395 of this title and Tables.

Stat. 1979. For complete classification of this Act to the Code, see Short Title of 1989 Amendment note set out under section 1305 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. 111-118, title I, §§1201(2), 1563(c)(1), formerly §1562(c)(1), title X, §10107(b)(1), Mar. 23, 2010, 124 Stat. 155, 892, and is classified to section 300gg(b) 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.

Paragraphs (2)(A), (B) and (3)(C)–(E) of section 1395u(b) of this title, referred to in subsec. (t)(3), were repealed by Pub. L. 108-173, title IX, §911(c)(3)(B), (C)(iv), Dec. 8, 2003, 117 Stat. 2384.


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. 111-118, §3210(b), substituted "(w), and (y)" for "", and (w)".


Subsec. (s)(2)(E), (F). Pub. L. 110-233, §104(a), added subpars. (E) and (F).


2007—Subsec. (y)(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 struck 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 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 or a part D drug plan offered in the area in which the individual resides, but the coverage under subparagraph (A) shall only become effective upon termination of coverage under the Medicare+Choice plan involved."


Subsec. (s)(3)(C)(iii). Pub. L. 108-173, §104(a)(2)(B), inserted "and subject to subsection (v)(1) of this section" after "subparagraph (B)(v))"


2000—Subsec. (s)(3)(A). Pub. L. 106-554, §1(a)(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, §1(a)(6) [title VI, §618(a)(2)], added subpar. (E) and struck out former subpar. (E) which read as follows: "(E)(i) 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 or discontinuance 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 V, §536(a)(1)], inserted before the date of application of the individual's enrollment with such provider under circumstances that are similar to the circumstances that would permit discontinuance of the individual's enrollment with such provider under 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 V, §536(a)(2)], inserted "any PACE provider under section 1395eee of this title, and or paragraph (E) after "in the case of an individual described in subparagraph (B) who in concluding provisions.

Subsec. (s)(3)(B)(II). Pub. L. 106-113, §1000(a)(6) [title V, §536(a)(1)], inserted before the date of application 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)(VI). Pub. L. 106-113, §1000(a)(6) [title V, §536(a)(3)], inserted or in a PACE program under section 1395eee of this title after "part C of this subchapter 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-


Pub. L. 105–33, § 4031(c), inserted “‘a policy described in clause (v),’” after “Medi-

Subsec. (g)(1). Pub. L. 105–33, § 4003(a)(3), inserted “‘and a Medicare+Choice plan plan or after “does not include” the first place appearing. 

Pub. L. 105–33, § 4002(a)(2), struck out “‘, during the period beginning on the date specified in subsection (p)(1)(F) of this section and ending on December 31, 1995,’” after “Omnibus Budget Reconciliation Act of 1989,” or. 

Pub. L. 105–33, § 4002(a)(1), inserted before period at end “plus the 2 plans described in paragraph (11)(A)”.


Subsec. (a)(2)(B). Pub. L. 105–33, § 4031(b)(1), substituted “‘subparagraphs (C) and (D)’” for “‘subparagraph (C)’”. 


Pub. L. 105–33, § 4031(a)(1)(C), redesignated third sentence as cl. (iii), 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 secondary 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 unlawful for a person to sell or issue a health insurance policy to an individual entitled to benefits under part A of this chapter who is less than an individual’s (who is described in section 1395aa–1) 65 years of age or older before “may be eligible”.

Pub. L. 103–432, § 171(d)(3)(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”. 

Pub. L. 103–432, § 171(d)(2)(D), substituted “‘has another medicare supplemental policy’” for “‘has another policy’”. 


Pub. L. 103–432, § 171(c)(3)(A), substituted “‘the sale or issuance of a group policy’” for “‘the sale or issuance of a medicare supplemental 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 duplicative copy is mailed”.


Subsec. (g)(1). Pub. L. 103–432, § 171(j)(1), substituted “an eligible organization (as defined in section 1985m(b) of this title) if the policy or plan provides benefits pursuant to a contract under section 1985m 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 1985m(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 1985m of this title or an agreement under section 1985m of this title.”

Subsec. (g)(2)(B). Pub. L. 103–432, § 171(c)(3), substituted “Secretary” for “Panel”.


Subsec. (p)(1)(A). Pub. L. 103–432, § 171(a)(2)(A), in introductory provisions, substituted “changes the revised NAIC Model Regulation (described in subsection (m) of this section) to incorporate” 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”.

Subsec. (p)(1)(B). Pub. L. 103–432, § 171(a)(2)(B), substituted “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”.


Subsec. (p)(2). Pub. L. 103–432, § 171(a)(2)(D), substituted “NAIC or Federal standards” for “NAIC standards or the Federal standards”.


Subsec. (p)(4)(A)(i). Pub. L. 103–432, § 171(a)(2)(F), inserted “or paragraph (6)” after “subparagraph (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) (but subject to paragraph (5)(F) for the regulation of the applicable 1991 NAIC Model Regulation or 1991 Federal Regulation insofar as such regulation relates to the requirements of subsection (e) or (q) of this section or clause (i), (ii), or (iii) of paragraph (4)(A) for ‘after the effective date of the NAIC or Federal standards with respect to the policy, in violation of the previous requirements of this subsection’”.


Subsec. (p)(10). Pub. L. 103–432, § 171(a)(2)(L), substituted “consistent with paragraph (1)(A)(i)” for “consistent with this subsection”.

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 “member 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 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 renewed (or 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 under clause (i) of 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.”


Subsec. (r)(1)(B). Pub. L. 103–432, § 171(e)(1)(B), inserted “for periods after the effective date of these provisions” after “the policy can be expected”.

Subsec. (r)(1)(D). 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)(2)(A). Pub. L. 103–432, § 171(e)(1)(F)(1), substituted “by standard package” for “by policy number”, in first sentence and “until 12 months following issue”, for “with respect to the first 2 years in which it is in effect” in second sentence, struck out “in order to apply paragraph (1)(B) to the first 2 years in which policies are effective” after “may be appropriate” in third sentence, and inserted at end “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 171(m)(4) of the Social Security Act Amendments of 1994.”


Subsec. (r)(6)(A). Pub. L. 103–432, § 171(e)(1)(L), substituted “fails to provide refunds or credits as required...” for “...fails to provide refunds or credits...”
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 “of 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”.

Subsec. (d)(2)(B). Pub. L. 103–432, §171(g)(3), substituted “before the policy became effective” for “before it became effective”.

Pub. L. 101–508, §4351(a)(1), substituted “If a medicare supplemental policy meets the 1991 NAIC Model Regulation or 1991 Federal Regulation for ‘If a policy meets the NAIC Model Standards’.


1990—Pub. L. 101–508, §4353(b)(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, §4353(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 return to policyholders in the following proportion: 90% of aggregate benefits provided under the policy, at least 75% of the aggregate amount of premiums collected in the case of group policies and at least 90% of the aggregate amount of premiums collected in the case of individual policies.”


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 subpar. (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, § 4355(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 1395cc of this title or an agreement with the Secretary under section 1395cc of this title.”

Subsecs. (a), (p), Pub. L. 101–508, § 4353(1), formerly § 4353(a)(3), as renumbered and amended by Pub. L. 103–422, § 171(a)(1), added subsecs. (e) and (p).


1989—Subsecs. (a), (b)(1), Pub. L. 101–234, § 203(a)(1)(A), substituted “subject to subsection (k)(3), (c)(4), (m), and (n) of this section” for “subject to subsection (k)(3) of this section” after “determined” in subsec. (a)(1)(A), added subsec. (t).


Subsec. (k)(3). Pub. L. 101–234, § 203(a)(1)(B)(11), substituted “subject to subsections (m), (n), and (o) of this section” for “subject to (l) of this section” after “determined” in subsec. (a)(1)(C).

Subsec. (m), (n). Pub. L. 101–234, § 203(a)(1)(C), added subsec. (m) and (n).

1985—Subsec. (a), Pub. L. 100–360, § 221(d)(1), substituted “Subject to subsection (k)(3) of this section, such” for “Such”.

Subsec. (b)(1). Pub. L. 100–360, § 221(d)(2), substituted “subject to subsection (k)(3) of this section, for so long as” for “for so long as” in concluding provisions.


Pub. L. 100–360, § 221(b)(1), substituted “(A), (B), and (C)” for “(A) and (B)”.

Subsec. (b)(1)(D). Pub. L. 100–360, § 221(b)(2), redesignated former subpars. (C) and (D) as (D) and (E), respectively.

Subsec. (b)(2)(A). Pub. L. 100–360, § 221(f), substituted “appointed by the Secretary for appointed by the President”.

Subsec. (b)(3). Pub. L. 100–360, § 221(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 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 1395dd 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 1395dd of this title.


"(1) I" 

Section 4031(d) 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 1345 of the Omnibus Budget Reconciliation Act of 1996 [Pub. L. 104–191]."

Section 4033(d)(2) of Pub. L. 105–33 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 4353(d) of Pub. L. 101–508, as amended by Pub. L. 103–432, title I, § 171(i)(2), Oct. 31, 1994, 108 Stat. 4449, 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. 30, 1999]."

Section 4355(d) of Pub. L. 101–508, as amended by Pub. L. 103–432, title I, § 171(i)(2), Oct. 31, 1994, 108 Stat. 4449, provided that: "The amendment made by subsection (a) [amending this section] shall apply to policies issued or sold more than 6 months after the effective date of this Act and before January 1, 1995, to individuals who are at least 65 years of age, and on or after January 1, 1996, to all individuals who are at least 65 years of age."
The enactments of this Act [July 1, 1988].''


"(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 [subsec. (k)(1)(B) or (k)(2)(B) of 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 reimbursement of members of 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)(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.

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.

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)).

"(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 requirement 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, 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.

"(C) The Implement the NAIC Medicare Supplemental Insurance Minimum Standards Model Act') on March 11, 2007, as modified to reflect the changes made under this Act [see Short Title of 2008 Amendment note set out under this title].

"(D) TRANSITION DATES

"(1) IN GENERAL.—Nothing in this Act [see Tables for classification] shall be construed to require an issuer of a medicare supplemental policy under section 1882 of the Social Security Act (42 U.S.C. 1395rr) [42 U.S.C. 1395ss] to participate as a PDP sponsor under part D of title XVIII of such Act [part D of this chapter], as added by section 101, as a condition for issuing such policy.

"(2) PROHIBITION ON STATE REQUIREMENT.—A State may not require an issuer of a medicare supplemental policy under section 1882 of the Social Security Act (42 U.S.C. 1395rr) [42 U.S.C. 1395ss] to participate as a PDP sponsor under such part D as a condition for issuing such policy.

"(E) IMPLEMENTATION OF NAIC RECOMMENDATIONS

"(1) IN GENERAL.—The Secretary of Health and Human Services (in this section [enacting section 1395ss–1 of this title and amending this section] referred to as the 'Secretary') shall provide for implementation of the changes in the NAIC model law and regulations approved by the National Association of Insurance Commissioners in its Model #651 (Model Regulation to Implement the NAIC Medicare Supplement Insurance Minimum Standards Model Act') on March 11, 2007, as modified to reflect the changes made under this Act [see Short Title of 2008 Amendment note set out under section 1395ss of this title] and the Genetic Information Nondiscrimination Act of 2008 (Public Law 110–233) [see Short Title note set out under section 2000ff of this title].

"(2) IMPLEMENTATION DATES.—

"(A) IN GENERAL.—The modifications to Model #651 required under paragraph (1) shall be completed by the National Association of Insurance Commissioners not later than October 31, 2008. 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) EXTENSION OF EFFECTIVE DATE FOR STATE LAW AMENDMENT.—In the case of a State which the Secretary determines requires State legislation in order to conform the regulatory program established by the State to such revised NAIC model law and regulations, the State shall not be regarded as failing to comply with the requirements of this section solely on the basis of its failure to meet such 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 the enactment of this Act [July 1, 2006]. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session is considered to be a separate regular session of the State legislature.

"(C) TRANSITION DATES.—No carrier may issue a new or revised medicare supplemental policy or certificate under section 1882 of the Social Security Act
Section 4031(f) of Pub. L. 105–33 provided that: "(1) I
N 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, 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.

(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 [§ 1395ss] 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) 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, not later than July 1, 2009, 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) I
N 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 [§ 1395ss] 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 [§ 1395ss] 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) 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 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.

(2) 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 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 271(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 in respect of 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)).

“(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)).

“(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)(ii) of the Social Security Act [subsection (d)(3)(C)(ii) 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 15C 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.—Subject to paragraph (3), no legal action shall be brought or continued in any Federal or State court in respect of 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)).

“(2) NAIC REGULATORY PROGRAMS.—If the NAIC makes such change until the date specified in paragraph (4), no legal action shall be brought or continued in any Federal or State court in respect of 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 Amendments of 1984 [Pub. L. 98–218, § 171(d)(3)(C)], the Social Security Act Amendments of 1984 [Pub. L. 98–218, § 171(d)(3)(C)] and before the end of the 30-day period beginning on the date of the enactment of this Act, no legal action shall be brought or continued in any Federal or State court in respect of 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)).

“(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.”

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 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 chapter. 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 subparagraph (B).

(B)(i) The reasonable cost of the services consists 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 subsections (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.

(ii) 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.

(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 section 1395cc of this title, has been determined to have received post-hospital extended care services 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.

1 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 staffing 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, if (a) the hospital reaches the limit specified in this paragraph as a hospital operated by the hospital (b) the hospital has been granted a certificate of need for the provision of long-term care services from the State health planning and development agency (designated under section 1396o of this title) for the State in which the hospital is located.

AMENDMENTS


2000—Subsec. (a)(2)(A). Pub. L. 106–203, § 4201(d)(3), substituted “(1) except as provided under subsection (g) of this section, the hospital is located in a rural area and has less than 100 beds, and” for “(1) except as provided under subsection (g) of this section, the hospital is located in a rural area and has at least 100 beds, and”.

1997—Subsec. (d). Pub. L. 106–113, § 1100(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. (a)(2)(B)(i)(II). Pub. L. 105–508 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)” for “the previous calendar year” and all that follows thereof.

Subsec. (a)(3). Pub. L. 104–193 substituted “the previous calendar year” for “the previous calendar year under the State plan”.

Subsec. (b)(1). Pub. L. 106–203, § 4201(d)(3), struck out “the reasonable costs” before “of law amended or repealed by such section are restored wherever appearing.”

Subsec. (b)(2). Pub. L. 106–203 substituted “this section” for “this section or section 1395ww”.
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, § 1000(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 and section 1396 of this title] shall become effective on the date 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 [Dec. 21, 2000]."

**Effective Date of 1997 Amendment**

Amendment by Pub. L. 105–33 applicable to items and services furnished on or after July 1, 1999, 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 608(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 1395d of this title.

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(b)(4)(D), (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. 100–360, 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, 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.

**Effective Date**

Section 904(d) 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 1396f 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 1395l(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 1396x 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, 1985, 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 1395ww(d) 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.

Establishment and Evaluation of Transitional Allowances; Report and Recommendations to Congress

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 1395u(b)(3)(B)(ii) of this title, where such institution or person—

(1) has (or previously had) in effect an agreement with a State agency to furnish medical care and services under a State plan approved under subchapter XIX of this chapter, and

(2) from which (or from whom) such State agency (A) has been unable to recover 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.

(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 under subchapter XIX of this chapter, and

(3) assure the restoration to the institution or person of amounts withheld under this section which are ultimately determined to be in excess of overpayments under subchapter XIX of this chapter and to which the institution or person would otherwise be entitled under this subchapter.

(c) Payment to States of amounts recovered

Notwithstanding any other provision of this chapter, from the trust funds established under sections 1395i 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 such 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 by the applicable percentage increase (as defined in subsection (b)(3)(B) of this section).

(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—
(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, or
(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 with respect to inpatient hospital services as such costs are determined on an average per admission or per discharge basis (as determined by the Secretary), 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 (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 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). 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 any fiscal year, the "applicable percentage increase" shall be—

(I) for fiscal year 1986, 1⁄4 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\(^1\) 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

\(^1\) 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;\(^2\) 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 minus 0.13 percentage points,

(IV) a subsequent fiscal year ending on or before September 30, 1993, is the market basket percentage increase,

(V) fiscal years 1994 through 1997, is the market basket percentage increase minus the applicable reduction (as defined in clause (v)(II)), or in the case of a hospital for a fiscal year for which the hospital’s update adjustment percentage (as defined in clause (v)(I)) is at least 10 percent, the market basket percentage increase,

(VI) for fiscal year 1998, is 0 percent,

(VII) for fiscal years 1999 through 2002, is the applicable update factor specified under clause (vi) for the fiscal year, and

(VIII) subsequent fiscal years is the market basket percentage increase.

(iii) For purposes of this subparagraph, the term “market basket percentage increase” means, with respect to cost reporting periods and discharges occurring in a fiscal year, the percentage, estimated by the Secretary before the beginning of the period or fiscal year, by which the cost of the mix of goods and services (including personnel costs but excluding non-operating costs) comprising routine, ancillary, and special care unit inpatient hospital services, based on an index of appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services included in such inpatient hospital services, for the period or fiscal year will exceed the cost of such mix of goods and services for the preceding 12-month cost reporting period or fiscal year.

(iv) For purposes of subparagraphs (C) and (D), the “applicable percentage increase” is—

(I) for 12-month cost reporting periods beginning during fiscal years 1986 through 1993, the applicable percentage increase specified in clause (ii),

(II) for fiscal year 1994, the market basket percentage increase minus 2.3 percentage points (adjusted to exclude any portion of a cost reporting period beginning during fiscal year 1993 for which the applicable percentage increase is determined under subparagraph (I)),

(III) for fiscal year 1995, the market basket percentage increase minus 2.2 percentage points, and

(IV) for fiscal year 1996 and each subsequent fiscal year, the applicable percentage increase under clause (i).

(v) 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 subclause (V) 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.

(vi) 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 (per 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-\(^2\) So in original. The semicolon probably should be a comma.
 hilarious, 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 ⅔ of such target amount for the hospital, the applicable update factor specified under this clause is 0 percent.

(vi)(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), (x), (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.

(IX)(aa) Subject to item (bb), effective for payments beginning with fiscal year 2013, each measure specified by the Secretary under this clause shall be endorsed by the entity with a contract under section 1395aaa(a) of this title.

(bb) 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.

(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) 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 33½ percent for fiscal year 2015, 66⅔ 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 a 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) 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.

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—

(1) 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) for each of fiscal years 2012 and 2013, by 0.25 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.

So in original. Probably should be “(n)(6)(B)”).
(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), 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 subparagraph was in effect with respect to such hospital, increased in a compounded manner by—

(II) the allowable 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)(v) 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 (i), the target amount for the preceding year in which that later cost reporting period begins, or (F) in the case of a hospital described in clause (ii), and 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 1998 is equal to the average described in clause (ii).

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.

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.

(F) In the case of a hospital described in clause (i), the target amount for the preceding year in which that later cost reporting period begins, or

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.

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.

(F) In the case of a hospital described in clause (i), the target amount for the preceding year in which that later cost reporting period begins, or

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.

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.

(F) In the case of a hospital described in clause (i), the target amount for the preceding year in which that later cost reporting period begins, or

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.

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.

(F) In the case of a hospital described in clause (i), the target amount for the preceding year in which that later cost reporting period begins, or

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.

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.

(F) In the case of a hospital described in clause (i), the target amount for the preceding year in which that later cost reporting period begins, or

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.

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.

(F) In the case of a hospital described in clause (i), the target amount for the preceding year in which that later cost reporting period begins, or

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.

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.

(F) In the case of a hospital described in clause (i), the target amount for the preceding year in which that later cost reporting period begins, or

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.

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.

(F) In the case of a hospital described in clause (i), the target amount for the preceding year in which that later cost reporting period begins, or

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.

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.

(F) In the case of a hospital described in clause (i), the target amount for the preceding year in which that later cost reporting period begins, or

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.

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.

(F) In the case of a hospital described in clause (i), the target amount for the preceding year in which that later cost reporting period begins, or

(ii) with respect to a later cost reporting period, the target amount for the preceding 12-month cost reporting period, increased by the applicable percentage increase under subparagraph (B)(ii) for that later cost reporting period.
(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 1998 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 70 percent (as determined by the Secretary under subsection (d)(5)(P)(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) 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 increase.

(III) For cost reporting periods beginning during each of fiscal years 1999 through 2002, subject to subparagraph (J), the Secretary shall update such amount by a factor equal to the market basket percentage increase.

(iii) In applying clause (ii)(I) 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 hospital.

(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.

(IV) 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 (ii));

(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)(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 “paragraph (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)(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 which 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.

(ii) The payment reductions under paragraph (3)(B)(iv)(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 (D) 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
report, the amount of the payment with respect to operating costs described in paragraph (1) under part A of this subchapter on a per discharge or per admission basis (as the case may be) is equal to the lesser of—

(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 subsection 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 1395mm(b) 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 1395cc(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 Secretary 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 such 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 such 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 (a) of this section) which is less than the aggregate rate of increase in such costs under this subchapter for hospitals in the United States.
(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), and (E) of paragraph (1) 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—
(i) 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 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) 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 Secretary 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;

(iii) 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

(iv) on or after October 1, 1986, and before October 1, 1987, the target percentage is 45 percent and the DRG percentage is 35 percent; and

(v) on or after October 1, 1986, and before October 1, 1987, the target percentage is 45 percent and the DRG percentage is 35 percent; and

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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 55 percent; or

(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; or

(iii) on or after October 1, 1985, and before October 1, 1986, the “target percentage” is 40 percent and the “DRG percentage” is 40 percent; or

(iv) on or after October 1, 1986, and before October 1, 1987, the “target percentage” is 45 percent and the “DRG percentage” is 35 percent; and

(v) on or after October 1, 1987, the “target percentage” is 25 percent and the “DRG percentage” is 25 percent. 

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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 of neoplastic disease” 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 910(h) 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)(ii) resulting from the amendment made by section 462(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 Reimbursement Act of 1999, of section 302 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, or 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)v 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. A hospital located in a Metro-

ⅤSee References in Text note below.
politan Statistical Area shall be deemed to be located in the region in which the largest number of the hospitals in the same Metropolitan Statistical Area are located, or, at the option of the Secretary, the region in which the majority of the inpatient discharges (with respect to which payments are made under this subchapter) from hospitals in the same Metropolitan Statistical Area are made.

(E) **REducing for Value of Outlier Payments.**—The Secretary shall reduce each of the average standardized amounts determined under subparagraph (D) by a proportion equal to the proportion (estimated by the Secretary) of the amount of payments under this subsection based on DRG prospective payment rates which are additional payments described in paragraph (5)(A) (relating to outlier payments).

(F) **Maintaining Budget Neutrality.**—The Secretary shall adjust each of such average standardized amounts as may be required under subsection (e)(1)(B) of this section for the fiscal year.

(G) **Computing DRG-Specific Rates for Urban and Rural Hospitals in the United States and in Each Region.**—For each discharge classified within a diagnosis-related group, the Secretary shall establish a national DRG prospective payment rate and shall establish a regional DRG prospective payment rate for each region, each of which is equal—

(i) for hospitals located in an urban 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 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 (G) 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 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 with 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 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)(I) 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 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 1985, 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, 1986, 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, 1986, 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 9194 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) (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 shall be adjusted 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 subclause (IV), for discharges occurring on or after October 1, 2010, the area wage index applicable under this subparagraph shall be adjusted in a manner that assures that the aggregate payments under this subparagraph shall not be taken into account in adjusting the weighting factors 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 403(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and the amendments made by section 10324(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.

(iv) FLOOR ON AREA WAGE INDEX FOR HOSPITALS IN FRONTIER STATES.—

(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 classified under any such adjustment under clause (i) 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
For purposes of clause (v)(I), the indirect teaching adjustment factor is equal to $c \times (((1+r)^n - 1) / r)$, 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 1.47;
(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 equivalency 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 equivalency 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 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-
section 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)(F)(ii) of this section shall apply for purposes of this clause. The provisions of subsections (h)(4)(F)(vii) through (h)(4)(F)(viii) 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)(F)(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 for the cost reporting period and the preceding two 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) of this section, in computing the indirect teaching adjustment factor under clause (ii) the adjustment shall be computed in the same manner as provided under clause (ii) with respect to such resident positions.

(xi) The provisions of subparagraph (K) of section 1395f(b)(3) of this title; or

(II) The Secretary shall provide, under clause (ii) for the hospital’s cost reporting period.

(III) In determining the hospital’s number of full-time equivalent residents for purposes of this subsection, 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.

(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-
sectors (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 (b)) 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 State 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 1395yy(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 percent 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 percent determined in accordance with clause (xiii);
(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 (xv) and for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordn with clause (xi); (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 (vii) 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 (vii) 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 April 1, 2001), 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, 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 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, \( P \times (\text{P}^2 - 20)^{(.6)} + 5.62 \), (b) for discharges occurring on or after January 1, 1991, and on or before September 30, 1993, \( P \times (\text{P}^2 - 20)^{(.7)} + 5.62 \), (c) for discharges occurring on or after October 1, 1993, and on or before September 30, 1994, \( P \times (\text{P}^2 - 20)^{(.8)} + 5.88 \), and (d) for discharges occurring on or after October 1, 1994, \( P \times (\text{P}^2 - 20)^{(.825)} + 5.88 \); 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, \( P \times (\text{P}^2 - 15)^{(.6)} + 2.5 \), (b) for discharges occurring on or after January 1, 1991, and on or before September 30, 1993, \( P \times (\text{P}^2 - 15)^{(.6)} + 2.5 \), (c) for discharges occurring on or after October 1, 1993, \( P \times (\text{P}^2 - 15)^{(.65)} + 2.5 \), and 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: \( P \times (\text{P}^2 - 30)^{(.6)} + 4.0 \), where

\[ \text{So in original. Probably should be followed by "and".} \]
“P” is the hospital’s disproportionate patient percentage (as defined in clause (vi)).

(ix) 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 rural referral centers), in the case of a hospital for a cost reporting period with a disproportionate patient percentage (as defined in clause (vi)) where “P” is the hospital’s disproportionate patient percentage (as defined in clause (vi))—

(I) is less than 19.3, the disproportionate share adjustment percentage is determined in accordance with the following formula:

\[
¥P > 15)(.65) + 2.5; \]

(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.

(xi) Subject to clause (xiv), for purposes of clause (iv)(V) (relating to urban hospitals with less than 100 beds), in the case of a hospital for a cost reporting period or for discharges in the fiscal year (as defined in subsection (b)(3)(D) of this section) during fiscal year (as defined in subsection (b)(3)(D) of this section) exceeds the amount determined under paragraph (1)(A)(iii); and

(II) for discharges occurring during any subsequent cost reporting period (or portion thereof) and before October 1, 1994, or discharges occurring on or after October 1, 1997, and before October 1, 2012, 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 clause (ii) and the amount determined under paragraph (1)(A)(ii).

(1) The amount determined under this clause is—

(I) for discharges occurring during the 36-month period beginning with the first day of the cost reporting period that begins on or after April 1, 1990, the amount by which the hospital’s target amount for the cost reporting period (as defined in subsection (b)(3)(D) of this section) exceeds the amount determined under paragraph (1)(A)(iii); and

(II) for discharges occurring during any subsequent cost reporting period (or portion thereof) and before October 1, 1994, or discharges occurring on or after October 1, 1997, and before October 1, 2012, 50 percent (or 75 percent in the case of discharges occurring on or after October 1, 2006) of the amount by which the hospital’s target amount for the cost reporting period or for discharges in the fiscal year (as defined in subsection (b)(3)(D) of this section) exceeds the amount determined under paragraph (1)(A)(iii).

(iii) In the case of a medicare dependent, small rural 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.

(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 (i)), 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 (ii), 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 (i), 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 an 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 effected 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
and revision of codes under paragraph (4)(D), and
(C) the determination of whether services provided prior to a patient's inpatient admission are related to the admission (as described in subsection (a)(4)).

§ 1395ww (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 as if the hospitals so treated had not been excluded from calculation of the wage index for that rural 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 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.
(E)(1) 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 under paragraph (5)(D) if the hospital were located in a rural area.

(IV) The hospital meets such other criteria as the Secretary may specify.

(9)(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)(i) (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)(ii) 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 a weighted average of the amounts computed under clause (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.

(II) 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).

(iii) 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 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 (3)(B)) for that diagnosis-related group.

(iv) 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)(B)(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)(ii)(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 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 (3)(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)(i)(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—

(I) 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

*So in original. Probably should be section "557(b)".
subsidy, 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 ENROLLERS.—

(A) IN GENERAL.—For portions of cost reporting periods occurring on or after January 1, 1996, 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 individual who is enrolled with 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 (B) of this section) of the estimated average per discharge amount that would otherwise have been paid under paragraph (5)(B) if the individuals had not been enrolled as described in subparagraph (B).

(D) SPECIAL RULE FOR HOSPITALS UNDER REIMBURSEMENT SYSTEM.—The Secretary shall establish rules for the application of this paragraph 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.

(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 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.

(ii) 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 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
graph (E) shall be final and shall not be subject to judicial review.

(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)(II) and (d)(5) of this section for that fiscal year for operating costs of inpatient 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 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)(A) 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 1962) 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—

(A) 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

(B) the August 1 before such fiscal year after such consideration of public comment on the proposal as is feasible in the time available, the Secretary’s final recommendations under such paragraph for that year.

The Secretary shall include in the publication referred to in subparagraph (A) for a fiscal year the report of the Commission’s recommendations submitted under paragraph (3) for that fiscal year. 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.

(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 method 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. 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 1955x(v) of this title). For discharges occurring after September 30, 1993, the Secretary shall reduce by 7.4 percent the unadjusted standard Federal capital payment rate (as described in 42 CFR 412.308(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. 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 title 42 of the Code of Federal Regulations), to (i) the unadjusted standard Federal capital payment rate (as described in section 412.308(c) of that title, as in effect on September 30, 1997), and (ii) the unadjusted hospital-specific rate (as described in section 412.328(e)(1) of that title, as in effect on September 30, 1997), and, for discharges occurring on or after October 1, 1997, and before October 1, 2002, reduce the rates described in clauses (i) and (ii) by 2.1 percent.

(B) Such system—

(i) shall provide for (I) a payment on a per discharge basis, and (II) an appropriate weighting of such payment amount as relates to the classification of the discharge;
(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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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 subsection (l) 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 1395ww(a)(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; 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 training 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 medicine.
(ii) Counting primary care residents on certain approved leaves of absence in base year FTE count

(I) In general

In determining the number of such full-time equivalent residents for a hospital’s most recent cost reporting period ending on or before December 31, 1996, for purposes of clause (i), the Secretary shall count an individual to the extent that the individual would have been counted as a primary care resident for such period but for the fact that the individual, as determined by the Secretary, was on maternity or disability leave or a similar approved leave of absence.

(II) Limitation to 3 FTE residents for any hospital

The total number of individuals counted under subclause (I) for a hospital may not exceed 3 full-time equivalent residents.

(G) Counting interns and residents for FY 1998 and subsequent years

(i) In general

For cost reporting periods beginning during fiscal years beginning on or after October 1, 1997, subject to the limit described in subparagraph (F), the total number of full-time equivalent residents for determining a hospital’s graduate medical education payment shall equal the average of the actual full-time equivalent resident counts for the cost reporting period and the preceding two cost reporting periods.

(ii) Adjustment for short periods

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 resident counts pursuant to clause (i) are based on the equivalent of full twelve-month cost reporting periods.

(iii) Transition rule for 1998

In the case of a hospital’s first cost reporting period beginning on or after October 1, 1997, clause (i) shall be applied by using the average for such period and the preceding cost reporting period.

(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 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 such 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) 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 sub-specialty 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 Committee as meeting the standards necessary for such accreditation.

(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—
(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
(as determined without regard to the increase in such amount described in clause (i)(I)) does not exceed $10,000.

(K) Nonprovider setting that is primarily engaged in furnishing patient care

The term "nonprovider setting that is primarily engaged in furnishing patient care" means a nonprovider setting in which the primary activity is the care and treatment of patients, as defined by the Secretary.

(6) 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;\(^\text{12}\)

(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 20 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.

\(^{12}\)So 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 settled 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
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resident 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. 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).

(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
to such reduction. Any such necessary adjustments shall be effective for portions of cost reporting periods occurring on or after July 1, 2005.

(E) Judicial review

There shall be no administrative or judicial review under section 1395f, 1395oo of this title, or otherwise, with respect to determinations made under this this\textsuperscript{13} paragraph, paragraph (8), or paragraph (4)(H)(vi).

(8) Distribution of additional residency positions

(A) Reductions in limit based on unused positions

(i) In general

Except as provided in clause (ii), if a hospital’s reference resident level (as defined in subparagraph (H)(i)) is less than the otherwise applicable resident limit (as defined in subparagraph (H)(ii)), effective for portions of cost reporting periods occurring on or after July 1, 2011, the otherwise applicable resident limit shall be reduced by 65 percent of the difference between such otherwise applicable resident limit and such reference resident level.

(ii) Exceptions

This subparagraph shall not apply to—

(I) a hospital located in a rural area (as defined in subsection (d)(2)(D)(ii)) with fewer than 250 acute care inpatient beds;

(II) a hospital that was part of a qualifying entity which had a voluntary residency reduction plan approved under paragraph (6)(B) or under the authority of section 402 of Public Law 90-248, if the hospital demonstrates to the Secretary that it has a specified plan in place for filling the unused positions by not later than 2 years after March 23, 2010; or

(III) a hospital described in paragraph (4)(H)(v).

(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 redistribution in accordance with the requirements of this paragraph.

(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 (5)(H) (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)(v)).

(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)(b)) as a health professional shortage area (as of the date of enactment of this paragraph); to

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(I) the total population of the State, territory, or District (as determined by the Secretary based on the most recent available population data published by the Bureau of the Census).

(iii) Whether the hospital is located in a rural area (as defined in subsection (d)(2)(D)(ii)).

(E) Reservation of positions for certain hospitals

(i) In general

Subject to clause (ii), the Secretary shall reserve the positions available for distribution under this paragraph as follows:

(I) 70 percent of such positions for distribution to hospitals described in clause (i) of subparagraph (D).

(ii) 30 percent of such positions for distribution to hospitals described in clause (i) and (iii) of such subparagraph.

(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.

(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.

(i) Avoiding duplicative payments to hospitals participating in rural demonstration programs

The Secretary shall reduce any payment amounts otherwise determined under this section to the extent necessary to avoid duplication of any payment made under section 4005(e) of the Omnibus Budget Reconciliation Act of 1987.

(j) Prospective payment for inpatient rehabilitation services

(1) Payment during transition 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 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, 2000, and before 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, 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—

(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.

(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 facility for a payment unit in a cost reporting period beginning on or after October 1, 2002, or, in the case of a facility making an election under subparagraph (F), for any cost reporting period described in such subparagraph, is equal to the per unit payment rate established under this subsection for the fiscal year in which the payment unit of service occurs.

(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 using the most recent data available (as estimated by the Secretary as of the date of establishment of the system) adjusted—

(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 (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.
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(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)(F)) 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)(xi)(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)(ii)(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;
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 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 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.

(l) Payment for nursing and allied health education for managed care enrollees

(1) In general

For portions of cost reporting periods occurring in a year (beginning with 2000), the Secretary shall provide for an additional payment amount for any hospital that receives payments for the costs of approved educational activities for nurse and allied health professional training under section 1395x(v)(1) of this title.

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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 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 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 1395i 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-
tributable to individuals who are enrolled with a Medicare Advantage organization under part C; and

(ii) the denominator of which is the product of—

(I) the estimated total number of inpatient-bed-days with respect to the eligible hospital during such period; and

(II) the estimated total amount of the eligible hospital’s charges during such period, not including any charges that are attributable to charity care (as such term is used for purposes of hospital cost reporting under this subchapter), divided by the estimated total amount of the hospital’s charges during such period.

Insofar as the Secretary determines that data are not available on charity care necessary to calculate the portion of the formula specified in clause (ii)(II), the Secretary shall use data on uncompensated care and may adjust such data so as to be an appropriate proxy for charity care including a downward adjustment to eliminate bad debt data from uncompensated care data. In the absence of the data necessary, with respect to a hospital, for the Secretary to compute the amount described in clause (ii)(II), the amount under such clause shall be deemed to be 1. In the absence of data, with respect to a hospital, necessary to compute the amount described in clause (i)(II), the amount under such clause shall be deemed to be 0.

(E) Transition factor specified

(i) In general

Subject to clause (ii), the transition factor specified in this subparagraph for an eligible hospital for a payment year is as follows:

(I) For the first payment year for such hospital, 1.

(II) For the second payment year for such hospital, \( \frac{3}{4} \).

(III) For the third payment year for such hospital, \( \frac{1}{2} \).

(IV) For the fourth payment year for such hospital, \( \frac{1}{4} \).

(V) For any succeeding payment year for such hospital, 0.

(ii) Phase down for eligible hospitals first adopting EHR after 2013

If the first payment year for an eligible hospital is after 2013, then the transition factor specified in this subparagraph for a payment year for such hospital is the same as the amount specified in clause (i) for such payment year for an eligible hospital for which the first payment year is 2013. If the first payment year for an eligible hospital is after 2015 then the transition factor specified in this subparagraph for such hospital and for such year and any subsequent year shall be 0.

(F) Form of payment

The payment under this subsection for a payment year may be in the form of a single consolidated payment or in the form of such periodic installments as the Secretary may specify.

(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 under such subsection for a fiscal year) 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)(ii) 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)(ii); 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) 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(l) 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 1395w–4(o)(4) 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 rehospitalizations, 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:

   (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 any 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 any 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
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)(i)(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 (I) 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
adjustment to hospital payments for hospital
Applicable hospitals

adjustment to hospital payments for hospital
Applicable hospitals

adjustment to hospital payments for hospital
Applicable hospitals

adjustment to hospital payments for hospital
Applicable hospitals

adjustment to hospital payments for hospital
Applicable hospitals

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,

(ii) Risk adjustment

In carrying out clause (i), the Secretary
shall establish and apply an appropriate

(C) Exemption

In the case of a hospital that is paid under
section 1395f(b)(3) of this title, the Secretary
can exempt such hospital from the applica-
tion 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 partici-
pating hospital or hospitals achieves or sur-
passes the measured results in terms of pa-
tient health outcomes and cost savings estab-
lished under this subsection.

(3) Hospital acquired conditions

For purposes of this subsection, the term
“hospital acquired condition” means a condi-
tion identified for purposes of subsection
(d)(4)(D)(iv) and any other condition deter-
mained appropriate by the Secretary that an
individual acquires during a stay in an appli-
cable hospital, as determined by the Sec-
retary.

(4) Applicable period

In this subsection, the term “applicable pe-
iod” 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 con-
idential reports to applicable hospitals with
respect to hospital acquired conditions of the
applicable hospital during the applicable pe-
riod.

(6) Reporting hospital specific information

(A) In general

The Secretary shall make information
available to the public regarding hospital ac-
quired conditions of each applicable hos-
pital.

(B) Opportunity to review and submit correc-
tions

The Secretary shall ensure that an appli-
cable hospital has the opportunity to review,
and submit corrections for, the information
to be made public with respect to the hos-
pital 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.
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(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 the hospital under subsection (d) (or section 1395f(b)(3) of this title, as the case may be) in an amount equal to the product of—

(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 seek the endorsement described in subparagraph (A)(ii)(I), for an applicable hospital for such condition for which measures have been endorsed by the entity 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 subsection (d)(1)(B) and, as determined feasible and appropriate by the Secretary, other hospitals not otherwise described in this subparagraph.

(r) Adjustments to medicaid 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 such purposes.

(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 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)), see section 124 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)(3)(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 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.

(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 paragraph (1) for a subsequent rate year.

(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 psychotic 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.

References in Text

Parts A, B, C, and D of this subchapter, referred to in text, are classified to sections 1395c et seq., 1395l et seq., and 1395x-1 et seq., respectively, of this title.

Section 5001(b) of the Deficit Reduction Act of 2005, referred to in subsec. (b)(3)(B)(iv)(I), is section 5001(b) of Pub. L. 109-171, which is set out below.


The Internal Revenue Code of 1986, referred to in subsec. (b)(6), is classified generally to Title 26, Internal Revenue Code.


Section 6063(c) of the Omnibus Budget Reconciliation Act of 1989, referred to in subsec. (d)(2)(C)(iv), is section 6063(c) of Pub. L. 101–239, which amended this section and enacted provisions set out below.

Section 4002(b) of the Omnibus Budget Reconciliation Act of 1990, referred to in subsec. (d)(2)(C)(iv), is section 4002(b) of Pub. L. 101–508, which amended this section and enacted provisions set out below.

Section 363 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, referred to in subsec. (d)(2)(C)(iv), is section 363 of Pub. L. 101–508, which amended this section and enacted provisions set out as a note under this section.


Section 10324(a)(1) of the Act, amended this section. For complete classification of this Act to the Code, see Short Title note set out under section 18001 of this title and Tables.

Section 302 of the Medicare, Medicaid, and SCHIP Balanced Budget Reconciliation Act of 2000, referred to in subsec. (d)(3)(E)(i) and (r)(2)(B)(i)(I), is section 302 of Pub. L. 106–113, which enacted this section and provided for the determination of value-based incentive payments under subsection (o),”.

Subsec. (b)(3)(B)(viii)(V). Pub. L. 111–148, § 3401(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, § 3001(a)(2)(A), substituted “clauses (viii), (ix), (x), and (xii)” for “clause (viii)”.


Section 332 of the Public Health Service Act, which is classified to section 332 of this title, was added by Pub. L. 103–244, Mar. 22, 1994.


Subsec. (b)(3)(B)(x)(IV). Pub. L. 111–152, § 1105(a)(1)(B), added subcl. (III) and struck out former subcl. (III) which read “subject to clause (xiii), for each of fiscal years 2014 through 2019, by 0.2 percentage point,”.

Pub. L. 111–148, § 10319(a)(4), redesignated subcl. (II) as (III) and substituted “2014” for “2012”.

Subsec. (b)(3)(B)(x)(V). Pub. L. 111–152, § 1105(a)(2), struck out cl. (x) which read as follows: “(x) 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, §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 “;” at end, added cl. (ii), and inserted concluding provisions.

Subsec. (b)(4)(F)(i). Pub. L. 111–148, §5003(a)(1), substituted “paragraphs (7) and (8)” for “paragraph (7)”.

Subsec. (b)(4)(H)(i). Pub. L. 111–148, §5003(a)(2), substituted “paragraphs (7) and (8)” for “paragraph (7)”.


Subsec. (h)(7)(E). Pub. L. 111–148, §5006(e), substituted “this paragraph, paragraph (8), or paragraph (4)(H)(vi)” for “paragraph or paragraph (8)”.

Pub. L. 111–148, §5006(a)(3), inserted “or paragraph (8)” before period at end.


Subsec. (j)(3)(C). Pub. L. 111–148, §3004(b)(2), substituted “(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, §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 “;” at end, added cl. (ii), and inserted concluding provisions.

Subsec. (b)(4)(F)(i). Pub. L. 111–148, §5003(a)(1), substituted “paragraphs (7) and (8)” for “paragraph (7)”.

Subsec. (b)(4)(H)(i). Pub. L. 111–148, §5003(a)(2), substituted “paragraphs (7) and (8)” for “paragraph (7)”.


Subsec. (h)(7)(E). Pub. L. 111–148, §5006(e), substituted “this paragraph, paragraph (8), or paragraph (4)(H)(vi)” for “paragraph or paragraph (8)”.

Pub. L. 111–148, §5006(a)(3), inserted “or paragraph (8)” before period at end.


Subsec. (j)(3)(C). Pub. L. 111–148, §3004(b)(2), substituted “(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, §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 “;” at end, added cl. (ii), and inserted concluding provisions.

Subsec. (b)(4)(F)(i). Pub. L. 111–148, §5003(a)(1), substituted “paragraphs (7) and (8)” for “paragraph (7)”.

Subsec. (b)(4)(H)(i). Pub. L. 111–148, §5003(a)(2), substituted “paragraphs (7) and (8)” for “paragraph (7)”.


Subsec. (h)(7)(E). Pub. L. 111–148, §5006(e), substituted “this paragraph, paragraph (8), or paragraph (4)(H)(vi)” for “paragraph or paragraph (8)”.

Pub. L. 111–148, §5006(a)(3), inserted “or paragraph (8)” before period at end.


Subsec. (j)(3)(C). Pub. L. 111–148, §3004(b)(2), substituted “(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, §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 “;” at end, added cl. (ii), and inserted concluding provisions.

Subsec. (b)(4)(F)(i). Pub. L. 111–148, §5003(a)(1), substituted “paragraphs (7) and (8)” for “paragraph (7)”.

Subsec. (b)(4)(H)(i). Pub. L. 111–148, §5003(a)(2), substituted “paragraphs (7) and (8)” for “paragraph (7)”.


Subsec. (h)(7)(E). Pub. L. 111–148, §5006(e), substituted “this paragraph, paragraph (8), or paragraph (4)(H)(vi)” for “paragraph or paragraph (8)”.

Pub. L. 111–148, §5006(a)(3), inserted “or paragraph (8)” before period at end.


Subsec. (j)(3)(C). Pub. L. 111–148, §3004(b)(2), substituted “(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, §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 “;” at end, added cl. (ii), and inserted concluding provisions.

Subsec. (b)(4)(F)(i). Pub. L. 111–148, §5003(a)(1), substituted “paragraphs (7) and (8)” for “paragraph (7)”.

Subsec. (b)(4)(H)(i). Pub. L. 111–148, §5003(a)(2), substituted “paragraphs (7) and (8)” for “paragraph (7)”.
Subsec. (m)(4)(A)(ii). Pub. L. 111–152, §1105(b)(3), redesignated cls. (i) and (iii) as subpars. (B) and (C), respectively, and realigned margins.

Subsec. (r)(2)(B)(i). Pub. L. 111–152, §1104(2)(C), substituted “minus 0.2 percentage points for each of fiscal years 2018 and 2019” for “and, for each of 2018 and 2019, minus 1.5 percentage points” in concluding provisions.


Subsec. (s)(3). Pub. L. 111–152, §1105(d)(3), struck out subpar. (A) designation and heading, redesignated cls. (i) to (v) of former subpar. (A) as subpars. (A) to (E), respectively, and realigned margins.


Subsec. (s)(3)(A)(i). Pub. L. 111–152, §1105(d)(1)(A), placed cl. (i), which was directed to be struck out by Pub. L. 111–148, §10319(e)(3), after cl. (i) and struck out “and” at end. See Amendment note below.


Subsec. (s)(3)(A)(iii). 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 2019, 0.2 percentage point.”

Subsec. (r)(2). Pub. L. 111–152, §1104(2)(A), substituted “(ii) 5 percentage points.” after “shall be applied with respect to any of rate years 2014 through 2019 by substituting ‘0.0 percentage points’ for ‘0.2 percentage points’ 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 each of the rate years beginning in 2014 through 2019, 0.2 percentage point.”

Pub. L. 111–148, §10319(e)(2), (4), redesignated cl. (ii) as (ii) and substituted “2014” for “2012”.


Pub. L. 111–152, §1105(d)(1)(B), added cls. (v) and (vi).

Pub. L. 111–152, §1105(d)(2), struck out subpar. (B). Prior to amendment, text read as follows: “subject to subparagraph (B), for each of the rate years beginning in 2014 through 2019, 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 (as estimated by the Secretary); exceeds “(ii) 5 percentage points.”


Subsec. (m)(4)(C) to (F). Pub. L. 111–152, §1105(b)(3), redesignated cls. (iii) to (vi) of former subpar. (A) as subpars. (C) to (F), respectively, and realigned margins.

Subsec. (m)(4)(A) to (F). Pub. L. 111–148, §10319(e)(3), after subpar. (A) and redesignated former subpar. (A) as (iv).

Subsec. (m)(4)(A)(iv). Pub. L. 111–148, §10319(e)(3), after “years” in heading and subpar. (A)(iv), inserted “2014,” after “years” in heading and paragraph for each of fiscal years 2008 and 2009 shall be applied with respect to any of rate years 2014 through 2019 by substituting ‘0.0 percentage points’ for ‘0.2 percentage points’ if for such rate year—“(i) the excess (if any) of—“(i) the excess (if any) of—“(I) 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. 111–148, §1395ww


Subsec. (d)(3)(D). Pub. L. 108–173, §401(b)(1)(A), (B), (2)(B), in heading, struck out “in different areas” after “hospitals” and, in introductory provisions, inserted “for fiscal years before fiscal year 1997,” before “a regional DRG prospective payment rate” and struck out “each of” before “which is equal”—.


Subsec. (d)(3)(E). Pub. L. 108–173, §403(a), designated existing provisions as cl. (i), inserted cl. heading, substitute “Except as provided in clause (ii), the Secretary” for “The Secretary”, inserted at end “The Secretary shall apply the previous sentence for any period as if the amendments made by section 404(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 had not been enacted.” and added cl. (ii).


Subsec. (d)(5)(B)(v). Pub. L. 108–173, §422(b)(1)(B), inserted at end “The provisions of subsection (h)(7) of this section shall apply with respect to the first sentence of this clause in the same manner as it applies with respect to subsection (b)(4)(F)(i) of this section.”


Subsec. (d)(5)(K)(ii)(I). Pub. L. 108–173, §503(b)(1), inserted at end “Such mechanism shall be modified to meet the requirements of clause (viii).”

Subsec. (d)(5)(K)(ii)(II). Pub. L. 108–173, §503(b)(1), inserted “(applying a threshold specified by the Secretary that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between the amount and regional adjusted DRG prospective payment rate) and squared regional DRG prospective payment rate)” for “for hospitals.”
between 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 paragraph (12)(A)(iii)’’ after ‘‘to subsection (o)(1) of this section’’.

Subsec. (d)(9)(A). Pub. L. 108–173, § 401(c)(1)(B), added cl. (ii) and concluding provisions and struck out former cl. (ii) which read as follows: ‘‘for discharges beginning in a fiscal year beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1997, and September 30, 1997, 25 percent) of the discharge-weighted average standardized amount’’.

(I) the national adjusted DRG prospective payment rate (determined under paragraph (3)(D)) for hospitals located in a large urban area, and

(II) such rate for hospitals located in other urban areas, and

(III) 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.’’


§ 302(d)], realigned margins.

III, § 302(a)(4)], added subcl. (VI). Former subcl. (VI) redesignated (VII).

II, § 211(b)(3)(A)], inserted “or, for discharges occurring on or after April 1, 2001, is equal to the percent determined in accordance with clause (xii)” after “4 percent.”

§ 533(b)(3)], substituted “technology (including a new medical service or technology under paragraph (5)(K)),” for “technology.”

II, § 211(b)(5)(A)], inserted “or, for discharges occurring on or after April 1, 2001, the greater of the percentages determined in accordance with clause (xiii)” after “5 percent.”

II, § 211(b)(5)(B)], added cl. (xiii).

§ 303(a)(1)], struck out “each of” after “during” and inserted “and 2 percent, respectively” after “3 percent.”

III, § 303(a)(2)], substituted “3 percent” for “4 percent.”

§ 533(b)(1)], added subpars. (K) and (L).

§ 303(d)(1)], struck out “and before October 1, 1997,” before “the Secretary shall provide” in introductory provisions.


Subsec. (j)(3)(B). Pub. L. 106–554, § 1(a)(6) [title III, § 305(b)(2)], inserted “but not taking into account any payment adjustment resulting from an election permitted under paragraph (1)(F)” after “paragraphs (4) and (6)”.

Pub. L. 106–554, § 1(a)(6) [title III, § 305(a)], substituted “98 percent for fiscal year 2001 and 100 percent for fiscal year 2002” for “98 percent.”


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)(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. (d)(5)(F)(ix)(IV). Pub. L. 106–113, §1000(a)(6) [title I, §112(a)(2)(A)], redesignated subcl. (V) as (IV), substituted “reduced by 4 percent” for “reduced by 5 percent”, and struck out former subcl. (IV) which read as follows: “during fiscal year 2001, such additional payment amount shall be reduced by 4 percent.”


Subsec. (d)(6)(C). Pub. L. 106–113, §1000(a)(6) [title I, §112(a)(4)], redesignated former subcl. (V) as (IV), substituted “reduced by 4 percent” for “reduced by 5 percent”, and struck out former subcl. (IV) which read as follows: “during fiscal year 2001, such additional payment amount shall be reduced by 4 percent.”


Subsec. (h)(5)(I)(A). Pub. L. 106–113, §1000(a)(6) [title I, §125(a)(2)], amended cl. (i) generally. Prior to amendment, cl. (i) read as follows: “classes of patients of rehabilitation facilities (each in this subsection referred to as a ‘case mix group’), based on such factors as the Secretary deems appropriate, which most appropriately takes into account impairment, age, related prior hospitalization, comorbidities, and functional capability of the patient; and”.


Subsec. (h)(5)(I)(A). Pub. L. 106–113, §1000(a)(6) [title I, §125(a)(1)], struck out “, day of inpatient hospital services, or other unit of payment defined by the Secretary” before period at end.

Subsec. (h)(5)(I)(A). Pub. L. 106–113, §1000(a)(6) [title II, §321(b)(1)(A)], inserted heading and substituted “Subject to subparagraph (G)(v), the initial residency period” for “The initial residency period” in concluding provisions.

Subsec. (h)(5)(G)(ii). Pub. L. 106–113, §1000(a)(6) [title III, §312(a)(2)(A)], substituted “(iv), and (v)” for “and (v)”.


Subsec. (j)(2)(A)(i). Pub. L. 106–113, §4415(a), added cls. (i) and (ii) and concluding provisions and struck out former cls. (i) and (ii) and former 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)(1)(C). Pub. L. 105–33, §4415(c)(1), (2), redesignated subpar. (B) as (C) and substituted “greater than 130 percent of the target amount” for “greater than the target amount” and “exceed 110 percent of the target amount” for “exceed the target amount”.


Subsec. (b)(3)(A). Pub. L. 105–33, §§4413(a)(1), 4416(b), in introductory provisions, substituted “subject paragraph (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). Pub. L. 105–33, §4421(b)(2), inserted “and subsection (j) of this section” after “For purposes of subsection (d) of this section” in introductory provisions.

Subsec. (b)(3)(B)(ii). Pub. L. 105–33, §§4401(a), 4411(a), 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-
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. (g)(3)(B). Pub. L. 105–33, § 4201(c)(1), substituted "critical access" for "rural primary care".


Subsec. (h)(4)(F) to (H). Pub. L. 105–33, § 4623, added subpars. (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), inserted "(or, in the case of a hospital that is not a subsection (d) hospital, during the 1 day) after "3 days"."


Subsec. (b)(3)(E)(ii). 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. (b)(5)(A)(i). Pub. L. 103–66, § 13501(c)(2), 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. (b)(5)(B)(iv). Pub. L. 103–66, § 13506, inserted "(or, for discharges in fiscal years beginning on or after October 1, 1994, the target for "period, the target", "subparagraph (B)(iv)" for "subparagraph (B)(ii)"), and "for" and "period at end."


Subsec. (b)(6)(A). Pub. L. 106–36, § 13502(b), designated existing provisions as cl. (i) and added cl. (ii).

Subsec. (d)(3)(A)(iii). Pub. L. 106–36, § 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, 1993, 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."
laws and inserting “before October 1, 1994, in the case of a subsection (d) hospital which is a medicare-depend-ent, small rural hospital, payment under paragraph (1)(A) shall be—

‘‘(I) an amount based on 190 percent of the hospital’s target amount for the cost reporting period, as defined in section 13401(b)(3)(D) of this section, or

‘‘(II) the amount determined under paragraph (3)(D) of section 13401 of this title, whichever results in the greater payment to the hospital,” to reflect the probable intent of Congress.

Subsec. (b)(3)(B)(ii) to (iv). Pub. L. 103–66, § 13563(b)(1)(A), substituted “(A), (C), (D), and (E),” for “(A) and (E),” in introductory provisions.


Subsec. (h)(5)(H). Pub. L. 103–66, § 13563(a)(2), added subpar. (H) and redesignated former subpar. (B) as (C).

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, or any portion thereof, for services related to the admission (as defined by the Secretary) based on DRG prospective payment amounts under this subsection (as estimated by the Secretary) to take into account such reduction.”

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, 1986, and before October 1, 1987, is equal to 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 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.”


Subsec. (d)(3)(A)(ii) to (v). 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 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)(ii), substituted "occurring on or after October 1, 1986," through the end of cl. (ii) for "—" and subcls. (I) and (II) which read as follows:

"(I) on or after October 1, 1986, and before October 1, 1995, 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 Act 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 during such period instead of the factor described in clause (ii)(I) of that paragraph, and

"(II) on or after October 1, 1995, 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 Act of 1985 and by section 4003(a)(1) of the Omnibus Budget Reconciliation Act of 1987.

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 (or, 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)(iii). Pub. L. 101–508, § 4002(c)(2)(B)(iv)(III), 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, the use 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), which is based upon such evidence but shall consider the record as a whole as the Secretary in considering the appeal of an unsuccessful applicant shall consider the record as a whole as such record appeared before the Board" and substituted "1 member shall be a member of the Prospective Payment Assessment Commission, and at least one urban area as being located in another urban area—"

Subsec. (d)(3)(D)(iv). Pub. L. 101–508, § 4002(c)(2)(B)(iv)(IV), 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 of payments to rural hospitals not affected by subparagraph (B) or (C) of 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—"

Subsec. (d)(3)(E). 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 of payments to rural hospitals not affected by subparagraph (B) or (C) of 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—"


Subsec. (d)(3)(F)(iii). Pub. L. 101–508, § 4002(c)(2)(B)(v)(III), struck out subpar. (D) which read as follows: "For purposes of clause (i)(II), the indirect teaching adjustment factor for discharges occurring on or after May 1, 1986, is equal to 1.89\((1+r)\)−1, or 1.43\((1+r)\)−1, where \(r\) is the ratio of the hospital’s full-time equivalent interns and residents to beds.


Subsec. (d)(4)(D). Pub. L. 101–508, § 4002(c)(2)(B)(vi), 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 of payments to rural hospitals not affected by subparagraph (B) or (C) of 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—"

Subsec. (d)(5)(D). Pub. L. 101–508, § 4002(c)(2)(B)(vii)(I), substituted "representative" for "representatives" and struck out "1 member shall be a member of the Prospective Payment Assessment Commission, and at least one urban area as being located in another urban area—"

Subsec. (d)(5)(E). Pub. L. 101–508, § 4002(c)(2)(B)(vii)(II), substituted "Congress" for "the Secretary" and inserted inserted "to the hospitals so treated (as if each affected rural county were a separate urban area)."

Subsec. (d)(5)(F)(i). Pub. L. 101–508, § 4002(c)(2)(B)(vii)(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—"

Subsec. (d)(5)(F)(ii). Pub. L. 101–508, § 4002(c)(2)(B)(vii)(IV), substituted "representative" for "representatives" and struck out "1 member shall be a member of the Prospective Payment Assessment Commission, and at least one urban area as being located in another urban area—"

Subsec. (d)(5)(F)(iii). Pub. L. 101–508, § 4002(c)(2)(B)(vii)(V), substituted "representative" for "representatives" and struck out "1 member shall be a member of the Prospective Payment Assessment Commission, and at least one urban area as being located in another urban area—"

Subsec. (d)(5)(F)(iv). Pub. L. 101–508, § 4002(c)(2)(B)(vii)(VI), substituted "representative" for "representatives" and struck out "1 member shall be a member of the Prospective Payment Assessment Commission, and at least one urban area as being located in another urban area—"
before period at end of 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)(4). Pub. L. 101–508, § 4002(g)(2)(D), designated existing provisions as subpar. (A) and added subpar. (B).

Subsec. (e)(5). Pub. L. 101–508, § 4002(g)(2)(E), substituted “recommendations” for “recommendation” in subpars. (A) and (B) and inserted at end “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. 101–508, § 4002(g)(2)(F), redesignated cls. (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)(3)(B). Pub. L. 101–508, § 4001(c), substituted “subparagraph (d) of section 1385(d)(ii) of this title” for “subparagraph (d)(ii) of section 1385(d) of this title.”


Subsec. (b)(3)(A). Pub. L. 101–239, § 6004(b)(1)(A), substituted “(C), (D), and (E)” for “(C) and (D)” in introductory provisions.

Subsec. (b)(3)(C). Pub. L. 101–239, § 6003(c)(2)(i), substituted “subparagraph (C)” for “subparagraph (C) and (D)” in introductory provisions.


Subsec. (d)(5)(I). Pub. L. 101–239, § 6003(c)(1)(B)(ii), substituted “For purposes of subparagraphs (A) and (D)” for “For purposes of subparagraphs (A) and (C)” in added subpar. (D).

Subsec. (d)(5)(I). Pub. L. 101–239, § 6003(c)(1)(B)(ii), substituted “For purposes of subparagraphs (A) and (D)” for “For purposes of subparagraph (A)” in added subpar. (D).


Subsec. (e)(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,”.

Subsec. (e)(4). Pub. L. 101–239, § 6022, substituted “the aggregate rate of increase from October 1, 1984, 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)(4)(C). Pub. L. 101–239, § 6003(b)(5), designated existing provisions as cl. (i) and added cls. (ii) to (iv).

Subsec. (d)(5)(C). Pub. L. 101–239, § 6003(c)(1)(A)(i), redesignated former cls. (ii), (iii), and (iv) as subpars. (D), (E), and (F), respectively.

Subsec. (d)(5)(D). Pub. L. 101–239, § 6003(c)(1)(A)(iv), added amended subpar. (C)(ii) generally, redesignating it as subpar. (D) and substituting cls. (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)(G)(iv)(I). Pub. L. 101–239, § 6003(c)(1)(A), substituted “the applicable formula described in clause (vii)” for “the following formula: (P – 10) × 2.5, where “P” is the hospital’s disproportionate patient percentage (as defined in clause (vii)).”

Subsec. (d)(5)(G)(v)(II). Pub. L. 101–239, § 6003(c)(2)(A)(ii), inserted “in subclause (IV) or (V)” or “after ‘described’.”


Subsec. (d)(5)(F)(v)(II). 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)(J). Pub. L. 101–239, § 6003(c)(3), amended subpar. (C) generally. Prior to amendment, subpar. (C) 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), (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 as if the wage index for that rural area (as applied under this subsection) is not being located in the rural area in a State, reduces the hospitals located in a rural county or counties as if not being located in the rural area in a State, reduces the wage index for that rural area.

(“(ii) Clause (i) shall only apply to discharges occurring on or after October 1, 1989, and before October 1, 1991.”)

Subsec. (d)(8)(C)(i). Pub. L. 101–239, § 6003(h)(2), substituted “subparagraph (B) or a decision of the Medicare Geographic Classification Review Board or the Secretary under paragraph (10),” for “subparagraph (B)” in two places.


Subsec. (d)(8)(D). 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) and (C)” in three places.


Subsec. (g)(3)(A)(iv). Pub. L. 101–239, § 301(b)(3), (c)(3), amended cl. (iv) identically, substituting “(as the case may be)” for “(as the case may be)”, “(as the case may be)” for “(as the case may be)”.


Pub. L. 100–360, § 411(b)(1)(A), substituted “for hospitals located in other urban areas” for “for hospitals located in other urban areas”.

Pub. L. 100–360, § 411(b)(1)(C), inserted “increase” after “market basket percentage”.

Subsec. (d)(1)(A)(iii). Pub. L. 100–360, § 411(b)(1)(G), substituted “if the average standardized amount (described in clause (ii)(i) or clause (ii)(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 “if greater”.

Subsec. (d)(2)(C)(i). Pub. L. 100–647, § 1018(b)(1), struck out Pub. L. 99–514, § 1895(b)(1), (2), redesignated cl. (i) as (ii), redesignated cl. (ii) as (iii), redesignated cl. (iii) as (iv), and redesignated cl. (iv) as (v).
county or counties of any adjacent urban area is equal to at least 15 percent of the number of residents of the rural county who are employed, or (II) the sum of the number of residents of any adjacent urban area who commute for employment to the central county or counties of any adjacent urban area and the number of residents of any adjacent urban area who commute for employment to the rural county is at least equal to 20 percent of the number of residents of the rural county who are employed.”

Subsec. (d)(3)(A). 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)(ii). Pub. L. 100–203, 4002(c)(1)(B), (C), as amended by Pub. L. 100–369, 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, 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.

Pub. L. 100–203, 4002(c)(1)(D)(i), 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 “urban area”.

Subsec. (d)(3)(E). Pub. L. 100–203, 4004(a)(1), formerly 4004(a), as redesignated by Pub. L. 100–369, 411(b)(3), 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.”


Subsec. (d)(5)(C)(v). Pub. L. 100–203, 4006(b)(2)(A), substituted “other capital-related costs” as defined by the Secretary for periods beginning prior to October 1, 1987 for “with respect to costs incurred in cost reporting periods beginning prior to October 1987 of (or such later year as the Secretary may, in his discretion, select), other capital-related costs, as defined by the Secretary”.

Subsec. (d)(5)(C)(vi). Pub. L. 100–203, 4002(e)(1), struck out “subparagraph (A) for 12-month cost reporting periods beginning during a fiscal year and for purposes of”, after “For purposes of clause (i)”.

Subsec. (d)(5)(C)(vii). Pub. L. 100–203, 4002(a), struck out “and for fiscal year 1988, the market basket percentage increase as defined in clause (ii) minus 2.0 percentage point, and the market basket percentage increase as defined in clause (ii) minus 1.15 percentage.”.

Subsec. (d)(5)(D)(i). Pub. L. 100–203, 4009(j)(6)(A), added subcls. (II) to (IV), (V), Pub. L. 100–203, 4002(a), added cl. (II) to (V) and struck out former subcl. (III) which read “for fiscal year 1989 and subsequent fiscal years, the percentage determined by the Secretary pursuant to subsection (e)(4) of this section,”.

Subsec. (d)(5)(D)(ii). Pub. L. 100–203, 4002(e)(2), added cl. (II), redesignated former cl. (I) as (III), and substituted “For purposes of this subparagraph” for “For purposes of clause (i)”.

Subsec. (d)(5)(D)(iii). Pub. L. 100–203, 4002(d)(1), inserted a period before “end”, or, if greater for discharges occurring during the period beginning on 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”.


Pub. L. 100–203, 4003(c), substituted “1990” for “1989” in subcls. (I) and (II).


Pub. L. 100–203, 4003(b)(2), struck out “the lesser of 15 percent, or, after “equal to”,”.


Subsec. (d)(6). Pub. L. 100–203, 4003(a)(1), as amended by Pub. L. 100–369, 411(b)(1)(A), designated existing provisions as subpar. (A), redesignated former subpar. (A) and cls. (i) and (ii) as cl. (i) and subcls. (I) and (II),
respectively, redesignated former subpar. (B) and cls. (i) and (ii) as cl. (ii) and subcl. (I) and (II), respectively, and added subpars. (B) and (C).


Subsec. (d)(9)(C)(iv). Pub. L. 100–203, § 4009(a)(2), as added by Pub. L. 100–360, § 411(b)(3)(b), inserted at end "the second and third sentences of paragraph (3)(B) 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) hospital.''


Subsec. (e)(4). Pub. L. 100–203, § 4002(f)(1)(C), substituted "for each fiscal year (beginning with fiscal year 1989)" 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.''


Pub. L. 100–203, § 4002(f)(1)(D), struck out "or determine" after "recommendation" in subpars. (A) and (B).

Subsec. (e)(6)(B). Pub. L. 100–203, § 4009(d)(1), as amended by Pub. L. 100–360, § 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 out 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, including the employment benefits of the Commission, which 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 1395v(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 1395v(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-re- lated costs for inpatient hospital services, no payment may be made under this subchapter for capital-related costs of capital expenditures (as defined in section 1320a–1(g) of this title and except as provided in section 1320a–1(j) of this title) for inpatient hospital services in a State, which expenditures are obligated after September 30, 1987, unless the State has an agreement with the Secretary under section 1320a–1(b) of this title under the agreement the State has recommended approval of the capital expenditures.''

Subsec. (g)(3)(A)(ii) to (iv). Pub. L. 100–203, § 4006(a), as amended by Pub. L. 100–360, § 411(b)(5)(B), substituted "on or after October 1, 1987, and before January 1, 1988," for "", and", at end of cl. (ii), added cls. (iii) and (iv), and struck out former cl. (iii) which read as follows: "10 percent for payments attributable to portions of cost reporting periods or discharges (as the case may be) occurring during fiscal year 1988.''

Subsec. (g)(3)(C). Pub. L. 100–203, § 4006(b)(2)(B), struck out subpar. (C) which read as follows: "If the Secretary provides, under subsection (a)(4) of this section, for the inclusion of other capital-related costs in operating costs of inpatient hospital services, the Secretary shall provide—

(i) notwithstanding any other provision of this subchapter, for the continuation of payment under the reasonable cost methodology described in section 1395v(x)(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(g)(5), substituted "subsection (D)" for "subsection (E)".

Subsec. (g)(4)(D). Pub. L. 100–203, § 4009(g)(5), struck out "costs of anesthesia services provided by a certified registered nurse anesthetist," after "approved educational activities.

Subsec. (h)(4)(B). Pub. L. 99–349 substituted "October 1 of 1987 or (of such later year as the Secretary may, in his discretion, select)" for "October 1, 1987'.


Pub. L. 99–272, § 1907(a)(2), inserted "a return on equity capital," after "anesthetist," and "other" before "capital-related costs'.

Subsec. (h)(5)(B). Pub. L. 99–272, § 1901(b)(1), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: "For purposes of subparagraph (A) and (B) of this section and except as provided in subsection (e) of this section, the 'applicable percentage increase' for any 12-month cost reporting period or fiscal year shall be equal to one-quarter of 1 percentage point plus the percentage, estimated by the Secretary before the beginning of the period or year, by which the cost of the mix of goods and services (including personnel costs but excluding non-operating costs) comprising routine, ancillary, and special care unit inpatient hospital services, based on an index of appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services included in such inpatient hospital services, for such cost reporting period or fiscal year will exceed the cost of such mix of goods and services for the preceding 12-month cost reporting period or fiscal year. In determining a percentage change under subsection (e) (of this section with respect to discharges occurring in any cost reporting period or fiscal year beginning on or after October 1, 1985, and before October 1, 1986, the Secretary may not establish a percentage increase which exceeds the applicable percentage increase otherwise determined for that period or fiscal year under the preceding sentence.'"
Subsec. (b)(3)(B)(i)(II). Pub. L. 99–509, §392(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 (i)) and

Pub. L. 99–514, §1895(b)(1)(A), struck out “for each of fiscal years 1985 and 1986” for “for fiscal year 1985” after “(B), and added (II) that sum using the factor specified in paragraph (5)(B)(ii)(II).”


Pub. L. 99–514, §1895(b)(2)(A), 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)(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 who are not employees of such hospital.”


Pub. L. 99–272. §9104(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. §9104(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 the 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).
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1395ww par. (J). Pub. L. 98–21, §601(a)(2), inserted provision that term "operating costs of inpatient hospital services" does not include costs of improved education 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. (d)(B). Pub. L. 98–21, §601(b)(5)–(8), inserted "or "applicable, the requirements of paragraph (A)" for "meets the requirements of subparagraphs (A), (D), and (E) of paragraph (1) and, if applicable, the requirements of paragraph (3)".

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 paras. (4) to (6).

Subsec. (d). Pub. L. 98–21, §601(d)(2), (e), 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.

Subsec. (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. 113–61, 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. 1261, 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 sections 1395f, 1395m, 1395n, 1395rr, 1395yy, and 1395fff 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, §5505(c), Mar. 23, 2010, 124 Stat. 665, 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 (b), shall apply to cost reporting periods beginning on or after July 1, 2009.

(3) PPS.—Section 1886(d)(2)(B)(X)(III) of the Social Security Act [42 U.S.C. 1395ww(d)(2)(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


paragraph (1) [amending this section] shall not apply to payment units occurring before April 1, 2008.


**Effective Date of 2006 Amendment**

Amendment by section 109(a)(2) of Pub. L. 109–432 applicable to payment for services furnished on or after Jan. 1, 2009, see section 109(c) of Pub. L. 109–432, set out as a note under section 1395u of this title.

Amendment by section 205(b)(1) of Pub. L. 109–432 effective as if included in the enactment of Pub. L. 109–171, see section 205(c) of Pub. L. 109–432, set out as a note under section 1395u of this title.

**Effective Date of 2003 Amendment**

Pub. L. 108–171, title IV, §407(b), Dec. 8, 2003, 113 Stat. 2270, provided that: "The amendment made by subsection (a) [amending this section] shall apply to cost reporting periods beginning on or after January 1, 2004."

Pub. L. 108–171, title V, §562(c), Dec. 8, 2003, 113 Stat. 2291, provided that: "The amendments made by this section [amending this section] shall apply to discharges occurring on or after April 1, 2004."

Pub. L. 108–171, title V, §563(e), Dec. 8, 2003, 113 Stat. 2292, provided that:

"(1) In General.—The Secretary [of Health and Human Services] shall implement the amendments made by this section [amending this section] so that they apply to classification for fiscal years beginning with fiscal year 2005.

"(2) Reconsiderations of Applications for Fiscal Year 2005 That Are Denied.—In the case of an application for the classification of a medical service or technology as a new medical service or technology under section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) that was filed for fiscal year 2004 and that is denied—

"(A) the Secretary shall automatically reconsider the application as an application for fiscal year 2005 under the amendments made by this section; and

"(B) the maximum time period otherwise permitted for such classification of the service or technology shall be extended by 12 months."

Pub. L. 108–171, title V, §565(c), Dec. 8, 2003, 113 Stat. 2294, provided that: "The amendments made by this section [amending this section and section 1395cc of this title] shall first apply to the wage index for discharges occurring on or after October 1, 2004. In initially implementing such amendments, the Secretary [of Health and Human Services] may modify the deadlines otherwise applicable under clauses (ii) and (iii)(I) of section 1886(d)(10)(C) of the Social Security Act (42 U.S.C. 1395ww(d)(10)(C)), for submission of, and actions on, applications relating to changes in hospital geographic reclassification."

**Effective Date of 2000 Amendment**

Pub. L. 106–554, §1(a)(6) [title II, §212(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–485, provided that: "The amendment made by this section [amending this section] shall apply on and after July 1, 2000, to residency programs that began before, on, or after the date of the enactment of this Act [Nov. 29, 1999]."

Pub. L. 106–554, §1(a)(6) [title II, §212(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–490, provided that: "The amendment made by paragraph (1) [amending this section] shall apply to discharges occurring on or after October 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 III, §305(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–496, provided that: "The amendments made by this section [amending this section] take effect 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. 1536, 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. 1536, 1501A–365, provided that: "The amendments made by subsection (a) [amending this section] apply on and 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(t)(m)] of Pub. L. 106–113, set out as a note under section 1395dd 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 1395dd–4 of this title.

Pub. L. 106–113, div. B, §1000(a)(6) [title IV, §407(b)(3)], Nov. 29, 1999, 113 Stat. 1536, 1501A–374, 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."


"(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. 1395ww(b)) 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. 1395ww)
1385ww(d)(5)(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 4203(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 4415(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 4415(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, 1996.”

Section 4415(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 4415(a)(3) of Pub. L. 105–33 provided that: “The amendments 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. 9, 1997].”

Section 4415(a)(2) of Pub. L. 105–33 provided that: “The amendments made by this section [amending this section] shall apply to combined medical residency training programs, to services furnished on or after the date of the enactment of this Act [Oct. 1, 1997].”

Section 4415(a)(3) of Pub. L. 105–33 provided that: “The amendments made by this section [amending this section] shall apply to combined medical residency training programs, to services furnished on or after the date of the enactment of this Act [Aug. 5, 1997].”

Effective Date of 1994 Amendment
Section 101(a)(2) of Pub. L. 103–322 provided that: “The amendment made by paragraph (1) [amending this section] shall take effect as if included in the enactment of OBRA–1989 [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 99–276).”

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 13503(b)(3) of Pub. L. 103–66 provided that: “The amendment made by paragraph (1) [amending this section] shall take effect as if included in the enactment of OBRA–1989 [Pub. L. 101–239].”

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)(3) 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, the amendment made by paragraph (2) [amending this section] shall apply to discharges occurring on or after October 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 apply to payments for discharges occurring on or after January 1, 1991, and the amendments made by paragraph (2)(B) [amending this section] shall take effect October 1, 1994.”

Section 4002(c)(5) of Pub. L. 101–508 provided that: “The amendments made by this section [amending this section] shall apply to discharges occurring on or after October 1, 1990.”

Section 4002(c)(3) of Pub. L. 101–508 provided that: “The amendments made by this section [amending this section] shall apply to discharges occurring on or after January 1, 1991.”

Section 4003(b) of Pub. L. 101–508 provided that: “The amendment 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;’’

‘‘(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 4005(a)(3) of Pub. L. 101–508 provided that: “The amendments made by paragraph (1) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 1991.”

Section 4005(c)(4) of Pub. L. 101–508 provided that: “The amendments made by paragraph (1) [amending this section and section 1395b of this title] shall take effect on the date of the enactment of this Act [Nov. 5, 1990], and the amendments made by paragraph (2) [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 4006(c)(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 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(b)(2) 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 1866(d)(5)(I) of the Social Security Act [subsec. (d)(5)(I) of this section] as redesignated by section 6969(c)(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 after 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 1866(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 this Act [Dec. 19, 1989], except as otherwise provided, as if included in the provision of the Tax Reform Act of 1986, Pub. L. 99–514, to the extent that 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.


Effective Date of 1988 Amendments

Amendment by section 1018(r)(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 the extent that 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. 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, section 636, set out as a note under section 101 of Title 42, The Public Health and Welfare.

Effective Date of 1987 Amendments

Section 6002(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, MORP portion of payment.—In the case of a subsection (d) hospital (as defined in paragraph (6))—

"(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 (described 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 made under section 1886(d)(1)(A)(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 so defined, as amended by subsection (a)); and

"(C) for cost reporting periods beginning on or after October 1, 1988, the applicable percentage increase (as so defined) with respect to the previous cost reporting period shall be deemed to have been the applicable percentage increase (as so defined, as amended by subsection (a)).

"(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)(A)(ii) of the Social Security Act [subsec. (d)(3)(A)(ii) 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, 1988."

Section 4005(c)(3)(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 4005(d)(1)(B) of Pub. L. 100–203 provided that: "The amendment made by paragraph (1) [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. 100–93 effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 15(a) of Pub. L. 100–93, set out as a note under section 1320a–7 of this title.

**EFFECTIVE DATE OF 1986 AMENDMENTS**

Section 1886(b)(1)(D) of Pub. L. 99–514, which provided for applicability of amendments to this section by section 1886(b)(1) of Pub. L. 99–514 to discharges occurring on or after Oct. 1, 1986, with certain exceptions, was repealed by Pub. L. 99–509, title IX, § 9307(c)(1)(B), Oct. 21, 1986, the applicable percentage increase (described in section 1886(d)(1)(D) of the Social Security Act [subsec. (d)(1)(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 paragraph (1) [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 with respect to discharges occurring on or after October 1, 1986.

Section 9303(b) of Pub. L. 99–509 provided that the amendment 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 9304(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 9305(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, 2nd 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(l), (k) of Pub. L. 99–509, as amended, set out as notes under section 1895b of this title.

Section 9321(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 1989."

Section 9310(d) of Pub. L. 99–272 provided that: "The amendment made by subsection (a) [amending section 5(c)(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 9310(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) of such subsection [(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 under section 1886(d)(1)(A) of the Social Security Act [subsec. (d)(1)(A) of this section] made on the basis of discharges occurring during a cost reporting period of a hospital, for the hospital's cost reporting periods beginning on or after October 1, 1986;

(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 [subsec. (d)(1)(D) of this section]), the applicable combined adjusted DRG prospective payment rate for a subsection (d) hospital to which the amendments made by this section [amending this section] do not apply is, for discharges occurring on or after October 1, 1985, and before May 1, 1986, 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 for such discharges.''

Section 910(c) of Pub. L. 99–272 provided that: "(1) Except as provided in paragraph (2), the amendments made by this section [amending this section] shall apply to discharges occurring on or after May 1, 1986.

(2) The amendments made by this section shall not first be applied to discharges occurring as of a date unless, for discharges occurring on that date, the amendments made by section 9105 [amending this section] are also being applied.''

Section 910(e) of Pub. L. 99–272 provided that: "The amendments made by this section [amending this section] shall apply to discharges occurring on or after May 1, 1986.''

Section 910(b) of Pub. L. 99–272 provided that: "The amendment made by subsection (a) [amending this section] shall apply to cost reporting periods beginning on or after January 1, 1986.''

Section 910(c)(1) of Pub. L. 99–272 provided that: "The amendments made by subsection (a) [amending this section] shall apply to hospital cost reporting periods beginning on or after October 1, 1986.''

Section 910(b) of Pub. L. 99–272 provided that: "The amendment made by subsection (a) [amending this section] shall apply to cost reporting periods beginning on or after October 1, 1983, and before October 1, 1989.''

Section 9202(b) of Pub. L. 99–272 provided that: "The amendments made by subsection (a) [amending this section] shall apply to hospital cost reporting periods beginning on or after July 1, 1985.''

**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 1395ww 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 cost reporting periods beginning in, and discharges occurring in, fiscal year 1985 and thereafter.''

Section 2311(d) of Pub. L. 98–369 provided that: "(1) Except as provided in paragraph (2), the amendments made by subsections (b) and (c) [amending this section] shall be effective with respect to cost reporting periods beginning on or after October 1, 1983, and the amendment made by subsection (a) [amending this section] shall be effective with respect to cost reporting periods beginning on or after October 1, 1984.

(2) The amendment made by subsection (b) [amending this section] shall not apply so as to reduce any payment under section 1886(d) of the Social Security Act [subsec. (d) of this section] to a hospital the region of which is deemed to be changed pursuant to such amendment for discharges occurring in any cost reporting period beginning before October 1, 1984.''


**TITLE 42—THE PUBLIC HEALTH AND WELFARE**

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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 23(3)(a), (b), and (d) of Pub. L. 98–369, set out as an Effective Date of 1984 Amendment note under section 1356y of this title. Section 23(3)(g) of Pub. L. 98–369 provided that: "The amendments made by subsections (a) and (b) [amending this section and sections 1395j–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 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 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, 1983, 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. 98–21, as amended by Pub. L. 98–369, div. B, title III, §§2151(f)(1), July 18, 1984, 98 Stat. 1080, provided that: "(a)(1) Except as provided in section 602(b) [amending section 1395cc of this title] and in paragraph (2), the amendments made by the preceding provisions of this title [amending this section and sections 1395j–2 and 1395cc of this title and enacting and amending provisions set out as notes under this section] apply to items and services furnished before that period. In the case of a hospital's first cost reporting period that begins after September 1983, to take effect on 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.

The Secretary of Health and Human Services shall be necessary to implement this section [amending this section and amending section 1395x of this title] shall be effective as though they had been 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. 97–248 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. 101–506 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 23(3)(g) of Pub. L. 98–369 provided that: "Notwithstanding section 604(c) of the Social Security Amendments of 1983 [section 604(c) of Pub. L. 98–21, set out above], the Secretary of Health and Human Services shall issue such regulations (on an interim or other basis) 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 steps as may be necessary to provide opportunity for public comment, and appropriate revision based thereon, so as to provide that such regulations are not on an interim basis later than 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. 669, 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. 109–432, set out as a note under section 1395b–6 of this title.

SPECIAL RULE FOR FISCAL YEAR 2011 AND ADJUSTMENT FOR CERTAIN HOSPITALS IN FISCAL YEAR 2011

“(2) SPECIAL RULE FOR FISCAL YEAR 2011.—

“(A) 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. 109–432, 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(b) 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.

“(B) 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 1882(d) of the Social Security Act (42 U.S.C. 1395ww(d)) only if including such data results in a higher applicable reclassified wage index. Any revision to hospital wage indexes made as a result of this subparagraph shall not be effectuated in a budget neutral manner.

“(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—

“(i) 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 bundled 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 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. 1395 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.

"(ii) 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 program under this paragraph.

"(B) BUDGET NEUTRALITY REQUIREMENT.—In conducting the demonstration program under this paragraph, 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 paragraph was not implemented.

"(C) REPORT.—Not later than 18 months after the completion of the demonstration program under this paragraph, the Secretary shall submit to Congress a report that includes a plan to reform the Medicare program for applicable hospitals with respect to inpatient hospital services and recommendations for such other legislation and administrative action as the Secretary determines appropriate.

"(ii) APPLICABLE HOSPITAL DEFINED.—For purposes of this paragraph, the term ‘applicable hospital’ means a hospital described in subclause (III) or (IV) of section 1886(o)(1)(C)(iii) of the Social Security Act [42 U.S.C. 1395ww(g)(1)(C)(iii)], as added by subsection (a)(1).

"(III) DURATION.—The demonstration program under this paragraph shall be conducted for a 3-year period.

"(D) DURATION.—The demonstration program under this paragraph shall be conducted for a 3-year period.

"(E) ENSURE.—In developing the plan under paragraph (1), the Secretary shall account for the goals for reforming such system set forth in the Medicare Payment Advisory Commission June 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 state-wide 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 of the system on patient safety as a result of the implementation of the system; and

"(F) provides for a transition.

"(ii) CONSIDER.—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 expiration of law, in making decisions on applications for reclassification as of September 30, 2008. The preceding sentence shall be effected 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 42.64 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) of such section 42.64 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, §5006(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 1886(h)(4)(H)(v) of the Social Security Act (42 U.S.C. 1395ww(h)(4)(H)(v)).

Graduate nurse education demonstration


(a) In general.—

(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 (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. 1395xx(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. 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) Prohibition.—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. 1395xx)).

(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...
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 an 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. 296]) 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 (e) 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 PARTNER.—The term ‘eligible partner’ 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. 1395 et seq.]; and

“(ii) subject to subparagraph (B), at least half of which is provided in a non-hospital community-based care setting.

“(B) WAIVER OF REQUIREMENT HALF OF TRAINING 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 412.534 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 412.534 of title 42, Code of Federal Regulations, shall not be subject to any payment adjustment under such section if no 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 SATELLITE FACILITIES.—

“(i) 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 no more than 50 percent of the hospital’s Medicare discharges (other than discharges described in paragraph (c)(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 July 1, 2007, for applicable long-term care hospitals and satellite facilities described in section 412.534(g) of title 42, Code of Federal Regulations for a 5-year period.

“(3) NO APPLICATION OF VERY SHOR-T-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 Fed. Reg. 26004, 26092) made to the short-stay outlier payment provision for long-term care hospitals contained in section 412.52(e)(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 412.532(d)(3)(i) of title 42, Code of Federal Regulations, or any similar provision.

“(5) MORMATURUM ON THE ESTABLISHMENT OF LONG-TERM CARE HOSPITALS, LONG-TERM CARE SATELLITE FACILITIES AND ON THE INCREASE OF LONG-TERM CARE HOSPITAL BEDS IN EXISTING LONG-TERM CARE HOSPITALS OR SATELLITE 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-
elitist facility, other than an existing long-term care hospital or facility; and

(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 142.22(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); or

"(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 effect the limitation on increasing beds under sections 421.22(h)(3) and 421.22(i) of title 42, Code of Federal Regulations.

"(C) EXISTING HOSPITAL OR SATELLITE 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 421 of title 42, Code of Federal Regulations, as of the date of the enactment of this Act.

"(4) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869 of the Social Security Act (42 U.S.C. 1395fff), section 1787 of such Act (42 U.S.C. 1395oo), or otherwise, of the application of this subsection by the Secretary.

"(5) EFFECTIVE DATE OF AMENDMENT.—The effective date of amendment by Pub. L. 111–5, see section 4202(c) of Pub. L. 111–5, set out as a note following section 421(a) of Pub. L. 110–173, set out above.

EXPANDED REVIEW OF MEDICAL NECESSITY

Pub. L. 110–173, title I, §114(f), Dec. 29, 2007, 121 Stat. 2565, provided that:

"(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 [subsection (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 sufficient 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 reviewed as contained in section 1886(d)(1)(B)(iv) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)(iv)).

"(3) CONTINUATION OF REVIEWS.—Under contracts under this subsection, the Secretary shall establish an error rate with respect to such reviews that could require further review of the medical necessity of admissions and continued stay in the hospital involved and other actions as determined by the Secretary.

"(4) TERMINATION OF REVIEWS.—

"(A) IN GENERAL.—Subject to subparagraph (B), the previous provisions of this subsection shall cease to apply for discharges occurring on or after October 1, 2010.

"(B) CONTINUATION.—As of the date specified in subparagraph (A), the Secretary shall determine whether to continue to guarantee, through continued medical review and sampling under this paragraph, recovery of at least 75 percent of overpayments received by long-term care hospitals due to medically unnecessary admissions and continued stays.

"(5) FUNDING.—The costs to fiscal intermediaries or Medicare administrative contractors conducting the medical necessity reviews under paragraph (1) shall be funded from the aggregate overpayments recouped by the Secretary of Health and Human Services from long-term care hospitals due to medically unnecessary admissions and continued stays. The Secretary may use an amount not in excess of 40 percent of the overpayments recouped under this paragraph to compensate the fiscal intermediaries or Medicare administrative contractors for the costs of services performed.

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)(5)(1)(I) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(1)(I)) and contained in the final rule promulgated by the Secretary in the Federal Register on August 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. 57634), and any subsequent corrections.

CORRECTION OF APPLICATION OF WAGE INDEX DURING TAX RELIEF AND HEALTH CARE ACT EXTENSION

Pub. L. 110–173, title I, §117(c), Dec. 29, 2007, 121 Stat. 2568, provided that: "In the case of a subsection (d) hospital (as defined for purposes 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 for the period beginning on April 1, 2007, and ending on September 30, 2007, pursuant to subsection (a) of section 104(b) of the Tax Relief and Health Care Act of 2006 [Pub. L. 109–332] (42 U.S.C. 1395ww note); and
“(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, the Secretary of Health and Human Services shall require the recalculation of the wage index for purposes of section 1886 of title 42, United States Code, for purposes of such section a qualified gainsharing demonstration program under which the Secretary shall approve demonstration projects by not later than January 1, 2007, to test and evaluate methodologies and arrangements between hospitals and physicians designed to govern the utilization of inpatient hospital resources and physician work to improve the quality and efficiency of care provided to Medicare beneficiaries and to develop improved operational and financial hospital performance with sharing of remuneration as specified in the project. Such projects shall be operational by not later than January 1, 2007.

(b) Requirements Described.—A demonstration project under this section shall meet the following requirements for purposes of maintaining or improving quality while achieving cost savings:

(1) Arrangement for Remuneration as Share of Savings.—The demonstration project shall involve an arrangement between a hospital and a physician under which the hospital provides remuneration to the physician that represents solely a share of the savings incurred directly as a result of collaborative efforts between the hospital and the physician.

(2) Written Plan Agreement.—The demonstration project shall be conducted pursuant to a written agreement that—

(A) is submitted to the Secretary prior to implementation of the project; and

(B) includes a plan outlining how the project will achieve improvements in quality and efficiency.

(3) Patient Notification.—The demonstration project shall include a notification process to inform patients who are treated in a hospital participating in the project of the participation of the hospital in such project.

(4) Monitoring Quality and Efficiency of Care.—The demonstration project shall provide measures to ensure that the quality and efficiency of care provided to patients who are treated in a hospital participating in the demonstration project is continuously monitored to ensure that such quality and efficiency is maintained or improved.

(5) Independent Review.—The demonstration project shall certify, prior to implementation, that the elements of the demonstration project are reviewed by an organization that is not affiliated with the hospital or the physician participating in the project.

(6) Referral Limitations.—The demonstration project shall not be structured in such a manner as to reward any physician participating in the project on the basis of the volume of referrals to the hospital by the physician.

(c) Waiver of Certain Restrictions.—

(1) In General.—An incentive payment made by a hospital to a physician under and in accordance with a demonstration project shall not constitute—
“(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); or 

“(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) Solicitud de aplicaciones.—Por no later than 90 days after 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 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). 

“(f) 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, $1,500,000, to carry out this section. 

“(2) AVAILABILITY.—Funds appropriated under paragraph (1) shall remain available for expenditure through fiscal year 2014 or until expended. 

“(g) 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-
tation 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)(ii), the term ‘target amount’ means, with respect to a rural community hospital for a particular 12-month cost reporting period—

“(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 (1) 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 to 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 1886(d)(2)(D) of such Act (42 U.S.C. 1395ww(d)(2)(D)) or treated as being so located pursuant to section 1886(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.

“In determining which States to include in such expansion, the Secretary shall use the same criteria and data that the Secretary used to determine the States under such subsection for purposes of the initial 5-year period.

“(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.—

“(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 first day of the 5-year extension period, for

“Applicability of Chapter 35 of Title 44


Report on Extension of Applications Under Redistribution Program

Pub. L. 108–173, title IV, §422(c), Dec. 8, 2003, 117 Stat. 2286, provided that: “Not later than July 1, 2005, the Secretary [of Health and Human Services] shall submit to Congress a report containing recommendations regarding whether to extend the deadline for applications for an increase in resident limits under section 1886(h)(4)(I)(i)(II) of the Social Security Act [section 1886(h)(4) (subsec. (h)(4) of this section) does not contain a subpar. (I) as added by subsection (a)].”

MedPAC Study on Rural Hospital Payment Adjustments

“(a) IN GENERAL.—The Medicare Payment Advisory Commission shall conduct a study to determine the impact of sections 401 through 406, 411, 415, and 605 [amending this title and sections 1395f, 1395g, 1395i–4, 1395l, 1395m, and 1395p of this title] and enacting provisions set out as notes under this section and sections 1395f, 1395g, 1395i–4, 1395l, 1395m of this title]. The Comptroller General of the United States shall submit to Congress an interim report on total payments, growth in costs, capital spending, and such 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, 1395l, and 1395p of this title] and enacting provisions set out as notes under sections 1395f, 1395g, 1395i–4, and 1395m 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, using the most current data available, 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 legislatively 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 [this Act] 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 not 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 event 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 subsection (d) hospital as defined in section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)) that—

“(1) does not qualify for a change in wage index classification under paragraph (b) by virtue of section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)) that—

“does not apply 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)) for area differences in hospital wage levels that applies to such hospital under paragraph (3)(E) of such section.

“(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 109–332] [set out above], a hospital reclassified under this section shall not be taken into account for the purposes of reclassifying the other hospitals in such area from continuing such a group for such purpose.”
EXCEPTION TO INITIAL RESIDENCY PERIOD FOR GERIATRIC RESIDENCY OR FELLOWSHIP PROGRAMS


(a) CLARIFICATION OF CONGRESSIONAL INTENT.—Congress intended section 1886(h)(5)(F)(I) of the Social Security Act (42 U.S.C. 1395ww(h)(5)(F)(I)), 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)(5)(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 subclause (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) 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 303(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]) reaising and revising the hospital market basket index (as defined in section 1886(b)(3)(B)(ii)(V) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(ii)(V))), 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:
“(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.

Process 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. 1395ww–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 INDEPENDENT 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

Pub. L. 106–554, § 1(a)(6) [title III, § 304(c)(1)],[1] Dec. 21, 2000, 114 Stat. 2763, 2763A–99, provided that: “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: “By not later than September 30, 2003, for application beginning October 1, 2004, the Secretary shall first complete—

(A) the collection of data under paragraph (1) [set out above]; and

(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

Pub. L. 106–554, § 1(a)(6) [title III, § 306], Dec. 21, 2000, 114 Stat. 2763, 2763A–496, provided that: “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’.”

Expediting Recognition of New Technologies Into Inpatient PPS Coding System

Pub. L. 106–554, § 1(a)(6) [title V, § 533(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

Pub. L. 106–554, § 1(a)(6) [title V, § 533(b)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–549, provided that: “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 IME Payment For Fiscal Year 2000

Pub. L. 106–113, div. B, § 1100(a)(6) [title I, § 111(b)], Nov. 29, 1999, 113 Stat. 1356, 1351A–329, provided that: “(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 1.6 rather than 1.47. Additional payments made under this section shall be made applying the same structure as applies to payments made under section 1886(d)(5)(B) of such Act.”
“(2) No effect on other payments or determinations.—In making such additional payments, the Secretary shall not change payments, determinations, or billing, neutrality adjustments made for such period under section 1886(d) of such Act (42 U.S.C. 1395ww(d)),”.

DATA COLLECTION


“(1) In general.—The Secretary of Health and Human Services shall require any subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B))) to submit to the Secretary, in the cost reports submitted to the Secretary by such hospital for discharges occurring during a fiscal year, data on the costs incurred by the hospital for providing inpatient and outpatient hospital services for which the hospital is not compensated, including non-medicare bad debt, charity care, and charges for medical services provided in long-term care hospitals.

“(2) Effective date.—The Secretary shall require the submission of the data described in paragraph (1) in cost reports for cost reporting periods beginning on or after October 1, 2001.’’

PER DISCHARGE PROSPECTIVE PAYMENT SYSTEM FOR LONG-TERM CARE HOSPITALS


Pub. L. 106–554, §1(a)(6) [title III, §307(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–496, provided that:

“(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) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B)) under the medicare program under title XVIII of such Act [this subchapter] required under section 123 of BBRA [Pub. L. 106–113, §1000(a)(6) [title I, §123], set out as a note below], the Secretary of Health and Human Services shall examine the feasibility and the impact of basing payment under such a system on the use of existing (or refined) hospital diagnosis-related groups (DRGs) that have been modified to account for different resource use of long-term care hospital patients as well as the use of the most recently available hospital discharge data. The Secretary shall examine and may provide for appropriate adjustments to the long-term hospital payment system, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment consistent with section 1886(b)(5)(F) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(F)).

“(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 for such hospitals that bases payment under such a system using existing hospital diagnosis-related groups (DRGs), modified where feasible to account for resource use of long-term care hospital patients using the most recently available hospital discharge data for such services furnished after that date.”


“(a) Development of system.—

“(1) In general.—The Secretary of Health and Human Services shall develop a per discharge prospective payment system for payment for inpatient services of psychiatric hospitals and units (as defined in paragraph (1)) under the medicare program. Such system shall include an adequate patient classification system that is based on diagnosis-related groups (DRGs) and that reflects the differences in patient resource use and costs, and shall maintain budget neutrality.

“(b) Report.—Not later than October 1, 2001, the Secretary shall submit to the appropriate committees of Congress a report that includes a description of the system developed under subsection (a)(1).

“(c) Implementation of prospective payment system.—Notwithstanding section 1886(b)(3) of the Social Security Act (42 U.S.C. 1395ww(b)(3)), the Secretary shall provide, for cost reporting periods beginning on or after October 1, 2002, for payments for inpatient hospital services furnished by long-term care hospitals under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) in accordance with the system described in subsection (a).”

PER DISCHARGE PROSPECTIVE PAYMENT SYSTEM FOR PSYCHIATRIC HOSPITALS


“(a) Development of system.—

“(1) In general.—The Secretary of Health and Human Services shall develop a per discharge 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 among such hospitals and shall maintain budget neutrality.

“(2) Collection of data and evaluation.—In developing the system described in paragraph (1), the Secretary may require such psychiatric hospitals and units to submit such information to the Secretary as the Secretary may require to develop the system.

“(3) Definition.—In this section, the term ‘psychiatric hospitals and units’ means a psychiatric hospital or psychiatric hospital and units (as defined in section 1886(b)(3) of the Social Security Act (42 U.S.C. 1395ww(b)(3))) and psychiatric units described in the matter following clause (v) of such section.

“(b) Report.—Not later than October 1, 2001, the Secretary shall submit to the appropriate committees of Congress a report that includes a description of the system developed under subsection (a).

“(c) Implementation of prospective payment system.—Notwithstanding section 1886(b)(3) of the Social Security Act (42 U.S.C. 1395ww(b)(3)), the Secretary shall provide, for cost reporting periods beginning on or after October 1, 2002, for payments for inpatient hospital services furnished by psychiatric hospitals and units under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) in accordance with the prospective payment system established by the Secretary under this section in a budget neutral manner.”

STUDY ON IMPACT OF IMPLEMENTATION OF PROSPECTIVE PAYMENT SYSTEM


“(1) 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 the current laws and regulations for geographic reclassification of hospitals to determine whether such reclassification is appropriate for purposes of applying wage indices under the medicare program and whether such reclassification results in more accurate payments for all hospitals. Such study shall examine data on the number of hospitals that are reclassified and their reclassified status in determining payments under the medicare program. The study shall evaluate—

"(1) the magnitude of the effect of geographic reclassification on rural hospitals that are not reclassified;

"(2) whether the current thresholds used in geographic reclassification reclassify hospitals to the appropriate labor markets;

"(3) the effect of eliminating geographic reclassification through use of the occupational mix data;

"(4) the group reclassification policy;

"(5) changes in the number of reclassifications and the compositions of the groups;

"(6) the effect of State-specific budget neutrality compared to national budget neutrality; and

"(7) whether there are sufficient controls over the intermediary evaluation of the wage data reported by hospitals.

"(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 4202(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 1991 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 4203 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)(E)(i) of the Social Security Act (42 U.S.C. 1395ww(d)(10)(E)(i)) of a hospital described in 1886(d)(1)(D) of such Act (42 U.S.C. 1395ww(d)(1)(D)) 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 subclause (I) of section 1886(d)(10)(C)(i) of such Act to reclassification by reason of subsection (a) until the Secretary of Health and Human Services promulgates separate guidelines for such reclassifications.

"(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 calculated under 42 U.S.C. 1395ww(d)(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 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 aggregate allowable operating costs of inpatient hospital services (as defined in section 1886(a)(4) of such Act) for all such hospitals in such 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)(i))) 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)(3)(B) of such Act (42 U.S.C. 1395ww(d)(3)(B)) or a payment under section 1886(h) of such Act (42 U.S.C. 1395ww(h)) 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(b), (c) of Pub. L. 105–33 provided that:

"(b) REPORT ON NEW PAYMENT FORMULA.—

"(1) REPORT.—Not later than 1 year after the date of the enactment of this Act [Aug. 5, 1997], 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 contains a formula for determining additional payment amounts to hospitals under section 1886(d)(5)(F) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(F)).

"(2) FACTORS IN DETERMINATION OF FORMULA.—In determining such formula the Secretary shall—

"(A) establish a single threshold for costs incurred by hospitals in serving low-income patients, and

"(B) consider the costs described in paragraph (3)."

"(3) The costs described in this paragraph are as follows:

"(A) The costs incurred by the hospital during a period (as determined by the Secretary) of furnishing hospital services to individuals who are entitled to benefits under part A of title XVIII of the Social Security Act [part A of this subchapter] and who receive supplemental security income benefits under title XVI of such Act [subchapter XVI of this chapter] (excluding any supplementation of those benefits by a State under section 1615 of such Act (42 U.S.C. 1396a(c))).

"(B) The costs incurred by the hospital during a period (as so determined) of furnishing hospital services to individuals who receive medical assistance under the State plan under title XIX of such Act [subchapter XIX of this chapter] and are not entitled to benefits under part A of title XVIII of such Act (part A of this subchapter) (including individuals enrolled in a managed care organization (as defined in section 1903(m)(1)(A) of such Act (42 U.S.C. 1396b(m)(1)(A))) or any other managed care plan under such title and individuals who receive medical assistance under such title pursuant to a waiver approved by the Secretary under section 1115 of such Act (42 U.S.C. 1315)).

"(c) DATA COLLECTION.—In developing the formula described in subsection (b), the Secretary of Health and Human Services may require any subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(1)(B))) receiving additional payments by reason of section 1886(d)(5)(F) of such Act (42 U.S.C. 1395ww(d)(5)(F)) to submit to the Secretary any information that the Secretary determines is necessary to develop such formula.

GEOGRAPHIC RECLASSIFICATION FOR CERTAIN DISPROPORTIONATELY LARGE HOSPITALS

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 and use 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;

"(2) not less than 40 percent of the adjusted non-inflated wages paid by all hospitals located in such Area are attributable to wages paid by the hospital; and

"(3) 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 410 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 paragraph (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 1886(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 1998, 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 1998.

REPORT ON EFFECT OF AMENDMENTS BY PUB. L. 105–33, § 4415, ON PSYCHIATRIC HOSPITALS

Section 4415(d) of Pub. L. 105–33 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 1886(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 1886(d)(1)(B)(iv) of such Act (42 U.S.C. 1395ww(d)(1)(B)(iv)) 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, 2766A–252, provided that:

“(1) APPLICATION TO COST REPORTING PERIODS.—Any classification by reason of section 1886(d)(1)(B)(v)(III) of the Social Security Act [subsec. (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 1886(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 1886(d)(1)(B)(v)(III) of such Act (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 the enactment of this Act [Aug. 5, 1997].”

REPORT ON EXCEPTIONS

Section 4419(b) of Pub. L. 105–33 provided that: “The Secretary of Health and Human Services shall publish annually in the Federal Register a report describing the total amount of payments to hospitals by reason of section 1886(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. 105–33 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 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 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 1886(d) of the Social Security Act [subsec. (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 PHYSICANS’ SERVICES

Section 4506 of title IV of Pub. L. 105–33 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 1886(c)(2) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(G)) of such Act). The Secretary, acting through the hospital’s medical executive committee, may require such hospital to submit such information as may be necessary to determine such hospital-specific relative value.
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1395w–4(c)(2)(D) 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 project for a teaching hospital in a year shall be equal to the sum of—

“(A) the average per discharge relative value (as determined under subsection (a)) for physicians’ services furnished to inpatients of the hospital by interns and residents of the hospital during 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 based on the best available data and may make such adjustment in the aggregate.

“(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)(5) of the Social Security Act (42 U.S.C. 1395ww(d)(5)). The adjustment for teaching status or disproportionate share shall not be less than zero.

“(4) DEFINITIONS.—For purposes of this section:

“(1) HOSPITAL.—The term ‘hospital’ means a section 1886(d) of the Social Security Act (42 U.S.C. 1395ww(d)).

“(2) MEDICAL STAFF.—An individual furnishing a physician’s service is considered to be on the medical staff of a hospital—

“(A) if (in accordance with requirements for hospitals established by the Joint Commission on Accreditation of Health Organizations) 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,

“(B) subject to the bylaws, rules, and regulations, the individual has clinical privileges granted by the hospital’s governing body, and

“(C) under the clinical privileges, the individual may provide physicians’ services independently within the scope of the individual’s clinical privileges, or

“(D) 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(e)(3) of the Social Security Act (42 U.S.C. 1395ww(e)(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. 1395x(b)(6))."

INCENTIVE PAYMENTS UNDER PLANS FOR VOLUNTARY REDUCTION IN NUMBER OF RESIDENTS; RELATION TO DEMONSTRATION PROJECTS AND AUTHORITY; REGULATIONS

Section 4628(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 (subsec. (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 XVII 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 (subsec. (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 of each of the trust 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 4629 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 4830 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(b) 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.

DRG Prospective Payment Rate Methodology; Transition Rule for Fiscal Year 1998

Section 4644(a)(2) of Pub. L. 105–33 provided that:

‘‘With respect to the publication in the Federal Register of the DRG prospective payment rate methodology under such section for fiscal year 1998, the term ‘60 days’ in section 801(a)(3)(A) and section 802(a) of title 5, United States Code, is deemed to be a reference to ‘30 days’.’’

Hospital Payment Updates; Transition Rule for Fiscal Year 1998

Section 4644(b)(2) of Pub. L. 105–33 provided that:

‘‘With respect to the publication in the Federal Register of the appropriate change factor for inpatient hospital services for discharges in fiscal year 1998 under section 1886(e)(5)(B) (42 U.S.C. 1395ww(e)(5)(B)), the term ‘60 days’ in section 801(a)(3)(A) and section 802(a) of title 5, United States Code, is deemed to be a reference to ‘30 days’.’’

Geographical Reclassification; Special Rule for Applications Received in Fiscal Year 1997

Section 4644(c)(2) of Pub. L. 105–33 provided that:

‘‘In the case of an application for a change in geographic classification under such section [subsec. (d)(10)(C)(ii) of this section] for fiscal year 1999, the Secretary of Health and Human Services shall shorten the deadlines under such section so as to permit completion of a final decision by the Secretary by June 15, 1998.’’

No Standardized Amount Adjustments for Fiscal Years 1992 or 1993

Section 13501(b)(2) of Pub. L. 103–66 provided that:

‘‘The Secretary of Health and Human Services shall not revise the fiscal year 1992 or fiscal year 1993 standardized amounts pursuant to subsections (d)(8)(D) of section 1886 of the Social Security Act [subsec. (d)(3)(B) and (d)(8)(D) of this section] to account for the amendment made by paragraph (1) [amending this section].’’

Extension of Regional Referral Center Classifications Through Fiscal Year 1994; Reclassification

Section 13501(d) of Pub. L. 103–66 provided that:

‘‘(1) Extension of Classification Through Fiscal Year 1994.—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, 1992, shall continue to be so classified for cost reporting periods beginning during fiscal year 1992 or fiscal year 1994, unless the area in which the hospital is located is redesignated as a Metropolitan Statistical Area by the Office of Management and Budget for such a fiscal year.

‘‘(2) Permitting hospitals to decline reclassification.—If any hospital fails to qualify as a rural referral center under section 1886(d)(5)(C) of the Social Security Act 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 year 1993 or fis-
HOSPITALS LOSING CLASSIFICATION: RETROACTIVE PAYMENTS


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cal year 1994, the Secretary of Health and Human Services shall—

"(A) notify each hospital of such failure to qualify, and

"(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).

"(3) REQUIRING LUMP-SUM RETROACTIVE PAYMENT FOR HOSPITALS LOSING CLASSIFICATION.—

"(A) IN GENERAL.—In the case of a hospital described 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 aggregate payment made to the hospital under section 1886 of such Act (excluding outlier payments under subsection (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 enactment of this Act [Aug. 10, 1993].

HOSPITALS DECLINING URBAN AREA RECLASSIFICATIONS: RETROACTIVE PAYMENTS


"(A) The ‘base cost reporting period’ for a hospital is 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].

"(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 enactment of this Act [Aug. 10, 1993].

"(C) If the hospital 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

"(D) If the hospital fails to decline such reclassification, administer the Social Security Act without regard to paragraph (1).

"(3) REQUIRING LUMP-SUM RETROACTIVE PAYMENT.—

"(A) IN GENERAL.—In the case of a hospital treated as a medicare-dependent, small rural hospital under section 1886(d)(8)(D) of the Social Security Act, the Secretary of Health and Human Services shall make a lump-sum payment to the hospital equal to the difference between the aggregate payment made to the hospital under section 1886 of such Act (excluding outlier payments under subsection (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, section 1886(d)(5)(G) of such Act had been in effect.

"(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 enactment of this Act [Aug. 10, 1993].

"(1) IN GENERAL.—In determining the amount of payment to be made under section 1886(h) of the Social Security 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 Secretary of Health and Human Services shall redetermine the approved PTE resident amount to reflect the amount that would have been paid the hospital if, during the hospital’s base cost reporting period, the hospital had been liable for FICA taxes or for contributions 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 program.

"(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 medical 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 described in paragraph (1) with respect to such interns and residents because of the amendments made by section 11332(b) of OBRA–1990 [Pub. L. 101–508, amending section 412 of Title 26, 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 during fiscal year 1993.

"(B) The term ‘FICA taxes’ means, with respect to a hospital, the taxes under section 3111 of the Internal Revenue Code of 1986 [26 U.S.C. 3111].

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 discharges occurring on or after January 1, 1991, and before 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 described in subparagraph (A) without regard to a previous survey of wages and wage-related costs.

STUDY AND REPORT ON RELATIONSHIP BETWEEN NON-WAGE-RELATED INPUT PRICES AND ADJUSTED AVERAGE 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-related portion of the adjusted average standardized amounts established under subsec. (d)(3) of this section that 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 recommendations regarding a methodology for adjusting such average standardized amounts to reflect such variations.

DEADLINE FOR SUBMISSION OF APPLICATIONS TO GEOGRAPHIC CLASSIFICATION REVIEW BOARD

Section 4002(b)(2)(A) of Pub. L. 101–508 provided that:

"For purposes of determining whether a hospital requesting a change in 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 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]."
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 any 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 4139 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(h)(2) (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 that are attributable to the clinical training costs of the approved program, and allowable under (b)(1) during the cost reporting period does not exceed the proportion of total allowable costs that were attributable to the clinical training costs during the cost reporting period described in subparagraph (A);

(3) the hospital receives a benefit for the support it furnishes to such program through the provision of clinical services by nursing or allied health students participating in such program; and

(4) 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.

(5) 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 to such hospital under such title due to a determination that costs which were reported by the hospital under such title a determination that costs which were reported by the hospital under such title which were attributable to the clinical training costs during the most recent 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 of the approved program, and allowable under (b)(1) during the cost reporting period does exceed the proportion of total allowable costs that were attributable to clinical training costs during the cost reporting period described in subparagraph (A).

(2) the proportion of the hospital's total allowable costs that is attributable to the clinical training costs of the approved program, and allowable under (b)(1) during the cost reporting period does exceed the proportion of total allowable costs that were attributable to clinical training costs during the cost reporting period described in subparagraph (A).

(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 to such hospital under such title due to a determination that costs which were reported by the hospital under such title which were attributable to the clinical training costs during the most recent 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 of the approved program, and allowable under (b)(1) during the cost reporting period does exceed the proportion of total allowable costs that were attributable to clinical training costs during the cost reporting period described in subparagraph (A).
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]).

(b) RETURN 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 E of title XVIII of the Social Security Act) to 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(e)(2)(B) of the Social Security Act [subsec. (d)(1)(B) of this section]) receive payment for the operating and capital-related costs of inpatient hospital 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 1899(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 [section 1395f(i)(2)(E) of this title] shall be deemed to be 0.

(4) The percentage change in the consumer price index applicable under section 1886(b)(2)(D) of such Act shall be deemed to be 0.

(2) 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(b) 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 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, §150(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
XVIII of the Social Security Act (this subchapter) in a fiscal year (beginning with fiscal year 1991 and ending with fiscal year 1993, or, if later, the last fiscal year for which the Secretary is required to determine the amount specified under section 601(a)(1) of the Congressional Budget and Impoundment Control Act of 1974 [2 U.S.C. 665(a)(1)]) of more than $50,000,000, except as follows: 

"(A) The Secretary may issue such a proposed regulation, instruction, or other policy with respect to the fiscal year preceding the May 15 preceding the beginning of the fiscal year. 

"(B) The Secretary may issue such a final regulation, instruction, or other policy with respect to the fiscal year on or after October 15 of the fiscal year. 

"(C) The Secretary may, at any time, issue such a proposed or final regulation, instruction, or other policy with respect to the fiscal year if required to implement specific provisions under statute."

**Prohibition of Payment Cycle Changes**


"Notwithstanding any other provision of law, the Secretary of Health and Human Services is not authorized to issue, after the date of the enactment of this Act [Nov. 5, 1990], any final regulation, instruction, or other policy change which is principally intended to have the effect of slowing down or speeding up claims processing, or delaying payment of claims, under title XVIII of the Social Security Act [this subchapter]."

**Extension of Area Wage Index**

Section 115(a) of Pub. L. 101–403 provided that: 

"For purposes of determining the amount of payment made to a hospital under part A of title XVIII of the Social Security Act [part A of this subchapter] for the operating costs of inpatient hospital services for discharges occurring on or after October 1, 1990, and on or before October 20, 1990, the Secretary of Health and Human Services, in adjusting such amount under section 1886(d)(3)(E) of such Act [subsec. (d)(3)(E) of this section] to reflect the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage index, shall apply the area wage index applicable to such hospital as of September 30, 1990."

**Adjustments Resulting from Extensions of Regional Floor on Standardized Amounts**

Section 115(b)(2) of Pub. L. 101–403 provided that: 

"The Secretary of Health and Human Services shall make any adjustments resulting from the amendment made by paragraph (1) [amending this section] in the amount of the payments made to hospitals under section 1886(d)(4) of the Social Security Act [subsec. (d)(4) of this section] in a fiscal year for the operating costs of inpatient hospital services in a manner that ensures that the aggregate payments under such section are not greater or less than those that would have been made in the year without such adjustments."

**Indexing of Future Applicable Percentage Increases**

Section 6003(a)(3) of Pub. L. 101–239 provided that: 

"For discharges occurring on or after October 1, 1990, the applicable percentage increase (described in section 1886(b)(3)(B) of the Social Security Act [subsec. (b)(3)(B) of this section]) for discharges occurring during fiscal year 1990 is deemed to have been such percentage increase as amended by paragraph (1)."

**Continuation of Sole Community Hospital Designation for Current Sole Community Hospitals**

Section 6003(c)(3) of Pub. L. 101–239 provided that: 

"Any hospital classified as a sole community hospital under section 1886(d)(5)(C)(ii) of the Social Security Act [subsec. (d)(5)(C)(ii) of this section] on the date of the enactment of this Act [Dec. 19, 1989] that will no longer 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 Erroneously 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— 

"(i) the error resulted from the submission of erroneous data, except 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 6011(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]."

**Publication of Instructions Relating to Exceptions and Adjustments in Target Amounts**

Section 6015(b) of Pub. L. 101–239 provided that: 

"By not later than 180 days after the date of enactment of
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)(4)(A) of the Social Security Act [subsec. (b)(4)(A) of this section]."

DELABY IN RECUPIMENT OF CERTAIN NURSING AND ALLIED EDUCATION COSTS

Section 626(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 payment amounts provided under subsec. (a)(4) of this section for inpatient hospital services to account for inpatient 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]."

ELECTION OF PERSONNEL POLICY FOR PROPA C EMPLOYEES

Section 8405 of Pub. L. 100–647 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 personnel policy under the last sentence of section 1886(e)(6)(D) of the Social Security Act [subsec. (e)(6)(D) of this section]."

ADJUSTMENTS IN PAYMENTS FOR INPATIENT HOSPITAL SERVICES


"(1) PPS HOSPITALS.—In adjusting DRG prospective payment rates under section 1886(a) of the Social Security Act [subsec. (d) of this section], outlier cutoff points under section 1886(d)(5)(A) of such Act, and weighting factors under section 1886(d)(4) of such Act for discharges occurring on or after October 1, 1989, and before January 1, 1990, the Secretary of Health and Human Services shall, to the extent appropriate, take into consideration the reductions in payments to hospitals by (or on behalf of) 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))."

"(2) PPS-EXEMPT HOSPITALS.—In adjusting target amounts under section 1886(b)(3) of the Social Security Act [subsec. (b)(3) of this section for purposes of cost reporting periods occurring on or after January 1, 1989, and before January 1, 1990, the Secretary shall, on a hospital-specific basis, take into consideration the reductions in payments to hospitals by (or on behalf of) 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)), without regard to whether such a hospital is paid on the basis described in subparagraph (A) or (B) of section 1886(b)(1) of such Act, and weighting factors under section 1886(d)(4) of such Act for discharges occurring on or after December 22, 1987, and before January 1, 1990, to reflect the effects of the amendments made by section 101 of Pub. L. 100–360, set out above, by section 101(c)(1), (2)(A) of Pub. L. 101–234 effective as if included in enactment of Pub. L. 100–360, see section 101(d) of Pub. L. 101–234, set out as a note under section 1395e of this title]."

PROPA C 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 target amounts for inpatient hospital services provided for inpatient hospital services to account for reduced costs to hospitals resulting from amendments made by section 203 of Pub. L. 100–360, amending sections 1320c–3, 1395b, 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 400(b) of Pub. L. 100–203 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 1395y 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: ‘‘The Secretary of Health and Human Services shall take appropriate steps to ensure that the total amount paid in a fiscal year under title XVIII of the Social Security Act (this Act) by reason of the amendment made by paragraph (1)(B) [amending this section] does not exceed $5,000,000 in the case of fiscal year 1988 and $10,000,000 for fiscal year 1989.’’

**Study of Criteria for Classification of Hospitals as Rural Referral Centers; Report**

Section 4005(d)(2) of Pub. L. 100–203 directed Secretary of Health and Human Services to provide for a study of the criteria used for the classification of hospitals as rural referral centers, and report to Congress, by not later than Mar. 1, 1989, on the study and on recommendations for the criteria that should be applied for the classification of hospitals as rural referral centers for cost reporting periods beginning on or after Oct. 1, 1989.

**Grant Program for Rural Health Care Transition**

Section 4005(e) of Pub. L. 100–203, as amended by Pub. L. 101–229, title VI, §6003(b)(1)(B)(i), Dec. 19, 1989, 103 Stat. 2150; Pub. L. 103–432, title I, §103(a)(1), (b), (c), Oct. 31, 1994, 108 Stat. 4404, 4405, provided that: ‘‘(1) The Administrator of the Health Care Financing Administration, in consultation with the Assistant Secretary for Health (or a designee), shall establish a program of grants to assist eligible small rural hospitals and their communities in the planning and implementation of projects to modify the type and extent of services such hospitals provide 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 1866(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;  

‘‘(C) the extent to which the proposal of the hospital, using appropriate data, demonstrates an understanding of—  

‘‘(i) the primary market or service area of the hospital, and  

‘‘(ii) the health care needs of the elderly and disabled that are not currently being met by providers in such market or area; and  

‘‘(D) 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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debt incurred with respect to any capital expenditure made prior to the date on which the project is initiated.

(C) Not more than one-third of any grant made under this subsection may be expended for capital-related costs (as defined by the Secretary for purposes of section 1866(a)(4) of the Social Security Act (subsec. (a)(4) of this section or this project, except that this limitation shall not apply with respect to a grant used for the purposes described in subparagraph (D))

A hospital may use a grant received under this subsection to develop a plan for converting itself to a rural primary care hospital (as defined in section 1820(a)(1) of the Social Security Act [section 1395i–4 of this title]) or to 3820(a)(1).

(D) A hospital receiving a grant under this section [amending this section and section 1395ttt 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. In preparing the report, the Secretary shall solicit and include the comments and recommendations of private and public entities with an interest in rural health care.

(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 the fiscal years 1990, 1991, and 1992 and $30,000,000 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. 105–7 in which item 6 on page 6 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 11, Money and Finance.]

[Section 108(a)(2) of Pub. L. 103–432 provided that: “The amendments made by paragraph (1) [amending section 4005(e)(2) of Pub. L. 100–203, set out above] shall apply to grants made on or after October 1, 1994.”]

[Pub. L. 103–432, §108(c), which directed amendment of section 4005(e)(8)(B) of Pub. L. 100–203, was executed by amending section 4005(e)(8)(B) of Pub. L. 100–203, set out above, to reflect the probable intent of Congress.]

[Section 6003(g)(1)(B)(ii) of Pub. L. 101–239 provided that: “The amendments made by clause (i) [amending section 4006(e) of Pub. L. 100–203, set out above] shall apply with respect to applications for grants under the Rural Health Care Transition Grant Program described in section 4005(e) of the Omnibus Budget Reconciliation Act of 1987 [Pub. L. 100–203] submitted on or after October 1, 1989, except that the amendments made by subclauses (V) and (VII) of such clause shall take effect on the date of the enactment of this Act [Dec. 19, 1989].”]

REPORTING HOSPITAL INFORMATION


(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 not later than June 1, 1989, a data base of the operating costs of inpatient hospital services with respect to all hospitals under title XVIII of the Social Security Act

(32 U.S.C. 1395 et seq.), which data base shall be updated at least once every quarter (and maintained for the 12-month period preceding any such update). The data base under this subsection may include data from preliminary cost reports (but the Secretary shall make available an updated analysis of the differences between preliminary and settled cost reports).

(b) [Amended subsec. (f) of this section and enacted provisions set out as an Effective Date of 1987 Amendment note above.]

(c) DEMONSTRATION PROJECT.—

“1) The Secretary of Health and Human Services shall provide for a demonstration project to develop, and determine the costs and benefits of establishing 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 submit to the Congress not later than 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.

“1) 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 programs 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 $5,000,000 for fiscal years 1988, 1989, and 1990 from existing research funds or from operations funds to develop the format, according to paragraph (1) and for data collection and analysis, but total funds shall not exceed $5,000,000.

“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-
ing under the demonstration system and will recommend improvements in hospital data collection and in analysis and display of data in support of policy-making.

"(d) Consultation.—The Secretary shall consult representatives of the hospital industry in carrying out the provisions of this section.

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)(ii) of the Social Security Act [subsec. (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 [subsec. (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 outlier 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 1395ll(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 [subsec. (d)(5)(B) of this section] and additional payments under section 1886(d)(5)(A) of such act.

Propac studies and reports

Section 4009(h) of Pub. L. 100–203 provided that:

"(1) propac reports on study of DRO 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 685(a)(2)(C)(i) of the Social Security Amendments of 1983 [section 685(a)(2)(C)(i) of Pub. L. 98–21, 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 [subsec. (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 [subsec. (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(i) 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 [subsec. (d)(2)(D) of this section], as amended by section 603(b) of this subtitle, as though 979,000 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.—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 2,700 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 counties 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 the project only) by an amount equal to the amount of any direct graduate medical education costs (as defined in paragraph (5) of such subsection)
(h) incurred by such hospital in supervising the education and training activities under a project under subsection (a).

DEFINITION OF PROJECT.—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 (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 (subsec. (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

Pub. L. 100–119, title I, §107(a)(1), Sept. 29, 1987, 101 Stat. 783, as amended by Pub. L. 100–203, title IV, §4039(e)(2), Dec. 22, 1987, 101 Stat. 1330–45, provided that: ‘‘(1) TEMPORARY FREEZE IN FPS HOSPITAL RATES.—For purposes of subsection (d) of such section for discharges occurring during the period beginning on Oct. 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 BASES.—

(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—

(1) during the extension period is the rate specified in subsection (d)(1)(D)(i) of such section, or

(2) 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 (i) (rather than clause (ii)) 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)(iv) of such section, and the applicable percentage increase in a hospital’s target amount shall be deemed to be 0 percent.

(2) TEMPORARY FREEZE IN AMOUNTS OF PAYMENT FOR CAPITAL.—For payments attributable to portions of cost reporting periods occurring during the extension period, the percent specified in subsection (g)(3)(A)(i) of such section is deemed to be 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 IN PAYMENTS RATES FOR FPS-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.

(FREEZE CERTAIN CHANGES IN MEDICARE PAYMENT REGULATIONS AND POLICIES

Pub. L. 100–119, title I, §107(b), Sept. 29, 1987, 101 Stat. 783, provided that: ‘‘(1) IN GENERAL.—Notwithstanding any other provision of law, the Secretary of Health and Human Services is not authorized to issue after September 18, 1987, and before November 21, 1987—

(A) any final regulation that changes the policy with respect to payment under title XVIII of the Social Security Act [this subchapter] to providers of service for reasonable costs relating to unrecovered costs associated with unpaid deductible and coinsurance amounts incurred under such title;

(B) any final regulation, instruction, or other policy change which is primarily intended to have the effect of slowing down claims processing, or delaying payment of claims, under such title; or

(C) any final regulation that changes the policy under such title with respect to payment for a return on equity capital for outpatient hospital services.

The final regulation of the Health Care Financing Administration published on September 1, 1987 (52 Federal Register 32920) and relating to changes to the return on equity capital provisions for outpatient hospital services is void and of no effect.

(2) OTHER COST SAVINGS POLICIES.—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 September 18, 1987, and before November 21, 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 in fiscal year 1988 of more than $50,000,000. Any regulation, instruction, or policy which is issued in violation of this paragraph is void and of no effect.

 Maintaining Current outlier policy in fiscal year 1987
 Section 3902(b)(3) of Pub. L. 99–509 provided that: ‘‘For payments made under section 1886(d) of the Social Security Act [subsection (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. 101–239 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 9302(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, 1986, and before October 1, 1989.

Section 9302(d)(2) of Pub. L. 99–509 provided that: "Any hospital that is classified as a regional referral center under section 1886(d)(5)(C)(i) of the Social Security Act [subsec. (d)(5)(C)(i) of this section] on the date of the enactment of this Act [Oct. 21, 1986] shall continue to be classified as a regional referral center for cost reporting periods beginning on or after October 1, 1986, and before October 1, 1989.

**BUDGET-NEUTRAL IMPLEMENTATION**

Section 9302(d)(3) of Pub. L. 99–509 provided that: "Paragaph (2) [set out as a note above] and the amendment made by paragraph (1)(A) [amending this section] shall be implemented in a manner that ensures that total payments under section 1886 of the Social Security Act [this section] are not increased or decreased by reason of the classifications required by such paragraph or amendment." 

**PROMULGATION OF NEW RATE**

Section 9302(f) of Pub. L. 99–509 provided that: "The Secretary of Health and Human Services shall provide, within 30 days after the date of the enactment of this Act [Oct. 21, 1986], for the publication of the payment rates that will apply under section 1886 of the Social Security Act [this section], for discharges occurring on or after October 1, 1986, taking into account the amendments made by this section [amending this section], without regard to the provisions of chapter 5 of title 5, United States Code.

**MISCELLANEOUS ACCOUNTING PROVISION**


(1) had a cost reporting period beginning on September 28, 29, or 30 of 1985;

(2) is located in a State in which inpatient hospital services were paid in fiscal year 1985 pursuant to a statewide demonstration project under section 402 of the Social Security Amendments of 1987 [section 402 of Pub. L. 90–248, enacting section 1395x(v)(1)(O) of this title and section 1395x(v)(1)(O) of this title], in order to more accurately reflect hospital labor markets, by taking into account the methodologies for computing the wage indices used for purposes of sections 1886(d)(2)(C)(ii), 1886(d)(2)(H), and 1886(d)(3)(E) of the Social Security Act [subsec. (d)(3)(E) of this section], in order to more accurately reflect hospital labor markets, by taking into account variations in wages and wage-related costs between the urban and nonurban areas.

(3) elects, by notice to the Secretary of Health and Human Services by not later than April 1, 1988, to have this subsection apply during the first 7 months of such cost reporting period the 'target percentage' shall be 75 percent and the 'DRG percentage' shall be 25 percent, and during the remaining 5 months of such period the 'target percentage' and the 'DRG percentage' shall each be 50 percent."

Section 4008(e) of Pub. L. 100–336 provided that the amendment of section 9307(d) of Pub. L. 99–509, set out above, by section 4008(e) of Pub. L. 100–303 is effective as if included in the enactment of Pub. L. 99–509.

**TREATMENT OF CAPITAL-RELATED REGULATIONS**


"(1) Prohibition of issuance of final regulations on capital-related costs as part of payment for operating costs before November 21, 1987.—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, 1987, any regulation that changes the methodology for computing the amount of payment for capital-related costs (as defined in 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 regulations 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)(d) 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(v)(j)(O) and 1886(g)(3)(C) of the Social Security Act [section 1395x(v)(j)(O) of this title and subsec. (g)(2) of this section] and section 1886(g)(3)(A) and (B) of the Social Security Act [subsec. (g)(3)(A) and (B) of this section] (as amended by section 2003(a) of this 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(d) 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 of Health and Human Services, in consultation with the Prospective Payment Assessment Commission, shall collect information and shall develop one or more methodologies to permit the adjustment of the wage indices used for purposes of sections 1886(d)(2)(C)(ii), 1886(d)(2)(H), and 1886(d)(3)(E) of the Social Security Act [subsec. (d)(2)(C)(ii), (H), and (3)(E) of this section], in order to more accurately reflect hospital labor markets, by taking into account variations in wages and wage-related costs between the central city portion of urban areas and other parts of urban areas.

(2) 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 has 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 1395–1 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 1395b–1 of this title], shall be deemed to meet the requirements of section 1395b–1 of the Social Security Act [subsec. (c)(1)(A) of this section] to the extent that such system—

(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 1395b–1 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, and the Congressional Research Service the most current information on the payments being made under section 1395bb of the Social Security Act [this section] to individual hospitals. Such information shall be made available in a manner that permits examination of the impact of such section on hospitals.

“(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 IV, 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 I of title XXIX of this title and this chapter), nor 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; ESTABLISHMENT OF 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

number of students supported or trained under each program;

(B) the fiscal and administrative relationships between the hospitals involved and the schools with which the programs and students are affiliated; and

(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 Committee 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 1395b–1 of the Social Security Act [subsec. (c)(1)(A) 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 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.

“(2) 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 2307(c) of the Medicare Amendments Act of 1984 [section 2307(c) of Pub. L. 98–380, set out as a note under section 1395u of this title].

STUDIES TO EXPAND ACCESS TO MEDICARE SERVICES

Section 1395ww of this title provided that:

“(b) INFORMATION ON NECESSITY AND EFFECT OF MEDICARE SERVICES.—(1) 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 (subpart A (§ 9101–9115) of part I of title XXIX of this title and this chapter), 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 TO EXPAND ACCESS TO MEDICARE SERVICES

Section 1395ww of this title provided that:

“(b) INFORMATION ON NECESSITY AND EFFECT OF MEDICARE SERVICES.—(1) 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 (subpart A (§ 9101–9115) of part I of title XXIX of this title and this chapter), 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.”
“(3) The Comptroller General shall report the results of the study to the committees described in subsection (c)(1) prior to December 31, 1987.

“(4) 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 the section 1886(h) 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;

“(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.


“(b) 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 this section and section 1395x of this title and enacting notes set out under this section and section 1395x of this title].

SPECIAL TREATMENT OF STATES FORMERLY UNDER WAIVER


“(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 State.—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) Making 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) Making 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 for a discharge occurring on (or the cost reporting period beginning immediately on or before) September 30, 1985.

“(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.

(Amendment of section 5 of Pub. L. 99–107, set out above, by section 9101(a) of Pub. L. 99–272 effective Mar. 15, 1986, see section 9101(d) of Pub. L. 99–272, set out above.)

DEFINITION OF HOSPITAL SERVING SIGNIFICANTLY DISPROPORTIONATE NUMBER OF LOW-INCOME PATIENTS OR PATIENTS ENTITLED TO HOSPITAL INSURANCE 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) 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 State.—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.’’
"(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


“(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, 1986], 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, 1986, to reflect the changes 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 601(a)(3) of Pub. L. 97–248, as amended by Pub. L. 99–272, title IX, §1303(a)(1), Apr. 7, 1986, 100 Stat. 156, 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 distinguished 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 HOSPITAL SERVICE CAPITAL-RELATED COSTS

Section 603(a) of title VI of Pub. L. 98–21, as amended by Pub. L. 98–369, div. B, title III, §2317, July 18, 1984, 98 Stat. 1981; Pub. L. 99–509, title IX, §9305(h)(1), Oct. 21, 1986, 100 Stat. 1993; Pub. L. 102–55, 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. 2498, 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 1068c of this title]."

§1395xx. Payment of provider-based physicians and payment under certain percentage arrangements

(a) Criteria; amount of payments

(1) The Secretary shall by regulation determine criteria for distinguishing those services (including inpatient and outpatient services) rendered in hospitals or skilled nursing facilities—

(A) which constitute professional medical services, which are personally rendered for an individual patient by a physician and which contribute to the diagnosis or treatment of an individual patient, and which may be reimbursed as physicians’ services under part B, and

(B) which constitute professional services which are rendered for the general benefit to patients in a hospital or skilled nursing facility and which may be reimbursed only on a reasonable cost basis or on the bases described in section 1395ww of this title.

(2)(A) For purposes of cost reimbursement, the Secretary shall recognize as a reasonable cost of a hospital or skilled nursing facility only that portion of the costs attributable to services rendered by a physician in such hospital or facility which are services described in paragraph (1)(B), apportioned on the basis of the amount of time actually spent by such physician rendering such services.
(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 the 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 1604(a)(1) of Pub. L. 98–21, set out as a note under section 1395ww of this title.

§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, 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 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) The Secretary may, with respect to any skilled nursing facility, 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, 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.

(3) For purposes of this section, 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

(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).
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” means—

(1) 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

(2) 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 1998, the transportation costs of electrocardiogram equipment for electrocardiogram test services (HCPCS Code R0076). 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; 36480; 36530–36535; 36640; 36823; and 96405–96442 (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; L5613–L5986; L5988; 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—

(1) rural health clinic services (as defined in paragraph (1) of section 1395x(aa) of this title); and

(2) 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)(1)(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)(1)(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 the 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 nurs-
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(5) 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.

(6) Submission of resident assessment data

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 subparagraph (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.

(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 for variations in labor-related costs under paragraph (4)(G)(ii), and adjustments for variations in labor-related costs under paragraph (4)(G)(iii);

(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 1395i–1(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-
ment 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 1395l of this title (rather than from the Federal Supplementary Medical Insurance Trust Fund under section 1395f of this title).

(10) Required coding
No payment may be made under part B of this subchapter for items and services (other than services described in paragraph (2)(A)(ii)) furnished to an individual who is a resident of a skilled nursing facility or of a part of a facility that includes a skilled nursing facility (as determined under regulations), unless the claim for such payment includes a code (or codes) under a uniform coding system specified by the Secretary that identifies the items or services furnished.

(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)(4) 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 1395j 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, §313(a)(2)], added existing provisions as cl. (i), inserted heading, substituted “Subject to clause (ii)”, the term “for “The term”, and added cl. (ii).

Subsec. (f). Pub. L. 110–148, §401(b), substituted “furnished during such period” for “furnished during such period beginning on or after October 1, 1992” after “to non-settled cost reports.”


2005—Subsec. (e)(2)(A)(i). Pub. L. 108–173, §410(a)(1), substituted “clauses (ii), (iii), and (iv)” for “clauses (ii) and (iii)”.


Subsec. (e)(12). Pub. L. 108–173, §511(a), amended heading and text of par. (12) generally, substituting provisions relating to upward adjustment of per diem payment for residents of a skilled nursing facility with AIDS for provisions relating to per diem payment for certain qualified acute skilled nursing facilities.


Subsec. (e)(4)(E)(ii). Pub. L. 100–554, §1(a)(6) [title I, §313(a)(1), (2)], redesignated subcl. (II) as (III) and substituted “each of fiscal years 2002 and 2003” for “each of fiscal years 2001 and 2002” and “minus 0.5 percentage point” for “minus 1 percentage point”. Former subcl. (III) redesignated (IV).

Subsec. (e)(4)(E)(iii). Pub. L. 100–554, §1(a)(6) [title I, §313(a)(1), redesignated subcl. (III) as (IV)].

Subsec. (e)(4)(E)(iv). Pub. L. 100–554, §1(a)(6) [title I, §313(a)(1), redesignated subcl. (IV) as (V)].

2007—Subsec. (a). Pub. L. 105–33, §4431, added “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.

Subsec. (d)(1). Pub. L. 105–33, §1432(b)(8)(H), substituted “Subject to subsection (e) of this section, any skilled nursing facility” for “Any skilled nursing facility”.


Subsec. (e)(9), (10). Pub. L. 105–33, §4432(b)(3), added pars. (9) and (10).


Subsec. (f). Pub. L. 103–66, §13503(a)(3), inserted “Secretary may not recognize” for “Secretary shall recognize” and a period for “as determined by the Secretary”.

1990—Subsec. (a). Pub. L. 101–508, §4008(e)(2), struck out period at end and inserted “, 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”.

Subsec. (d)(1). Pub. L. 101–508, §4008(h)(2)(A)(i), substituted “(including the costs of services required to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each patient eligible for benefits under this subchapter) and capital-related costs” for “(and capital-related costs)”. 
Amendment by section 1000(a)(6) [title III, § 321(m)] of Pub. L. 106–113, set out as a note under section 1395d of this title.

The enactment of the Balanced Budget Act of 1997, Pub. L. 105–33 effective for cost reporting periods beginning on or after July 1, 1996, except that amendment by section 4432(b) applicable to items and services furnished on or after July 1, 1996, see section 4432(d) of Pub. L. 105–33, set out as a note under section 1395i–3 of this title.

Amendment by section 451(e) of Pub. L. 105–33 applicable with respect to services furnished and supplies provided on and after Jan. 1, 1998, see section 451(e) of Pub. L. 105–33, set out as a note under section 1395l of this title.

Effective Date of 1995 Amendment
Amendment by Pub. L. 105–33 effective for cost reporting periods beginning on or after July 1, 1996, see section 1395l of this title.

Effective Date of 2000 Amendment
Amendment by section 1(a)(6) [title II, § 203(a)] of Pub. L. 106–554 applicable to services furnished on or after Jan. 1, 2000, see section 1395aa of this title.

Effective Date of 1999 Amendment
Amendment by section 1000(a)(6) [title III, § 321(g)(1), Pub. L. 106–113, div. B, § 1000(a)(6) [title I, § 104(b)], Pub. L. 106–229, effective as if included in the enactment of this Act [Apr. 7, 1999].”

Effective Date of 1997 Amendment
Amendment by section 4432(a), (b)(3), (5)(H) of Pub. L. 105–33 effective for cost reporting periods beginning on or after July 1, 1996, except that amendment by section 4432(b) applicable to items and services furnished on or after July 1, 1996, see section 4432(d) of Pub. L. 105–33, set out as a note under section 1395i–3 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) [amending this section] shall apply to cost reporting periods beginning on or after Oct. 1, 1992.”

Effective Date of 1990 Amendment
Section 400(e)(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 of the Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101–239].”

Effective Date of 1987 Amendment

Effective Date of 1986 Amendments
Section 1395l(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 Oct. 1, 1986.”


Effective Date of 1995 Amendment
Section 2319(c) of Pub. L. 98–369 provided that: “The amendments made by subsections (a) and (b) [amending this section] become effective on the date of the enactment of this Act [Apr. 7, 1986].”

Effective Date of 1997 Amendment
Amendment by section 4432(a), (b)(3), (5)(H) of Pub. L. 105–33 effective for cost reporting periods beginning on or after July 1, 1996, except that amendment by section 4432(b) applicable to items and services furnished on or after July 1, 1996, see section 4432(d) of Pub. L. 105–33, set out as a note under section 1395l–3 of this title.

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 specifically provided in section 1395i–3 of this title, see section 4294(a) of Pub. L. 100–203, as amended, set out as an Effective Date note under section 1395l–3 of this title.

Effective Date of 1986 Amendments
Section 1395l(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 Oct. 1, 1986.”


Effective Date of 1986 Amendment

(2) The amendment made by subsection (b) [amending this section] shall be effective as if included in 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 1395x 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
in a representative sample of Medicare skilled nursing facilities, and shall include an analysis (by specific RUG classification) of the number and characteristics of such facilities.''

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: "(1) STUDY.—The Secretary of Health and Human Services shall conduct a study of the different systems in use to assess 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 study 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


(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 RATES

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, §§1311–1315, 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 1389u of this title] on increased nursing staff 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: "(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 immuno-compromised secondary to an infectious disease, with specific diagnoses as specified by the Secretary (under paragraph (12)(C), as added by subsection (a), of section 1888(e) of the Social Security Act (42 U.S.C. 1395yy(e))), 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 1395i–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 non-routine 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. 4465, provided that: "Not later than 1 year after the date 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 13503(a)(1) of Pub. L. 103–66 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 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 13503(b) of Pub. L. 103–66 provided that: "The Secretary of Health and Human Services may not change the amount of any prospective payment paid 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 amendment made by subsection (c)(1)(A) [amending section 1385x of this title]."

Prospective Payment System for Skilled Nursing Facility Services

Section 4008(k) 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) 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) 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) 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(c)(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 1395ddd 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 insofar as 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 1385ddd(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 subsecs. (b) and (c).


Subsecs. (e) to (g). Pub. L. 108–173, § 921(f)(1), added subsecs. (e) to (g).

Effective Date of 2003 Amendment


Effect Date


Small Provider Technical Assistance

Demonstration Program


"(a) Establishment.—

"(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 subchapter) (including provisions of title XI of such Act [subchapter XI of this chapter]) 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—
“(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).

(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-
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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; and

(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

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—

(a) such measures that have been endorsed by the entity; and

(b) 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(1)(5)(D), 1395f(1)(7), 1395f(t)(17), 1395f–4(k)(2)(C), 1395cc(k)(3), 1395rr(h)(2)(A)(iii), 1395ww(b)(3)(B)(viii), 1395ww(j)(7)(D), 1395ww(m)(5)(D), 1395ww(o)(2), 1395ww(s)(4)(D), and 1395ff(b)(3)(B)(v) of this title;

(II) such measures that have not been considered for endorsement by the entity; and

(iii) the implementation of quality and efficiency measures described in this subchapter 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.

(§ 1395aaa–1)

References in Text

Section 12(d) of the National Technology Transfer and Advancement Act of 1995, referred to in subsec. (c)(5), is section 12(d) of Pub. L. 104–113, which is set out as a note under section 272 of Title 15, Commerce and Trade.

Codification


Prior Provisions


Amendments


Subsec. (b)(7)(B). Pub. L. 111–148, § 10304, which directed substitution of “quality and efficiency” for “quality” wherever appearing, was executed by substituting “Quality and efficiency” for “Quality” in subpar. heading to reflect the probable intent of Congress.


§ 1395aaa–1. Quality and efficiency measurement

(a) Multi-stakeholder group input into selection of quality and efficiency measures

The Secretary shall establish a pre-rule-making process under which the following steps occur with respect to the selection of quality and efficiency measures described in section 1395aaa(b)(7)(B) of this title:

(1) Input

Pursuant to section 1395aaa(b)(7) of this title, the entity with a contract under section 1395aaa of this title shall convene multi-stakeholder groups to provide input to the Secretary on the selection of quality and efficiency measures described in subparagraph (B) of such paragraph.

(2) Public availability of measures considered for selection

Not later than December 1 of each year (beginning with 2011), the Secretary shall make available to the public a list of quality and efficiency measures described in section 1395aaa(b)(7)(B) of this title that the Secretary is considering under this subchapter.

(3) Transmission of multi-stakeholder input

Pursuant to section 1395aaa(b)(8) of this title, not later than February 1 of each year (beginning with 2012), the entity shall trans-
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 about the care and treatment to be provided by the agency, 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 charges 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–3(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, 1988, 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, 1988) 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 conditions and requirements are adequate to protect the health and safety of individuals under conditions and requirements specified in or pursuant to section 1395x(m) of this title as part of the clinical records described in section 1395x(o)(3) of this title.

(5) The agency operates and provides services in compliance with all applicable Federal, State, and local laws and regulations (including the requirements of section 1320a–3 of this title) and with accepted professional standards and principles which apply to professionals providing items and services in such an agency.

(6) The agency complies with the requirement of section 1395ccc(f) of this title (relating to maintaining written policies and procedures respecting advance directives).

(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 such each 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 such an extended survey (or a partial extended survey). The extended survey shall be conducted immediately after the standard survey (or, if not practical, not later than 2 weeks after the date of completion of the standard survey).

(E) Nothing in this paragraph shall be construed as requiring an extended (or partial extended) survey as a prerequisite to imposing a sanction against an agency under subsection (e) of this section on the basis of the findings of a standard survey.

(d) Assessment process; reports to Congress

(1) Not later than January 1, 1989, the Secretary shall designate an assessment instrument (or instruments) for use by an agency in complying with subsection (c)(2)(C)(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.

(3) The Secretary shall provide for the comprehensive training of State and Federal surveyors in matters relating to the performance of standard and extended surveys under this section, including the use of any assessment instrument (or instruments) designated under paragraph (1).

(e) 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)(iii) 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, 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.

(3) If the Secretary determines that a home health agency that is certified for participation under this subchapter is in compliance with the requirements specified in or pursuant to section 1395x(o) of this title or subsection (a) of this section but, as of a previous period, did not meet such requirements, the Secretary may provide for a civil money penalty under subsection (f)(2)(A)(i) of this section for the days in which it finds that the agency was not in compliance with such requirements.

(4) The Secretary may continue payments under this subchapter with respect to a home health agency not in compliance with the requirements specified in or pursuant to section 1395x(o) of this title or subsection (a) of this section over a period of not longer than 6 months, if—

(A) the State or local survey agency finds that it is more appropriate to take alternative action to assure compliance of the agency with the requirements than to terminate the certification of the agency,

(B) the agency has submitted a plan and timetable for corrective action to the Secretary for approval and the Secretary approves the plan of corrective action, and

(C) the agency agrees to repay to the Federal Government payments received under this subparagraph if the corrective action is not taken in accordance with the approved plan and timetable.

The Secretary shall establish guidelines for approval of corrective actions requested by home health agencies under this subparagraph.

(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
the geographic location at which the service is furnished, as determined by the Secretary.

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) shall cease to be applied, and the home health agency shall be transferred to the original management, by not later than April 1, 1989, if 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 subchapter only on the basis of the geographic location at which the service is furnished, as determined by the Secretary.

101–508, set out as a note under section 1395i–3 of this title.


Section 4207(h)(2), formerly 4027(h)(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 (i) [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 2-year period beginning on October 1, 1988—

"(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**


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(f)(2)(A) of such Act [subsec. (f)(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 4021(c) of Pub. L. 100–203, set out as an Effective Date of 1987 Amendment note under section 1395x of this title.

**Treatment of Branch Offices; GAO Study on Supervision of Home Health Care Provided in Isolated Rural Areas**

Pub. L. 106–554, §101(a)(6) [title V, § 506], Dec. 21, 2000, 114 Stat. 2763, 2765A–531, 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.

"(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 agency branches 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."

**§1395c prac. Offsets 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 with an individual 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’s 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)(ii) 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 3720A 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 with 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 1395f 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 physicians 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 physicians.

(e) Transfer from trust funds

Amounts equal to the amounts deducted pursuant to this section shall be transferred from...
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.


REFERENCES IN TEXT

Section 204(a)(1) of the Public Health Service Amendments of 1987, referred to in subssec. (a)(1)(B) and (b), is section 204(a)(1) of Pub. L. 100–177, title II, Dec. 1, 1987, 101 Stat. 1000, which is set out as a note under section 254 of this title.

The Public Health Service Act, referred to in subssecs. (a)(1)(B)(ii) and (b), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended. Subpart II of part D of title III of the Act is classified generally to subpart II (§254d et seq.) of part D of title III of the Public Health Service Act (as in effect before October 1, 1976) and which was continued “as if included in the enactment of that provision in the Public Health Service Act”.


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 608(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 section 411(f)(10)(A) of Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA–Effective Date note under section 106 of Title 1, General Provisions.

Section 411(f)(10)(C)(iii) of Pub. L. 100–360 provided that: “The Amendments made by this subparagraph [amending section 294 of this title] shall be effective 30 days after the date of the enactment of this Act [July 1, 1988].”

Effective Date

Section 4052(c) of Pub. L. 100–203 provided that: “The amendments made by this section [enacting this section and amending section 254e of this title] shall be effective on the date of the enactment of this Act [Dec. 22, 1987].”

§1395dd. Medicare Integrity Program

(a) Establishment of Program

There is hereby established 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.

(b) Activities described

The activities described in this subsection are as follows:
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(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 1385y(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)(5) 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 conducting 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 the Secretary shall enter into a plan with 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). Interest shall accrue on the balance through the period of repayment. Such plan shall meet terms and conditions determined to be appropriate by the Secretary.

(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 a 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 authorize any other person, including any independent contractor on such determination, to recoup the overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

(E) Relation to no fault provision

Nothing in this paragraph shall be construed as affecting the application of section 1395oo 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 1395ff(b)(1) of this title, the Secretary may not take any action (or authorize any other person, including any independent 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 1395ff(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

If a 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 1395zz(g) 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 1395ff 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
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(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) 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). 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) does not waive any appeal rights with respect to the alleged overpayment involved.

(7) Payment audits

(A) Written notice for post-payment audits

Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services or supplier under this subchapter, the contractor shall provide the provider of services or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

(B) Explanation of findings for all audits

Subject to subparagraph (C), if a medicare contractor audits a provider of services or supplier under this subchapter, the contractor shall—

(i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services or supplier and permits the development of an appropriate corrective action plan;
(ii) inform the provider of services or supplier of the appeal rights under this subchapter as well as consent settlement options (which are at the discretion of the Secretary);
(iii) give the provider of services or supplier an opportunity to provide additional information to the contractor; and
(iv) take into account information provided, on a timely basis, by the provider of services or supplier under clause (iii).

(C) Exception

Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.

(8) Standard methodology for probe sampling

The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.

(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);
(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 each contract 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 1902(h) 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;

(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 reinsurance 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 with which the Secretary contracts with 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 13956 of this title and the Federal Supplementary Insurance Trust Fund under section 1395j of this title, to carry out this section; and

(B) the effectiveness of the use of such funds.


Sections

Providing for the retroactive application of amendments. Pub. L. 111–148, §6402(j)(1), added subsec. (a), (d)(2)(B), is section 202(b) of Pub. L. 104–191, which substituted “Medicare program” for “Medicare program”.


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 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 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

Reference

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)."
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—

(1) the individual may enroll in the program under this section; and

(2) so long as the individual is so enrolled and in accordance with regulations—

(i) the individual shall receive benefits under this subchapter solely through such program; and

(ii) 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 1396u–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 as to amount, duration, or scope and without application of deductibles, copayments, 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 noncontract 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 that do not have a contract or other agreement with a PACE provider establishing payment amounts for services covered under such plan (but not under this subchapter) when such services are furnished to enrollees of that PACE provider, see section 1396a(a)(66) of this title.

(c) Eligibility determinations

(1) In general

The determination of whether an 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-
mum data set collected by PACE providers on potential PACE program eligible individuals.

(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 re-evaluated 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 requirement of subsection (a)(5)(B) of this section if, in accordance with regulations, in the absence of continued coverage under a PACE program the individual reasonably would be expected to meet such requirement 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 provider with 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.
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(B) Numerical limitation
   (i) In general
   The Secretary shall not permit the number of PACE providers with which agree-
ments are in effect under this section or under section 9412(b) of the Omnibus Budg-
et 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 limita-
tion under this subparagraph for the pre-
ceeding year plus 20.

Subclause (II) shall apply without regard to the actual number of agreements in ef-
fect 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 pro-
   vider 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 pro-
   gram 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 agree-
   ment);
   (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 regula-
   tions.

   (B) Service area overlap
   In designating a service area under a
   PACE program agreement under subpara-
   graph (A)(i), the Secretary (in consultation
   with the State administering agency) may
   exclude from designation an area that is al-
   ready covered under another PACE program
   agreement, in order to avoid unnecessary
   duplication of services and avoid impairing
   the financial and service viability of an ex-
   isting program.

(3) Data collection; development of outcome
   measures
   (A) Data collection
   (i) In general
   Under a PACE program agreement, the
   PACE provider shall—
   (I) collect data;
   (II) maintain, and afford the Secretary
   and the State administering agency ac-
   cess to, the records relating to the pro-
   gram, including pertinent financial, medi-
   cal, and personnel records; and
   (III) make available to the Secretary
   and the State administering agency re-
   ports that the Secretary finds (in con-
   sultation with State administering agen-
   cies) necessary to monitor the operation,
   cost, and effectiveness of the PACE pro-
   gram 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 eli-
   gible individuals.

(4) Oversight
   (A) Annual, close oversight during trial pe-
   riod
   During the trial period (as defined in sub-
   section (a)(9) of this section) with respect to
   a PACE program operated by a PACE pro-
   vider, the Secretary (in cooperation with the
   State administering agency) shall conduct a
   comprehensive annual review of the oper-
   ation of the PACE program by the provider
   in order to assure compliance with the re-
   quirements of this section and regulations.
   Such a review shall include—
   (i) an on-site visit to the program site;
   (ii) comprehensive assessment of a pro-
   vider’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 sub-
   stantial compliance with all significant re-
   quirements of this section and regulations;
   and
   (v) any other elements the Secretary or
   State administering agency considers nec-
   essary or appropriate.

   (B) Continuing oversight
   After the trial period, the Secretary (in co-
   operation with the State administering
   agency) shall continue to conduct such re-
   view of the operation of PACE providers and
   PACE programs as may be appropriate, tak-
   ing 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 para-
   graph 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 modify or waive any 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 1396a-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 1396a-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 1396a-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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(1) The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.
(2) The delivery of comprehensive, integrated acute and long-term care services.
(3) The interdisciplinary team approach to care management and service delivery.
(4) 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) Continuation of modifications or waivers of operational requirements under demonstration status

If a PACE program operating under demonstration authority has contractual or other operating arrangements which are not otherwise recognized in regulation and which were in effect on July 1, 2000, the Secretary (in close consultation with, and with the concurrence of, the State administering agency) shall permit any such program to continue such arrangements so long as such arrangements are found by the Secretary and the State to be reasonably consistent with the objectives of the PACE program.

(3) 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 1398nn 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 1395ww 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 paragraph (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.


REFERENCES IN TEXT

Parts A, B, and C of this subchapter, referred to in subsec. (a)(1), (e)(7), (f)(3), and (I), are classified to sections 1395 et seq., 1395E et seq., and 1395w–21 et seq., respectively, of this title.


Section 4804(b) of the Balanced Budget Act of 1997, referred to in subsec. (a)(3)(B)(ii), is section 4804(b) of Pub. L. 105–33, which is set out as a note below.

Section 903(c) of the Social Security Amendments of 1983, referred to in subsec. (a)(7)(A), is section 903(c) of Pub. L. 98–21, title VI, Apr. 7, 1986, 100 Stat. 183, which was not classified to the Code and was repealed by Pub. L. 105–33, title IV, §4803(d), Aug. 5, 1997, 111 Stat. 550, subject to transition provisions.


The following provisions (and regulations relating to such provisions) shall not apply:

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. 111–114, §3201(i)(1), which directed addition of subsec. (h) and the redesignation of former subsecs. (h) and (i) as (i) and (j), respectively, was repealed by Pub. L. 111–152, title I, §1102(a), Mar. 30, 2010, 124 Stat. 1040.

Prepared 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(j)(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–23n of this title, relating to the payment of performance bonuses.

"(4) Section 1395w–23o of this title, relating to grandfathering supplemental benefits for current enrollees after implementation of competitive bidding.

"(5) Section 1395w–23p 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.
(c) Any other efforts determined by the rural PACE pilot site to be critical to its successful startup, as approved by the Secretary.

(2) In general.—Out of funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary to carry out this subsection for fiscal year 2006 $7,500,000.

(2) Availability.—Funds appropriated under clause (1) shall remain available for expenditure through fiscal year 2008.

(b) Technical assistance program.—The Secretary shall establish a technical assistance program to provide—

(1) outreach and education to State agencies and provider organizations interested in establishing PACE programs in rural areas; and

(2) technical assistance necessary to support rural PACE pilot sites.

(c) Cost 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 (3)) incurred for eligible outlier participants (as defined in paragraph (2)) 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. 1396a(a)(5); 1396n–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 related physician and ancillary services for the eligible outlier participant in a given 12-month period:

(1) If the services are provided under a contract between the pilot site and the provider, the payment rate specified under the contract.

(2) The payment rate established under the original Medicare fee-for-service program for such service.

(3) 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 fiscal year 2006 through 2010.

(B) Availability.—Funds appropriated under subparagraph (A) shall remain available for obligations through fiscal year 2010.

(d) 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. 1396d–4).

Flexibility in exercising waiver authority


(1) shall approve or deny a request for a modification 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.”

Transitions; 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 [subtitle I (§§ 4801–4809) of title IV of Pub. L. 105–33, enacting this section and section 1398o–4 of this title, amending sections 1396b, 1396d, 1396r–5, and 1396v of this title, and enacting provisions set out as notes under this section and section 1398o–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 1398o–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 1934(e)(1)(B) of the Social Security Act’ [subsec. (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 REPLICAION 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 date on which the repeal 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 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 [sections 1894(a)(8) and 1934(a)(8) of this section and section 1396u–4(a) 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)(7) of such Act [subsec. (a)(7) of this section and section 1396u–4(a) 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 subsec. (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.

“(3) SPECIAL CONSIDERATION.—The Secretary shall give special consideration, in the processing of applications described in paragraph (1) and the awarding of waivers described in paragraph (2), to an entity which as of May 1, 1997, through formal activities (such as entering into contracts with other providers), has indicated a specific intent 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 laws are repealed:

“(A) Section 603(c) of the Social Security Amendments of 1983 (Public Law 98–21) [79 Stat. 168].

“(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. 2062].

“(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 amendment made by paragraph (1), including permitting the organization to assume progressively (over the initial 3-year period of the waiver) the full financial risk.

“(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 4804(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, 1396e–5, and 1396v of this title.

“(a) STUDY.—

“(1) IN GENERAL.—The Secretary of Health and Human Services (in close consultation with State administering agencies, as defined in sections 1894(a)(8) and 1934(a)(8) of the Social Security Act [subsec. (a)(8) of this section and section 1396u–4(a)(8) 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, 1396e–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 [subsec. (b) of this section and section 1396u–4(h) 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 1894(h) and 1934(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 preceding subparagraphs).

“(B) The population enrolled with such entities is less frail than the population enrolled with other PACE providers.

“(C) 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.

“(D) 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 be 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 subclause (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 (ii), for periods beginning after the period described in subclause (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 years 2002 and 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 (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 to the mix of goods and services comprising inpatient hospital services for the fiscal year or year.

(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 are 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 subclause (I), 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 (ii), 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)(x)(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-
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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 January 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 1395n(a)(2)(A) of this title; and

(2) 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 1395fr of this title, 1395so 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 II 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


Pub. L. 108–173, § 701(a)(2)(B), (C), redesignated subcl. (II) as (III) and substituted “2004 and any subsequent year” for “any subsequent fiscal year”.


Pub. L. 108–173, § 701(a)(4), inserted “or year” after “fiscal year” wherever appearing and “or years” after “fiscal years”.

Subsec. (b)(5). Pub. L. 108–173, § 701(a)(5), inserted “or year” after “fiscal year”.


1999—Subsec. (b)(1). Pub. L. 106–113, § 1000(a)(6) [title V, §§ 501(c)(1), (2), redesignated subcl. (II) as (III) and substituted “described in subclause (II)” for “described in subclause (I)”.


Pub. L. 106–554, § 504, added subcl. (e).

Subsec. (b)(3)(B)(v)(III). Pub. L. 106–113, § 1000(a)(6) [title V, §§ 501(c)(1), (2), redesignated subcl. (II) as (III) and substituted “described in subclause (II)” for “described in subclause (I)”.


Subsec. (b)(3)(B)(v)(V). Pub. L. 106–113, § 1000(a)(6) [title V, §§ 501(c)(1), (2), redesignated subcl. (II) as (III) and substituted “described in subclause (II)” for “described in subclause (I)”.


The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall conduct a study on home health agencies for cost reporting periods beginning on or after Oct. 1, 1999, see section 1000(a)(6) [title III, §321(k)(19)] of Pub. L. 106–113 effective as if included in the enactment of the Balanced Budget Act of 1997, Pub. L. 106–33, except as otherwise provided, see section 1000(a)(6) [title III, §321(m)] of Pub. L. 106–113, set out as a note under section 1395d of this title.

**Effective Date of 2000 Amendment**

Pub. L. 106–554, §1(a)(6) [title V, §501(c)(2)], Dec. 21, 2000, 114 Stat. 2763, 2763A–529, provided that: “Except as otherwise provided, the amendments made by paragraph (1) [amending this section] shall apply to episodes concluding on or after October 1, 2001.”

**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 for cost reporting periods beginning on or after Oct. 1, 1999, see section 1000(a)(6) [title III, §303(c)] of Pub. L. 106–113, set out as a note under section 1395x of this title.


**Effective Date**


**Study and Report on the Development of Home Health Payment Revisions in Order to Ensure Access to Care and Payment for Severity of Illness**


“(1) In General.—The Secretary of Health and Human Services (in this section referred to as the ‘Secretary’) shall conduct a study on home health agency costs involved with providing ongoing access to care to low-income Medicare beneficiaries or Medicare beneficiaries in medically underserved areas, and in treating beneficiaries with varying levels of severity of illness. In conducting the study, the Secretary may analyze items such as the following:

(A) Methods to potentially revise the home health prospective payment system under section 1885 of the Social Security Act (42 U.S.C. 1395fff) to account for costs related to patient severity of illness or to improving beneficiary access to care, such as—

(i) payment adjustments for services that may involve additional or fewer resources;

(ii) changes to reflect resources involved with providing home health services to low-income Medicare beneficiaries or Medicare beneficiaries residing in medically underserved areas;

(iii) ways outlier payments might be revised to reflect costs of treating Medicare beneficiaries with high levels of severity of illness; and

(iv) other issues determined appropriate by the Secretary.

(B) Operational issues involved with potential implementation of potential revisions to the home health payment system, including impacts for both home health agencies and administrative and systems issues for the Centers for Medicare & Medicaid Services, and any possible payment vulnerabilities associated with implementing potential revisions.

(C) Whether additional research might be needed.

(D) Other items determined appropriate by the Secretary.

(2) Considerations.—In conducting the study under paragraph (1), the Secretary may consider whether patient severity of illness and access to care could be measured by factors, such as—

(A) population density and relative patient access to care.

(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.);

(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 study conducted under paragraph (1), together with recommendations for such legislative and administrative action 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) Medicare 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 test whether making payment adjustments for home health services under the Medicare program would substantially improve access to care for patients with high severity levels of illness or for low-income or underserved Medicare beneficiaries.

(B) Waiving Budget Neutrality.—The Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1885 of the Social Security Act (42 U.S.C. 1395fff) 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.

(D) 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.

(E) Funding.—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. 1395k) and the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of such Act (42 U.S.C. 1395l), in such proportion as the Secretary determines appropriate, of $500,000,000 for the period of fiscal years 2015 through 2018. Such funds shall be made available for the study described in paragraph (1) and the design, implementation and evaluation of the demonstration project described in this paragraph. Amounts available under this subparagraph shall be available until expended.
"(F) EVALUATION AND REPORT.—If the Secretary determines it appropriate to conduct the demonstration project under this subsection, the Secretary shall—
"(i) provide for an evaluation of the project; and
"(ii) 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 section.

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 1886(d)(2)(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, 3 percent.

"(b) WAIVING BUDGET NEUTRALITY.—The Secretary shall reduce the standard prospective payment amount (or amounts) under section 1885 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 home health services, a portion of which consists of substitute medical 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 1885 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.

"(2) ADJUSTMENT IN CASE OF OVERTREATMENT 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.

"(c) 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.

"(d) DURATION.—The Secretary shall conduct the demonstration project for a period of 3 years.

"(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) PREFERENCES IN SELECTING AGENCIES.—In selecting home health agencies to participate in the demonstration project, the Secretary shall give preference 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(e) of the Social Security Act (42 U.S.C. 1395x(e)).

"(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 or 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—

(i) meet such criteria as the Secretary determines appropriate; and

(ii) 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 Collection 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. 1395fff). Such study shall examine whether systematic differences in payment margins are related to differences in care 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, 2763A–530, provided that:

(1) in General.—Notwithstanding the amendments made by subsection (a) [amending section 1895x 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, 2763A–530, provided that:

(a) in General.—Notwithstanding the amendments made by section 403(b) of BBA [Pub. L. 105–33, amending section 1895x 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. 1395fff(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. 2783, 2783A–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 1865 of such Act (42 U.S.C. 1395fff) 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. 2783, 2783A–553, provided that:
``(1) TRANSITIONAL ALLOWANCE FOR FULL MARKETBASKET (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) MARKETBASKET EFFECT 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) IN 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)), 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. 1395fff 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) OUTFOME 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. 2783, 2783A–529, provided that: ‘‘Not later than 180 days after 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. 1395fff).

(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 services during each of fiscal years 1998 through 2002.\n
``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: ‘’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.\n
‘’(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


§ 1395hbb. 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 and such designation by the State legislature occurred prior to December 8, 2003.

(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

the provision of a loan under this section with respect to a project shall not—

(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, $200,000,000; 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.


Effective 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, $0;

(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-
rectly 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. 111–148, which directed substitution of “$0” for “$22,290,000,000”, was executed by making the substitution for “$22,290,000,000” to reflect the probable intent of Congress and the intervening amendment by Pub. L. 111–118, § 1011(b)(1)(A). See 2009 Amendment note below.

Subsec. (b)(1)(B). Pub. L. 111–309 substituted “$2,290,000,000” for “$2,220,000,000”.

2009—Subsec. (a). Pub. L. 111–5, § 4103(b)(1), inserted ‘‘medicare’’ before ‘‘fee-for-service program under’’ and ‘‘including, but not limited to, an increase 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’’ before period at end.

Subsec. (b)(1). Pub. L. 111–5, § 4103(b)(2)(A), substituted “during—” for “during fiscal year 2014, $2,290,000,000 and, in addition for services furnished during fiscal years 2014 through 2017, $19,900,000,000.” and added subpars. (A) and (B).


2008—Subsec. (b)(1). Pub. L. 110–379 substituted “$2,290,000,000” for “$2,220,000,000”.

Pub. L. 110–275 inserted “and, in addition for services furnished during fiscal years 2014 through 2017, $19,900,000,000” before period at end.

§ 1395jjj. Shared savings program

(a) Establishment

(1) In general

Not later than January 1, 2012, the Secretary shall establish a shared savings program (in this section referred to as the ‘‘program’’) that promotes accountability for a patient population and coordinates items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery. Under such program—

(A) groups of providers of services and suppliers meeting criteria specified by the Secretary may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an accountable care organization (referred to in this section as an ‘‘ACO’’); and

(B) ACOS that meet quality performance standards established by the Secretary are eligible to receive payments for shared savings under subsection (d)(2).

(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.\footnote{1}{So in original. No par. (2) has been enacted.}
The ACO 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.

(D) The ACO shall include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO under section (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.

(E) The ACO 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).

(F) The ACO shall have in place a leadership and management structure that includes clinical and administrative systems.

(G) 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.

(H) 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 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 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, § 10307, 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, 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 not 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.

(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 not 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
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 1395w–2, 1395i–2, or 1395r 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(n) 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 (b) 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 (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)) exceeds

(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
final rules but not yet implemented as of the making of such calculation.

(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—

(i) with respect to a determination year that is prior to 2018, the average of the projected percentage increase (if any) in—

(I) the Consumer Price Index for All Urban Consumers (all items; United States city average); and

(II) the medical care expenditure category of the Consumer Price Index for All Urban Consumers (United States city average); and

(ii) with respect to a determination year that is after 2017, the nominal gross domestic product per capita plus 1.0 percentage point.

(7) Savings requirement

(A) In general

If, with respect to a determination year, the Chief Actuary of the Centers for Medicare & Medicaid Services makes a determination under paragraph (6)(A) that the growth rate described in clause (i) of such paragraph exceeds the growth rate described in clause (ii) of such paragraph, the Chief Actuary shall establish an applicable savings target for the implementation year.

(B) Applicable savings target

For purposes of this section, the applicable savings target for an implementation year shall be an amount equal to the product of—

(i) the total amount of projected Medicare program spending for the proposal year; and

(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) implementation year 2016, 1.0 percent;

(III) implementation year 2017, 1.25 percent; and

(IV) implementation year 2018 or any subsequent implementation year, 1.5 percent; and

(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 by 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 Committees on Finance of the Senate and to the Committee on Energy and Commerce and the Committee on Ways and Means in 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 on 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.

(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 4 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

4So 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 day 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 supersedes 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 1395ff 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

\footnote{So in original. Probably should be “Clauses”.}
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(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 Budget Act of 1974 or under budget resolutions pursuant to that Act. The motion is not debatable. A motion to reconsider the vote by which the motion is agreed to or disagreed to shall not be in order. If a motion to proceed to the consideration of the joint resolution is agreed to, the joint resolution shall remain the unfinished business of the Senate until disposed of.

(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 recommit the joint resolution is not in order.

(iii) Passage

In the Senate, immediately following the conclusion of the debate on a joint resolution described in paragraph (1), and a single quorum call at the conclusion of the debate if requested in accordance with the rules of the Senate, the vote on passage of the joint resolution shall occur.

(iv) Appeals

Appeals from the decisions of the Chair relating to the application of the rules of the Senate to the procedure relating to a joint resolution described in paragraph (1) shall be decided without debate.

(D) Other House acts first

If, before the passage by 1 House of a joint resolution of that House described in paragraph (1), that House receives from the other House a joint resolution described in paragraph (1), then the following procedures shall apply:

(i) The joint resolution of the other House shall not be referred to a committee.

(ii) With respect to a joint resolution described in paragraph (1) of the House receiving the joint resolution—

(I) the procedure in that House shall be the same as if no joint resolution had been received from the other House; but

(II) the vote on final passage shall be on the joint resolution of the other House.

(E) Excluded days

For purposes of determining the period specified in subparagraph (B), there shall be excluded any days either House of Congress is adjourned for more than 3 days during a session of Congress.

(F) Majority required for adoption

A joint resolution considered under this subsection shall require an affirmative vote of three-fifths of the Members, duly chosen and sworn, for adoption.

(3) Termination

If a joint resolution described in paragraph (1) is enacted not later than August 15, 2017—

(A) the Chief Actuary of the Medicare & Medicaid Services shall not—

(i) make any determinations under subsection (c)(6) after May 1, 2017; or

(ii) provide any opinion pursuant to subsection (c)(3)(B)(iii) after January 16, 2018;

(B) the Board shall not submit any proposals, advisory reports, or advisory recommendations under this section or produce a public report under subsection (n) after January 16, 2018; and

(C) the Board and the consumer advisory council under subsection (k) shall terminate on August 16, 2018.

(g) Board membership; terms of office; Chairperson; removal

(1) Membership

(A) In general

The Board shall be composed of—

(i) 15 members appointed by the President, by and with the advice and consent of the Senate; and

*So in original. Probably should be capitalized.
(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 non-voting 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; and

(iv) the minority leader of the House of Representatives 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 transaction 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) shall be derived by transfer from the Federal Hospital Insurance Trust Fund under section 1395t of this title; from the Federal Supplementary Medical Insurance Trust Fund under section 1395i of this title and 40 percent of amounts appropriated under such paragraph shall be derived by transfer from the Federal Hospital Insurance Trust Fund under section 1395a(b) of this title.

(n) Annual public report

(1) In general

Not later than July 1, 2014, and annually thereafter, 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 1395aa(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

sified to sections 1395c et seq., 1395j et seq., 1395w–21 et seq., and 1395w–101 et seq., respectively, of this title.


Section 1899A of the Social Security Act, referred to in subsecs. (c)(3)(A)(i), (f)(1)(C), (D), is section 1899A of act Aug. 14, 1935, which is classified to this section.


AMENDMENTS

2010—Subsec. (c)(1)(B). Pub. L. 111–148, §10320(a)(1)(A), inserted at end “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.”

Subsec. (c)(2)(A)(iv). Pub. L. 111–148, §10320(a)(1)(B)(i), inserted “or the full premium subsidy under section 1395w–114(a) of this title” before period at end of the last sentence.


Subsec. (c)(3)(A)(i). Pub. L. 111–148, §10320(a)(1)(D)(ii), substituted “submit a proposal under this section to Congress and the President” for “transmit a proposal under this section to the President”.

Subsec. (c)(3)(A)(i). Pub. L. 111–148, §10320(a)(1)(D)(iii), inserted “or” at end of subcl. (I), substituted a period for “; or” at end of subcl. (II), and struck out subcl. (III), which read as follows: “for proposal year 2019 and subsequent proposal years, a year in which the Chief Actuary of the Centers for Medicare & Medicaid Services makes a determination in the determinative year that the growth rate described in paragraph (8) exceeds the growth rate described in paragraph (6)(A)(ii).”

Subsec. (c)(4). Pub. L. 111–148, §10320(a)(1)(E), struck out “the Board under paragraph (3)(A)(i) or” before “the Secretary” and substituted “within 2 days” for “immediately.”


Subsec. (d)(1)(A). Pub. L. 111–148, §10320(a)(2)(A), inserted the “Board or” after “a proposal is submitted by” and “subsection (c)(3)(A)(i) or” after “the Senate under”.


Subsec. (e)(3). Pub. L. 111–148, §10320(a)(3)(B), substituted “‘Exceptions’” for “‘Exception’ in par. heading, designated existing provisions as subpar. (A) and inserted heading, substituted “The Secretary shall not implement the recommendations contained in a proposal submitted in a proposal year by the Board or” for “The Secretary shall not be required to implement the recommendations contained in a proposal submitted in a proposal year by redesignated former subpars. (A) and (B) as clss. (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 “‘advisory report, or advisory recommendations’” for “‘or advisory reports to Congress and inserted ‘or produce the public report under subsection (n)’ after “this section”.

Subsecs. (n), (o). Pub. L. 111–148, §10320(a)(5), added subsecs. (n) and (o).

CHANGE OF NAME

Pub. L. 111–148, title X, §10320(b), Mar. 23, 2010, 124 Stat. 952, provided that: “Any reference in the provisions of, or amendments made by, section 3403 [enacting this section and section 1395kkk–1 of this title and amending section 1395b–6 of this title and section 207 of Title 18, Crimes and Criminal Procedure] to the ‘Independent Medicare Advisory Board’ shall be deemed to refer to the ‘Independent Payment Advisory Board’.”

CONSTRUCTION

Pub. L. 111–148, title X, §10320(c), Mar. 23, 2010, 124 Stat. 952, provided that: “Nothing in the amendments made by this section [amending this section] shall preclude the Independent Medicare Advisory Board [now Independent Payment Advisory Board], as established under section 1899A of the Social Security Act [as added by section 3403] [42 U.S.C. 1395kkk], from solely using data from public or private sources to carry out the amendments made by subsection (a)(4).”

§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 1305 of this title and Tables.

The Independent Medicare Advisory Board substituted for “Independent Payment Advisory Board” substituted for “Independent Medicare Advisory Board” on authority of section 10320(b) of Pub. L. 111–148, set out as a note under section 1395kkk of this title.

SUBCHAPTER XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

§1396. Medicaid and CHIP Payment and Access Commission

(a) Establishment

There is hereby established the Medicaid and CHIP Payment and Access Commission (in this section referred to as “MACPAC”).

(b) Duties

(1) Review of access policies for all States and annual reports

MACPAC shall—

(A) review policies of the Medicaid program established under this subchapter (in this section referred to as “Medicaid”) and the State Children’s Health Insurance Program established under subchapter XXI (in this section referred to as “CHIP”) affecting access to covered items and services, including topics described in paragraph (2);

(B) make recommendations to Congress, the Secretary, and States concerning such access policies;

(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.