2003—Subsec. (a). Pub. L. 108–173, § 736(c)(7), substituted ''medicare program'' for ''Medicare program''.

Subsec. (f). Pub. L. 108–173, § 935(a), added subsec. (f).

EFFECTIVE DATE OF 2003 AMENDMENT

Pub. L. 108–173, title IX, § 935(b), Dec. 8, 2003, 117 Stat. 2411, provided that:

''(1) USE OF REPAYMENT PLANS.—Section 1893(f)(1) of the Social Security Act [subsec. (f)(1) of this section], as added by subsection (a), shall apply to requests for repayment plans made after the date of the enactment of this Act [Dec. 8, 2003].

''(2) LIMITATION ON RECOUPMENT.—Section 1893(f)(2) of the Social Security Act [subsec. (f)(2) of this section], as added by subsection (a), shall apply to actions taken after the date of the enactment of this Act.

''(3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of the Social Security Act [subsec. (f)(3) of this section], as added by subsection (a), shall apply to statistically valid random samples initiated after the date that is 1 year after the date of the enactment of this Act.

''(4) PROVISION OF SUPPORTING DOCUMENTATION.—Section 1893(f)(4) of the Social Security Act [subsec. (f)(4) of this section], as added by subsection (a), shall take effect on the date of the enactment of this Act.

''(5) CONSENT SETTLEMENT.—Section 1893(f)(5) of the Social Security Act [subsec. (f)(5) of this section], as added by subsection (a), shall apply to consent settlements entered into after the date of the enactment of this Act.

''(6) NOTICE OF OVERUTILIZATION.—Not later than 1 year after the date of the enactment of this Act, the Secretary [of Health and Human Services] shall first establish the process for notice of overutilization of billing codes under section 1893A(f)(6) [1893(f)(6)] of the Social Security Act [probably means subsec. (f)(6) of this section], as added by subsection (a).

''(7) PAYMENT AUDITS.—Section 1893A(f)(7) [1893(f)(7)] of the Social Security Act [probably means subsec. (f)(7) of this section], as added by subsection (a), shall apply to audits initiated after the date of the enactment of this Act.

''(8) STANDARD FOR ABNORMAL BILLING PATTERNS.—Not later than 1 year after the date of the enactment of this Act, the Secretary 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(h) 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(h).''

§ 1395eee. Payments to, and coverage of benefits under, programs of all-inclusive care for elderly (PACE)

(a) Receipt of benefits through enrollment in PACE program; definitions for PACE program related terms

(1) Benefits through enrollment in a PACE program

In accordance with this section, in the case of an individual who is entitled to benefits under part A of this subchapter or enrolled under part B of this subchapter and who is a PACE program eligible individual (as defined in paragraph (5)) with respect to a PACE program offered by a PACE provider under a PACE program agreement—

(A) the individual may enroll in the program under this section; and

(B) so long as the individual is so enrolled and in accordance with regulations—

(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 re-

spect 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 or condition 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 minimum 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 reevaluated at least annually.

(B) Exception

The requirement of annual reevaluation under subparagraph (A) may be waived during a period in accordance with regulations in those cases where the State administering agency determines that there is no reasonable expectation of improvement or significant change in an individual's condition during the period because of the severity of chronic condition, or degree of impairment of functional capacity of the individual involved.

(4) Continuation of eligibility

An individual who is a PACE program eligible individual may be deemed to continue to be such an individual notwithstanding a determination that the individual no longer meets the 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.

(B) Numerical limitation

(i) In general

The Secretary shall not permit the number of PACE providers with which agreements are in effect under this section or under section 9412(b) of the Omnibus Budget Reconciliation Act of 1986 to exceed—

(I) 40 as of August 5, 1997; or

(II) as of each succeeding anniversary of August 5, 1997, the numerical limitation under this subparagraph for the preceding year plus 20.

Subclause (II) shall apply without regard to the actual number of agreements in effect as of a previous anniversary date.

(ii) Treatment of certain private, for-profit providers

The numerical limitation in clause (i) shall not apply to a PACE provider that—

(I) is operating under a demonstration project waiver under subsection (h) of this section; or

(II) was operating under such a waiver and subsequently qualifies for PACE provider status pursuant to subsection (a)(3)(B)(ii) of this section.

(2) Service area and eligibility

(A) In general

A PACE program agreement for a PACE program—

(i) shall designate the service area of the program;

(ii) may provide additional requirements for individuals to qualify as PACE program eligible individuals with respect to the program;

(iii) shall be effective for a contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate and is subject to termination by the Secretary and the State administering agency at any time for cause (as provided under the agreement);

(iv) shall require a PACE provider to meet all applicable State and local laws and requirements; and

(v) shall contain such additional terms and conditions as the parties may agree to, so long as such terms and conditions are consistent with this section and regulations.

(B) Service area overlap

In designating a service area under a PACE program agreement under subparagraph (A)(i), the Secretary (in consultation with the State administering agency) may exclude from designation an area that is already covered under another PACE program agreement, in order to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program.

(3) Data collection; development of outcome measures

(A) Data collection

(i) In general

Under a PACE program agreement, the PACE provider shall—

(I) collect data;

(II) maintain, and afford the Secretary and the State administering agency access to, the records relating to the program, including pertinent financial, medical, and personnel records; and

(III) make available to the Secretary and the State administering agency reports that the Secretary finds (in consultation with State administering agencies) necessary to monitor the operation, cost, and effectiveness of the PACE program under this section and section 1396u–4 of this title.

(ii) Requirements during trial period

During the first 3 years of operation of a PACE program (either under this section or under a PACE demonstration waiver program), the PACE provider shall provide such additional data as the Secretary specifies in regulations in order to perform the oversight required under paragraph (4)(A).

(B) Development of outcome measures

Under a PACE program agreement, the PACE provider, the Secretary, and the State administering agency shall jointly cooperate in the development and implementation of health status and quality of life outcome measures with respect to PACE program eligible individuals.

(4) Oversight

(A) Annual, close oversight during trial period

During the trial period (as defined in subsection (a)(9) of this section) with respect to a PACE program operated by a PACE provider, the Secretary (in cooperation with the State administering agency) shall conduct a comprehensive annual review of the operation of the PACE program by the provider in order to assure compliance with the requirements of this section and regulations. Such a review shall include—

(i) an on-site visit to the program site;

(ii) comprehensive assessment of a provider's fiscal soundness;

(iii) comprehensive assessment of the provider's capacity to provide all PACE services to all enrolled participants;

(iv) detailed analysis of the entity's substantial compliance with all significant requirements of this section and regulations; and

(v) any other elements the Secretary or State administering agency considers necessary or appropriate.

(B) Continuing oversight

After the trial period, the Secretary (in cooperation with the State administering agency) shall continue to conduct such review of the operation of PACE providers and PACE programs as may be appropriate, taking into account the performance level of a provider and compliance of a provider with all significant requirements of this section and regulations.

(C) Disclosure

The results of reviews under this paragraph shall be reported promptly to the PACE provider, along with any recommendations for changes to the provider's program, and shall be made available to the public upon request.

(5) Termination of PACE provider agreements

(A) In general

Under regulations—

(i) the Secretary or a State administering agency may terminate a PACE program agreement for cause; and

(ii) a PACE provider may terminate an agreement after appropriate notice to the Secretary, the State agency, and enrollees.

(B) Causes for termination

In accordance with regulations establishing procedures for termination of PACE program agreements, the Secretary or a State administering agency may terminate a PACE program agreement with a PACE provider for, among other reasons, the fact that—

(i) the Secretary or State administering agency determines that—

(I) there are significant deficiencies in the quality of care provided to enrolled participants; or

(II) the provider has failed to comply substantially with conditions for a program or provider under this section or section 1396u–4 of this title; and

(ii) the entity has failed to develop and successfully initiate, within 30 days of the date of the receipt of written notice of such a determination, a plan to correct the deficiencies, or has failed to continue implementation of such a plan.

(C) Termination and transition procedures

An entity whose PACE provider agreement is terminated under this paragraph shall implement the transition procedures required under subsection (a)(2)(C) of this section.

(6) Secretary's oversight; enforcement authority

(A) In general

Under regulations, if the Secretary determines (after consultation with the State administering agency) that a PACE provider is failing substantially to comply with the requirements of this section and regulations, the Secretary (and the State administering agency) may take any or all of the following actions:

(i) Condition the continuation of the PACE program agreement upon timely execution of a corrective action plan.

(ii) Withhold some or all further payments under the PACE program agreement under this section or section 1396u–4 of this title with respect to PACE program services furnished by such provider until the deficiencies have been corrected.

(iii) Terminate such agreement.

(B) Application of intermediate sanctions

Under regulations, the Secretary may provide for the application against a PACE provider of remedies described in section 1395w–27(g)(2) (or, for periods before January

1, 1999, section 1395mm(i)(6)(B) of this title) or 1396b(m)(5)(B) of this title in the case of violations by the provider of the type described in section 1395w–27(g)(1) (or section 1395mm(i)(6)(A) of this title for such periods) or 1396b(m)(5)(A) of this title, respectively (in relation to agreements, enrollees, and requirements under this section or section 1396u–4 of this title, respectively).

(7) Procedures for termination or imposition of sanctions

Under regulations, the provisions of section 1395w–27(h) of this title (or for periods before January 1, 1999, section 1395mm(i)(9) of this title) shall apply to termination and sanctions respecting a PACE program agreement and PACE provider under this subsection in the same manner as they apply to a termination and sanctions with respect to a contract and a Medicare+Choice organization under part C of this subchapter (or for such periods an eligible organization under section 1395mm of this title).

(8) Timely consideration of applications for PACE program provider status

In considering an application for PACE provider program status, the application shall be deemed approved unless the Secretary, within 90 days after the date of the submission of the application to the Secretary, either denies such request in writing or informs the applicant in writing with respect to any additional information that is needed in order to make a final determination with respect to the application. After the date the Secretary receives such additional information, the application shall be deemed approved unless the Secretary, within 90 days of such date, denies such request.

(f) Regulations

(1) In general

The Secretary shall issue interim final or final regulations to carry out this section and section 1396u–4 of this title.

(2) Use of PACE protocol

(A) In general

In issuing such regulations, the Secretary shall, to the extent consistent with the provisions of this section, incorporate the requirements applied to PACE demonstration waiver programs under the PACE protocol.

(B) Flexibility

In order to provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations (such as those in rural areas or those that may determine it appropriate to use nonstaff physicians according to State licensing law requirements) under this section and section 1396u–4 of this title, the Secretary (in close consultation with State administering agencies) may modify or waive provisions of the PACE protocol so long as any such modification or waiver is not inconsistent with and would not impair the essential elements, objectives, and requirements of this section, but may not modify or waive any of the following provisions:

(i) The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.

(ii) The delivery of comprehensive, integrated acute and long-term care services.

(iii) The interdisciplinary team approach to care management and service delivery.

(iv) Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals.

(v) The assumption by the provider of full financial risk.

(C) 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 1395mm 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, 1395*l*, 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 subsection (a)(3) of this section that a PACE provider may not be a for-profit, private entity.

(2) Similar terms and conditions

(A) In general

Except as provided under subparagraph (B), and paragraph (1), the terms and conditions for operation of a PACE program by a provider under this subsection shall be the same as those for PACE providers that are nonprofit, private organizations.

(B) Numerical limitation

The number of programs for which waivers are granted under this subsection shall not exceed 10. Programs with waivers granted under this subsection shall not be counted against the numerical limitation specified in subsection (e)(1)(B) of this section.

(i) Miscellaneous provisions

Nothing in this section or section 1396u–4 of this title shall be construed as preventing a PACE provider from entering into contracts with other governmental or nongovernmental payers for the care of PACE program eligible individuals who are not eligible for benefits under part A of this subchapter, or enrolled under part B of this subchapter, or eligible for medical assistance under subchapter XIX of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1894, as added Pub. L. 105–33, title IV, § 4801, Aug. 5, 1997, 111 Stat. 528; amended Pub. L. 106–554, § 1(a)(6) [title IX, § 902(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–582; Pub. L. 108–173, title II, § 236(a)(2), Dec. 8, 2003, 117 Stat. 2210; Pub. L. 110–275, title I, § 161(c), July 15, 2008, 122 Stat. 2569; Pub. L. 111–148, title III, § 3201(i)(1), Mar. 23, 2010, 124 Stat. 453; Pub. L. 111–152, title I, § 1102(a), Mar. 30, 2010, 124 Stat. 1040.)

REFERENCES IN TEXT

The Internal Revenue Code of 1986, referred to in subsec. (a)(3)(A)(i), is classified generally to Title 26, Internal Revenue Code.

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 603(c) of the Social Security Amendments of 1983, referred to in subsec. (a)(7)(A), is section 603(c) of Pub. L. 98–21, title VI, Apr. 20, 1983, 97 Stat. 168, 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.

Section 9220 of the Consolidated Omnibus Budget Reconciliation Act of 1985, referred to in subsec. (a)(7)(A), is section 9220 of Pub. L. 99–272, title IX, 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.

Section 9412(b) of the Omnibus Budget Reconciliation Act of 1986, referred to in subsecs. (a)(7)(B) and (e)(1)(B)(i), is section 9412(b) of Pub. L. 99–509, title IX, Oct. 21, 1986, 100 Stat. 2062, 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.

For the effective date of this section, referred to in subsec. (a)(9)(B), see section 4803 of Pub. L. 105–33, set out below.

AMENDMENTS

2010—Subsecs. (h) to (j). Pub. L. 111–148, § 3201(i)(1), which directed addition of subsec. (h) and the redesignation of former subsecs. (h) and (i) as (i) and (j), respectively, was repealed by Pub. L. 111–152, § 1102(a). Prior to repeal, text of subsec. (h) read as follows:

''With respect to a PACE program under this section, the following provisions (and regulations relating to such provisions) shall not apply:

''(1) Section 1395w–23(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–23(n) of this title, relating to the payment of performance bonuses.

''(4) Section 1395w–23(*o*) of this title, relating to grandfathering supplemental benefits for current enrollees after implementation of competitive bidding.

''(5) Section 1395w–23(p) of this title, relating to transitional extra benefits.''

See Effective Date of 2010 Amendment note below.

2008—Subsec. (d)(3). Pub. L. 110–275 added par. (3).

2003—Subsec. (b)(3), (4). Pub. L. 108–173 added pars. (3) and (4).

2000—Subsec. (f)(2)(C). Pub. L. 106–554 added subpar. (C).

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 3201 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.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108–173 applicable to services furnished on or after Jan. 1, 2004, see section 236(c) of

Pub. L. 108–173, set out as a note under section 1395cc of this title.

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–554, §1(a)(6) [title IX, §902(c)], Dec. 21, 2000, 114 Stat. 2763, 2763A–583, provided that: ''The amendments made by this section [amending this section and section 1396u–4 of this title] shall be effective as [if] included in the enactment of BBA [Pub. L. 105–33].''

RURAL PACE PROVIDER GRANT PROGRAM

Pub. L. 109–171, title V, §5302, Feb. 8, 2006, 120 Stat. 51, as amended by Pub. L. 109–432, div. B, title II, §205(a), Dec. 20, 2006, 120 Stat. 2989, provided that:

''(a) DEFINITIONS.—In this section:

''(1) CMS.—The term 'CMS' means the Centers for Medicare & Medicaid Services.

''(2) PACE PROGRAM.—The term 'PACE program' has the meaning given that term in sections 1894(a)(2) and 1934(a)(2) of the Social Security Act (42 U.S.C. 1395eee(a)(2); 1396u–4(a)(2)).

''(3) PACE PROVIDER.—The term 'PACE provider' has the meaning given that term in section 1894(a)(3) or 1934(a)(3) of the Social Security Act (42 U.S.C. 1395eee(a)(3); 1396u–4(a)(3)).

''(4) RURAL AREA.—The term 'rural area' has the meaning given that term in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D)).

''(5) RURAL PACE PILOT SITE.—The term 'rural PACE pilot site' means a PACE provider that has been approved to provide services in a geographic service area that is, in whole or in part, a rural area, and that has received a site development grant under this section.

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

''(b) SITE DEVELOPMENT GRANTS AND TECHNICAL ASSISTANCE PROGRAM.—

''(1) SITE DEVELOPMENT GRANTS.—

''(A) IN GENERAL.—The Secretary shall establish a process and criteria to award site development grants to qualified PACE providers that have been approved to serve a rural area.

''(B) AMOUNT PER AWARD.—A site development grant awarded under subparagraph (A) to any individual rural PACE pilot site shall not exceed $750,000.

''(C) NUMBER OF AWARDS.—Not more than 15 rural PACE pilot sites shall be awarded a site development grant under subparagraph (A).

''(D) USE OF FUNDS.—Funds made available under a site development grant awarded under subparagraph (A) may be used for the following expenses only to the extent such expenses are incurred in relation to establishing or delivering PACE program services in a rural area:

''(i) Feasibility analysis and planning.

''(ii) Interdisciplinary team development.

''(iii) Development of a provider network, including contract development.

''(iv) Development or adaptation of claims processing systems.

''(v) Preparation of special education and outreach efforts required for the PACE program.

''(vi) Development of expense reporting required for calculation of outlier payments or reconciliation processes.

''(vii) Development of any special quality of care or patient satisfaction data collection efforts.

''(viii) Establishment of a working capital fund to sustain fixed administrative, facility, or other fixed costs until the provider reaches sufficient enrollment size.

''(ix) Startup and development costs incurred prior to the approval of the rural PACE pilot site's PACE provider application by CMS.

''(x) Any other efforts determined by the rural PACE pilot site to be critical to its successful startup, as approved by the Secretary.

''(E) APPROPRIATION.—

''(i) 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.

''(ii) AVAILABILITY.—Funds appropriated under clause (i) shall remain available for expenditure through fiscal year 2008.

''(2) TECHNICAL ASSISTANCE PROGRAM.—The Secretary shall establish a technical assistance program to provide—

''(A) outreach and education to State agencies and provider organizations interested in establishing PACE programs in rural areas; and

''(B) technical assistance necessary to support rural PACE pilot sites.

''(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 exceeds $50,000.

''(2) ELIGIBLE OUTLIER PARTICIPANT.—For purposes of this subsection, the term 'eligible outlier participant' means a PACE program eligible individual (as defined in sections 1894(a)(5) and 1934(a)(5) of the Social Security Act (42 U.S.C. 1395eee(a)(5); 1396u–4(a)(5))) who resides in a rural area and with respect to whom the rural PACE pilot site incurs more than $50,000 in recognized costs in a 12-month period.

''(3) RECOGNIZED OUTLIER COSTS DEFINED.—

''(A) IN GENERAL.—For purposes of this subsection, the term 'recognized outlier costs' means, with respect to services furnished to an eligible outlier participant by a rural PACE pilot site, the least of the following (as documented by the site to the satisfaction of the Secretary) for the provision of inpatient and related physician and ancillary services for the eligible outlier participant in a given 12-month period:

''(i) If the services are provided under a contract between the pilot site and the provider, the payment rate specified under the contract.

''(ii) The payment rate established under the original Medicare fee-for-service program for such service.

''(iii) The amount actually paid for the services by the pilot site.

''(B) INCLUSION IN ONLY ONE PERIOD.—Recognized outlier costs may not be included in more than one 12-month period.

''(3)[two pars. (3) have been enacted] OUTLIER EXPENSE PAYMENT.—

''(A)[no subpar. (B) has been enacted] PAYMENT FOR OUTLIER COSTS.—Subject to subparagraph (B), in the case of a rural PACE pilot site that has incurred outlier costs for an eligible outlier participant, the rural PACE pilot site shall receive an outlier expense payment equal to 80 percent of such costs that exceed $50,000.

''(4) LIMITATIONS.—

''(A) COSTS INCURRED PER ELIGIBLE OUTLIER PARTICIPANT.—The total amount of outlier expense payments made under this subsection to a rural PACE pilot site with respect to an eligible outlier participant for any 12-month period shall not exceed $100,000 for the 12-month period used to calculate the payment.

''(B) COSTS INCURRED PER PROVIDER.—No rural PACE pilot site may receive more than $500,000 in total outlier expense payments in a 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 460.80(c) of title 42, Code of Federal Regulations) and any working capital established through a site development grant awarded under subsection (b)(1), prior to receiving any payment from the outlier fund.

''(6) APPLICATION.—In order to receive an outlier expense payment under this subsection with respect to an eligible outlier participant, a rural PACE pilot site shall submit an application containing—

''(A) documentation of the costs incurred with respect to the participant;

''(B) a certification that the site has complied with the requirements under paragraph (4); and

''(C) such additional information as the Secretary may require.

''(7) APPROPRIATION.—

''(A) IN GENERAL.—Out of funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary $10,000,000 to carry out this subsection for the period of fiscal years 2006 through 2010.

''(B) AVAILABILITY.—Funds appropriated under subparagraph (A) shall remain available for obligation through fiscal year 2010.

''(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. 1395eee; 1396u–4).''

FLEXIBILITY IN EXERCISING WAIVER AUTHORITY

Pub. L. 106–554, §1(a)(6) [title IX, §903], Dec. 21, 2000, 114 Stat. 2763, 2763A–583, provided that: ''In applying sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Social Security Act (42 U.S.C. 1395eee(f)(2)(B), 1396u–4(f)(2)(B)), the Secretary of Health and Human Services—

''(1) shall approve or deny a request for a modification or a waiver of provisions of the PACE protocol not later than 90 days after the date the Secretary receives the request; and

''(2) may exercise authority to modify or waive such provisions in a manner that responds promptly to the needs of PACE programs relating to areas of employment and the use of community-based primary care physicians.''

TRANSITION; REGULATIONS

Pub. L. 105–33, title IV, §4803, Aug. 5, 1997, 111 Stat. 549, 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 (§§4801–4804) of title IV of Pub. L. 105–33, enacting this section and section 1396u–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 1395b–6 of this title] in a timely manner. Such regulations shall be designed so that entities may establish and operate PACE programs under sections 1894 and 1934 of the Social Security Act [this section and section 1396u–4 of this title] (as added by sections 4801 and 4802 of this subtitle) for periods beginning not later than 1 year after the date of the enactment of this Act [Aug. 5, 1997].

''(b) EXPANSION AND TRANSITION FOR PACE DEMONSTRATION PROJECT WAIVERS.—

''(1) EXPANSION IN CURRENT NUMBER AND EXTENSION OF DEMONSTRATION PROJECTS.—Section 9412(b) of the Omnibus Budget Reconciliation Act of 1986 [see subsec. (d) below], as amended by section 4118(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 REPLICATION REQUIREMENT.—Section 9412(b)(2)(B) of such Act, as so amended, shall not apply to waivers granted under such section after the date of the enactment of this Act [Aug. 5, 1997].

''(3) TIMELY CONSIDERATION OF APPLICATIONS.—In considering an application for waivers under such section before the effective date of the repeals under subsection (d), subject to the numerical limitation under the amendment made by paragraph (1), the application shall be deemed approved unless the Secretary of Health and Human Services, within 90 days after the date of its submission to the Secretary, either denies such request in writing or informs the applicant in writing with respect to any additional information which is needed in order to make a final determination with respect to the application. After the date the Secretary receives such additional information, the application shall be deemed approved unless the Secretary, within 90 days of such date, denies such request.

''(c) PRIORITY AND SPECIAL CONSIDERATION IN APPLICATION.—During the 3-year period beginning on the date of the enactment of this Act [Aug. 5, 1997]:

''(1) PROVIDER STATUS.—The Secretary of Health and Human Services shall give priority in processing applications of entities to qualify as PACE programs under section 1894 or 1934 of the Social Security Act [this section and section 1396u–4 of this title]—

''(A) first, to entities that are operating a PACE demonstration waiver program (as defined in sections 1894(a)(7) and 1934(a)(7) of such Act [subsec. (a)(7) of this section and section 1396u–4(a)(7) 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 for feasibility studies) 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 law are repealed:

''(A) Section 603(c) of the Social Security Amendments of 1983 (Public Law 98–21) [97 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 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, 1396r–5, and 1396v of this title].

''(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

Pub. L. 105–33, title IV, § 4804(a), (b), Aug. 5, 1997, 111 Stat. 551, provided that:

''(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, 1396r–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. (h) 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 succeeding 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 subchapter 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