

110-379, §2, Oct. 8, 2008, 122 Stat. 4075; Pub. L. 111-5, div. B, title V, §5005(b), Feb. 17, 2009, 123 Stat. 505; Pub. L. 111-127, §3, Jan. 27, 2010, 124 Stat. 4; Pub. L. 111-309, title I, §110(b), Dec. 15, 2010, 124 Stat. 3288; Pub. L. 112-78, title III, §310(b), Dec. 23, 2011, 125 Stat. 1286; Pub. L. 112-96, title III, §3101(b), Feb. 22, 2012, 126 Stat. 191; Pub. L. 112-240, title VI, §621(b), Jan. 2, 2013, 126 Stat. 2352; Pub. L. 113-67, div. B, title II, §1201(b), Dec. 26, 2013, 127 Stat. 1198; Pub. L. 113-93, title II, §201(b), Apr. 1, 2014, 128 Stat. 1045; Pub. L. 114-10, title II, §211(b), Apr. 16, 2015, 129 Stat. 151.)

Editorial Notes

PRIOR PROVISIONS

A prior section 1933 of act Aug. 14, 1935, was renumbered section 1939 and is classified to section 1396v of this title.

AMENDMENTS

2015—Subsec. (g)(2). Pub. L. 114-10, §211(b)(1), redesignated subpars. (I) to (W) as (A) to (O), respectively, added subpars. (P) and (Q), and struck out former subpars. (A) to (H) which related to total allocation amounts for various periods beginning on January 1, 2004, and ending on December 31, 2007.

Subsec. (g)(3). Pub. L. 114-10, §211(b)(2), substituted “or (P)” for “(P), (R), (T), or (V)” in introductory provisions.

Subsec. (g)(4). Pub. L. 114-10, §211(b)(3), added par. (4). 2014—Subsec. (g)(2)(T). Pub. L. 113-93, §201(b)(1)(A), struck out “and” at end.

Subsec. (g)(2)(U). Pub. L. 113-93, §201(b)(1)(B), substituted “September 30, 2014” for “March 31, 2014” and “\$485,000,000;” for “\$200,000,000.”

Subsec. (g)(2)(V), (W). Pub. L. 113-93, §201(b)(1)(C), added subpars. (V) and (W).

Subsec. (g)(3). Pub. L. 113-93, §201(b)(2), substituted “(T), or (V)” for “or (T)” in introductory provisions.

2013—Subsec. (g)(2)(S), (T). Pub. L. 112-240, §621(b)(1), added subpars. (S) and (T).

Subsec. (g)(2)(U). Pub. L. 113-67 added subpar. (U).

Subsec. (g)(3). Pub. L. 112-240, §621(b)(2), substituted “(R), or (T)” for “or (R)” in introductory provisions.

2012—Subsec. (g)(2)(Q), (R). Pub. L. 112-96, §3101(b)(1), substituted “September 30, 2012, the total allocation amount is \$450,000,000; and” for “February 29, 2012, the total allocation amount is \$150,000,000.” in subpar. (Q) and added subpar. (R).

Subsec. (g)(3). Pub. L. 112-96, §3101(b)(2), substituted “(P), or (R)” for “or (P)” in introductory provisions.

2011—Subsec. (g)(2)(Q). Pub. L. 112-78 added subpar. (Q).

2010—Subsec. (g)(2)(M). Pub. L. 111-127, §3(1), substituted “\$462,500,000” for “\$412,500,000”.

Subsec. (g)(2)(N). Pub. L. 111-127, §3(2), substituted “\$165,000,000” for “\$150,000,000”.

Subsec. (g)(2)(O), (P). Pub. L. 111-309, §110(b)(1), added subpars. (O) and (P).

Subsec. (g)(3). Pub. L. 111-309, §110(b)(2), substituted “(N), or (P)” for “or (N)” in introductory provisions.

2009—Subsec. (g)(2)(M), (N). Pub. L. 111-5, §5005(b)(1), added subpars. (M) and (N).

Subsec. (g)(3). Pub. L. 111-5, §5005(b)(2), substituted “(L), or (N)” for “or (L)” in introductory provisions.

2008—Subsec. (g)(2)(I). Pub. L. 110-379, §2(1), substituted “\$315,000,000” for “\$300,000,000”.

Pub. L. 110-275, §111(b)(1)(B)(i), (ii), substituted “September 30” for “June 30” and “\$300,000,000” for “\$200,000,000”.

Subsec. (g)(2)(J). Pub. L. 110-379, §2(2), substituted “\$130,000,000” for “\$100,000,000”.

Pub. L. 110-275, §111(b)(1)(A), (B)(iii), (C), added subpar. (J).

Subsec. (g)(2)(K), (L). Pub. L. 110-275, §111(b)(1)(C), added subpars. (K) and (L).

Subsec. (g)(3). Pub. L. 110-275, §111(b)(2), substituted “(H), (J), or (L)” for “or (H)” in introductory provisions.

2007—Subsec. (g)(2)(H). Pub. L. 110-90, §3(b)(1), added subpar. (H).

Subsec. (g)(2)(I). Pub. L. 110-173 added subpar. (I).

Subsec. (g)(3). Pub. L. 110-90, §3(b)(2), substituted “(F), or (H)” for “or (F)” in introductory provisions.

2005—Subsec. (g)(2)(D) to (G). Pub. L. 109-91, §101(b)(1), added subpars. (D) to (G).

Subsec. (g)(3). Pub. L. 109-91, §101(b)(2), inserted “(D), or (F)” after “subparagraph (B)” in introductory provisions.

2004—Subsec. (g). Pub. L. 108-448 amended heading and text of subsec. (g) generally. Prior to amendment, text read as follows: “With respect to the period that begins on January 1, 2004, and ends on September 30, 2004, a State shall select qualifying individuals, and provide such individuals with assistance, in accordance with the provisions of this section as in effect with respect to calendar year 2003, except that for such purpose—

“(1) references in the preceding subsections of this section to ‘fiscal year’ and ‘calendar year’ shall be deemed to be references to such period; and

“(2) the total allocation amount under subsection (c) of this section for such period shall be \$300,000,000.”

2003—Subsec. (c)(1)(E). Pub. L. 108-89, §401(b)(1), substituted “each of fiscal years 2002 and 2003” for “fiscal year 2002”.

Subsec. (c)(2)(A). Pub. L. 108-89, §401(b)(2), substituted “the total number of individuals described in section 1396a(a)(10)(E)(iv) of this title in the State; to” for “the sum of—

“(i) twice the total number of individuals described in section 1396a(a)(10)(E)(iv)(I) of this title in the State, and

“(ii) the total number of individuals described in section 1396a(a)(10)(E)(iv)(II) of this title in the State; to”.

Subsec. (g). Pub. L. 108-173, §103(f)(2)(A), substituted “September 30, 2004” for “March 31, 2004” in introductory provisions.

Pub. L. 108-89, §401(c), added subsec. (g).

Subsec. (g)(2). Pub. L. 108-173, §103(f)(2)(B), substituted “\$300,000,000” for “\$100,000,000”.

1999—Subsec. (b)(4). Pub. L. 106-113 inserted “a” after “for a month in”.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 110-90 effective as of Sept. 30, 2007, see section 3(c) of Pub. L. 110-90, set out as a note under section 1396a of this title.

EFFECTIVE DATE OF 2005 AMENDMENT

Amendment by Pub. L. 109-91 effective Sept. 30, 2005, see section 101(c) of Pub. L. 109-91, set out as a note under section 1396a of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by Pub. L. 108-173 applicable to calendar quarters beginning on or after Apr. 1, 2004, see section 103(f)(3) of Pub. L. 108-173, set out as a note under section 1396a of this title.

§ 1396u-4. Program of all-inclusive care for elderly (PACE)

(a) State option

(1) In general

A State may elect to provide medical assistance under this section with respect to PACE program services to PACE program eligible individuals who are eligible for medical assistance under the State plan and who are en-

rolled in a PACE program under a PACE program agreement. Such individuals need not be eligible for benefits under part A, or enrolled under part B, of subchapter XVIII to be eligible to enroll under this section. In the case of an individual enrolled with a PACE program pursuant to such an election—

(A) the individual shall receive benefits under the plan solely through such program, and

(B) the PACE provider shall receive payment in accordance with the PACE program agreement for provision of such benefits.

A State may establish a numerical limit on the number of individuals who may be enrolled in a PACE program under a PACE program agreement.

(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); 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 1395eee of this title (if applicable), and regulations promulgated to carry out such sections, among the PACE provider, the Secretary, 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), is determined under subsection (c) 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).

(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 this subchapter in the State) responsible for administering PACE program agreements under this section and section 1395eee 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) to carry out this section and section 1395eee 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, regardless of source of payment and directly or under contracts with other entities, at a minimum—

(i) all items and services covered under subchapter XVIII (for individuals enrolled under section 1395eee of this title) and all items and services covered under this subchapter, 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 such subchapter or this 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 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 subchapter XVIII) 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 subchapter XVIII furnished by noncontract providers of services, see section 1395cc(a)(1)(O) of this title.

(4) Reference to related provision for services covered under this subchapter but not under subchapter XVIII

For provisions relating to limitations on payments to providers participating under the State plan under this subchapter 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 subchapter XVIII) when such services are furnished to enrollees of that PACE provider, see section 1396a(a)(67) of this title.

(c) Eligibility determinations

(1) In general

The determination of—

(A) whether an individual is a PACE program eligible individual shall be made under and in accordance with the PACE program agreement, and

(B) who is entitled to medical assistance under this subchapter 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 min-

imum data set collected by PACE providers on potential eligible individuals.

(3) Annual eligibility recertifications

(A) In general

Subject to subparagraph (B), the determination described in subsection (a)(5)(B) 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 in which 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) 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 1395eee 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 a 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 State shall make prospective monthly payments of a capitation amount for each PACE program eligible individual enrolled under the agreement under this section.

(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 an amount, specified under the PACE agreement, which is less than the amount that would otherwise have been made under the State plan if the individuals were not so enrolled 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. The payment under this section shall be in addition to any payment made under section 1395eee of this title for individuals who are enrolled in a PACE program under such section.

(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 1395eee 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), or

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

(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) submit to the Secretary and the State administering agency such reports as the Secretary finds (in consultation with State administering agencies) necessary to monitor the operation, cost, and effectiveness of the PACE program.

(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)) 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 onsite 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 the 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 such an agreement after appropriate notice to the Secretary, the State administering 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 1395eee 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).

(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 1395eee 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 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 section 1395eee of this title or this section, 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 subchapter XVIII (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 1395eee 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 1395eee 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 1¹ 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 subchapter XVIII (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 such part C (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 subchapter XVIII (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 XVIII.

(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) shall not apply:

- (1) Section 1396a(a)(1) of this title, relating to any requirement that PACE programs or PACE program services be provided in all areas of a State.
- (2) Section 1396a(a)(10) of this title, insofar as such section relates to comparability of services among different population groups.
- (3) Sections 1396a(a)(23) and 1396n(b)(4) of this title, relating to freedom of choice of providers under a PACE program.

(4) Section 1396b(m)(2)(A) of this title, insofar as it restricts a PACE provider from receiving prepaid capitation payments.

(5) Such other provisions of this subchapter that, as added or amended by the Balanced Budget Act of 1997, the Secretary determines are inapplicable to carrying out a PACE program under this section.

(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) 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).

(i) Post-eligibility treatment of income

A State may provide for post-eligibility treatment of income for individuals enrolled in PACE programs under this section in the same manner as a State treats post-eligibility income for individuals receiving services under a waiver under section 1396n(c) of this title.

(j) Miscellaneous provisions

Nothing in this section or section 1395eee 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, or enrolled under part B, of subchapter XVIII or eligible for medical assistance under this subchapter.

(Aug. 14, 1935, ch. 531, title XIX, §1934, as added Pub. L. 105-33, title IV, §4802(a)(3), Aug. 5, 1997, 111 Stat. 539; amended Pub. L. 106-554, §1(a)(6) [title IX, §902(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A-583; Pub. L. 108-173, title II, §236(b)(2), Dec. 8, 2003, 117 Stat. 2211.)

Editorial Notes

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.

The Balanced Budget Act of 1997, referred to in subsecs. (a)(3)(B)(ii) and (g)(5), is Pub. L. 105-33, Aug. 5, 1997, 111 Stat. 251. Section 4804(b) of the Act is set out as a note under section 1395eee of this title. For complete classification of this Act to the Code, see Tables.

¹ So in original. Probably should be followed by a comma.

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 as a Transition; Regulations note under section 1395eee of this title.

PRIOR PROVISIONS

A prior section 1934 of act Aug. 14, 1935, was renumbered section 1939 and is classified to section 1396v of this title.

AMENDMENTS

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).

Statutory Notes and Related Subsidiaries

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 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

Amendment by Pub. L. 106-554 effective as if included in the enactment of Pub. L. 105-33, see section 1(a)(6) [title IX, § 902(c)] of Pub. L. 106-554, set out as a note under section 1395eee of this title.

§ 1396u-5. Special provisions relating to medicare prescription drug benefit

(a) Requirements relating to medicare prescription drug low-income subsidies, medicare transitional prescription drug assistance, and medicare cost-sharing

As a condition of its State plan under this subchapter under section 1396a(a)(66) of this title and receipt of any Federal financial assistance under section 1396b(a) of this title subject to subsection (e), a State shall do the following:

(1) Information for transitional prescription drug assistance verification

The State shall provide the Secretary with information to carry out section 1395w-141(f)(3)(B)(i) of this title.

(2) Eligibility determinations for low-income subsidies

The State shall—

(A) make determinations of eligibility for premium and cost-sharing subsidies under and in accordance with section 1395w-114 of this title;

(B) inform the Secretary of such determinations in cases in which such eligibility is established; and

(C) otherwise provide the Secretary with such information as may be required to carry out part D, other than subpart 4, of subchapter XVIII (including section 1395w-114 of this title).

(3) Screening for eligibility, and enrollment of, beneficiaries for medicare cost-sharing

As part of making an eligibility determination required under paragraph (2) for an individual, the State shall make a determination of the individual's eligibility for medical assistance for any medicare cost-sharing described in section 1396d(p)(3) of this title and, if the individual is eligible for any such medicare cost-sharing, offer enrollment to the individual under the State plan (or under a waiver of such plan).

(4) Consideration of data transmitted by the Social Security Administration for purposes of Medicare Savings Program

The State shall accept data transmitted under section 1320b-14(c)(3) of this title and act on such data in the same manner and in accordance with the same deadlines as if the data constituted an initiation of an application for benefits under the Medicare Savings Program (as defined for purposes of such section) that had been submitted directly by the applicant. The date of the individual's application for the low income subsidy program from which the data have been derived shall constitute the date of filing of such application for benefits under the Medicare Savings Program.

(b) Regular Federal subsidy of administrative costs

The amounts expended by a State in carrying out subsection (a) are expenditures reimbursable under the appropriate paragraph of section 1396b(a) of this title.

(c) Federal assumption of medicaid prescription drug costs for dually eligible individuals

(1) Phased-down State contribution

(A) In general

Each of the 50 States and the District of Columbia for each month beginning with January 2006 shall provide for payment under this subsection to the Secretary of the product of—

(i) the amount computed under paragraph (2)(A) for the State and month;

(ii) the total number of full-benefit dual eligible individuals (as defined in paragraph (6)) for such State and month; and

(iii) the factor for the month specified in paragraph (5).

(B) Form and manner of payment

Payment under subparagraph (A) shall be made in a manner specified by the Secretary that is similar to the manner in which State