Subsec. (f). Pub. L. 108–173, §222(g)(5)(A), inserted ''before 2006'' after ''additional benefits'' in heading.

Subsec. (f)(1)(A). Pub. L. 108–173, §222(g)(5)(B), substituted ''For years before 2006, each'' for ''Each''.

Subsec. (g). Pub. L. 108–173, §232(b), inserted ''or premiums paid to such organizations under this part'' after ''section 1395w–23 of this title''.

2002—Subsec. (a)(1). Pub. L. 107–188 substituted ''Not later than the second Monday in September of 2002, 2003, and 2004 (or July 1 of each other year)'' for ''Not later than July 1 of each year'' in introductory provisions.

2000—Subsec. (a)(5)(A). Pub. L. 106–554, §1(a)(6) [title VI, §622(a)], substituted ''values so submitted'' for ''value so submitted'' and inserted at end ''The Chief Actuary of the Health Care Financing Administration shall review the actuarial assumptions and data used by the Medicare+Choice organization with respect to such rates, amounts, and values so submitted to determine the appropriateness of such assumptions and data.''

Subsec. (f)(1)(E), (F). Pub. L. 106–554, §1(a)(6) [title VI, §606(a)(1)], added subpar. (E) and redesignated former subpar. (E) as (F).

1999—Subsec. (a)(1). Pub. L. 106–113, §1000(a)(6) [title V, §516(a)], substituted ''July 1'' for ''May 1'' in introductory provisions.

Pub. L. 106–113, §1000(a)(6) [title V, §515(a)(1)], inserted ''(or segment of such an area if permitted under subsection (h) of this section)'' after ''service area'' in introductory provisions.

Subsec. (a)(2)(A). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(6)(C)(i)(I)], inserted ''section'' before ''1395w–22(a)(1)(A) of this title'' in introductory provisions.

Subsec. (a)(2)(B). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(6)(C)(i)(II)], inserted ''section'' after ''described in'' in introductory provisions.

Subsec. (a)(3)(A), (B). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(6)(C)(ii)], inserted ''section'' after ''described in''.

Subsec. (a)(4). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(6)(C)(iii)(I)], which directed insertion of ''section'' after ''described in'', was executed by making the insertion after ''described in'' the second time appearing in introductory provisions to reflect the probable intent of Congress.

Subsec. (a)(4)(A). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(6)(C)(iii)(II)], inserted ''section'' after ''described in'' in introductory provisions.

Subsec. (a)(4)(B). Pub. L. 106–113, §1000(a)(6) [title III, §321(k)(6)(C)(iii)(III)], inserted ''section'' after ''described in''.

Subsec. (h). Pub. L. 106–113, §1000(a)(6) [title V, §515(a)(2)], added subsec. (h).

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 2010 AMENDMENT

Repeal of sections 3201 and 3203 of Pub. L. 111–148 and the amendments made by such sections, effective as if included in the enactment of Pub. L. 111–148, see section 1102(a) of Pub. L. 111–152, set out as a note under section 1395w–21 of this title.

Pub. L. 111–148, title III, §3201(d)(3), Mar. 23, 2010, 124 Stat. 445, which provided that amendments by section 3201(d) of Pub. L. 111–148 (amending this section) would apply to bid amounts submitted on or after Jan. 1, 2012, was repealed by Pub. L. 111–152, title I, §1102(a), Mar. 30, 2010, 124 Stat. 1040.

Pub. L. 111–148, title III, §3209(c), Mar. 23, 2010, 124 Stat. 460, provided that: ''The amendments made by this section [amending this section and section 1395w–111 of this title] shall apply to bids submitted for contract years beginning on or after January 1, 2011.''

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 222(a)(1), (b), (c), (g) of Pub. L. 108–173 applicable with respect to plan years beginning on or after Jan. 1, 2006, see section 223(a) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

Pub. L. 108–173, title II, §232(c), Dec. 8, 2003, 117 Stat. 2209, provided that: ''The amendments made by this subsection [probably should be ''this section'', amending this section and section 1395w–26 of this title] shall take effect on the date of the enactment of this Act [Dec. 8, 2003].''

EFFECTIVE DATE OF 2002 AMENDMENT

Pub. L. 107–188, title V, §532(b)(2), June 12, 2002, 116 Stat. 696, provided that: ''The amendment made by paragraph (1) [amending this section] shall apply to information submitted for years beginning with 2003.''

EFFECTIVE DATE OF 2000 AMENDMENT

Amendment by section 1(a)(6) [title VI, §606(a)(1)] of Pub. L. 106–554 applicable to years beginning with 2003, see section 1(a)(6) [title VI, §606(b)] of Pub. L. 106–554, set out as a note under section 1395r of this title.

Pub. L. 106–554, §1(a)(6) [title VI, §622(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–566, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to submissions made on or after May 1, 2001.''

EFFECTIVE DATE OF 1999 AMENDMENT

Amendment by section 1000(a)(6) [title III, §321(k)(6)(C)] of Pub. L. 106–113 effective as if included in the enactment of the Balanced Budget Act of 1997, Pub. L. 105–33, except as otherwise provided, see section 1000(a)(6) [title III, §321(m)] of Pub. L. 106–113, set out as a note under section 1395d of this title.

Pub. L. 106–113, div. B, §1000(a)(6) [title V, §515(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–384, provided that: ''The amendments made by this section [amending this section] apply to contract years beginning on or after January 1, 2001.''

Pub. L. 106–113, div. B, §1000(a)(6) [title V, §516(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–384, provided that: ''The amendment made by subsection (a) [amending this section] applies to information submitted by Medicare+Choice organizations for years beginning with 1999.''

§ 1395w–25. Organizational and financial requirements for Medicare+Choice organizations; provider-sponsored organizations

(a) Organized and licensed under State law

(1) In general

Subject to paragraphs (2) and (3), a Medicare+Choice organization shall be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a Medicare+Choice plan.

(2) Special exception for provider-sponsored organizations

(A) In general

In the case of a provider-sponsored organization that seeks to offer a Medicare+Choice plan in a State, the Secretary shall waive the requirement of paragraph (1) that the organization be licensed in that State if—

(i) the organization files an application for such waiver with the Secretary by not later than November 1, 2002, and

(ii) the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for approval of the application described in subparagraph (B), (C), or (D) has been met.

(B) Failure to act on licensure application on a timely basis

The ground for approval of such a waiver application described in this subparagraph is that the State has failed to complete action on a licensing application of the organization within 90 days of the date of the State's receipt of a substantially complete application. No period before August 5, 1997, shall be included in determining such 90-day period.

(C) Denial of application based on discriminatory treatment

The ground for approval of such a waiver application described in this subparagraph is that the State has denied such a licensing application and—

(i) the standards or review process imposed by the State as a condition of approval of the license imposes any material requirements, procedures, or standards (other than solvency requirements) to such organizations that are not generally applicable to other entities engaged in a substantially similar business, or

(ii) the State requires the organization, as a condition of licensure, to offer any product or plan other than a Medicare+Choice plan.

(D) Denial of application based on application of solvency requirements

With respect to waiver applications filed on or after the date of publication of solvency standards under section 1395w–26(a) of this title, the ground for approval of such a waiver application described in this subparagraph is that the State has denied such a licensing application based (in whole or in part) on the organization's failure to meet applicable solvency requirements and—

(i) such requirements are not the same as the solvency standards established under section 1395w–26(a) of this title; or

(ii) the State has imposed as a condition of approval of the license documentation or information requirements relating to solvency or other material requirements, procedures, or standards relating to solvency that are different from the requirements, procedures, and standards applied by the Secretary under subsection (d)(2).

For purposes of this paragraph, the term ''solvency requirements'' means requirements relating to solvency and other matters covered under the standards established under section 1395w–26(a) of this title.

(E) Treatment of waiver

In the case of a waiver granted under this paragraph for a provider-sponsored organization with respect to a State—

(i) Limitation to State

The waiver shall be effective only with respect to that State and does not apply to any other State.

(ii) Limitation to 36-month period

The waiver shall be effective only for a 36-month period and may not be renewed.

(iii) Conditioned on compliance with consumer protection and quality standards

The continuation of the waiver is conditioned upon the organization's compliance with the requirements described in subparagraph (G).

(iv) Preemption of State law

Any provisions of law of that State which relate to the licensing of the organization and which prohibit the organization from providing coverage pursuant to a contract under this part shall be superseded.

(F) Prompt action on application

The Secretary shall grant or deny such a waiver application within 60 days after the date the Secretary determines that a substantially complete waiver application has been filed. Nothing in this section shall be construed as preventing an organization which has had such a waiver application denied from submitting a subsequent waiver application.

(G) Application and enforcement of State consumer protection and quality standards

(i) In general

A waiver granted under this paragraph to an organization with respect to licensing under State law is conditioned upon the organization's compliance with all consumer protection and quality standards insofar as such standards—

(I) would apply in the State to the organization if it were licensed under State law;

(II) are generally applicable to other Medicare+Choice organizations and plans in the State; and

(III) are consistent with the standards established under this part.

Such standards shall not include any standard preempted under section 1395w–26(b)(3)(B) of this title.

(ii) Incorporation into contract

In the case of such a waiver granted to an organization with respect to a State, the Secretary shall incorporate the requirement that the organization (and Medicare+Choice plans it offers) comply with standards under clause (i) as part of the contract between the Secretary and the organization under section 1395w–27 of this title.

(iii) Enforcement

In the case of such a waiver granted to an organization with respect to a State, the Secretary may enter into an agreement with the State under which the State agrees to provide for monitoring and enforcement activities with respect to compliance of such an organization and its Medicare+Choice plans with such stand-

ards. Such monitoring and enforcement shall be conducted by the State in the same manner as the State enforces such standards with respect to other Medicare+Choice organizations and plans, without discrimination based on the type of organization to which the standards apply. Such an agreement shall specify or establish mechanisms by which compliance activities are undertaken, while not lengthening the time required to review and process applications for waivers under this paragraph.

(H) Report

By not later than December 31, 2001, the Secretary shall submit to the Committee on Ways and Means and the Committee on Commerce of the House of Representatives and the Committee on Finance of the Senate a report regarding whether the waiver process under this paragraph should be continued after December 31, 2002. In making such recommendation, the Secretary shall consider, among other factors, the impact of such process on beneficiaries and on the long-term solvency of the program under this subchapter.

(3) Licensure does not substitute for or constitute certification

The fact that an organization is licensed in accordance with paragraph (1) does not deem the organization to meet other requirements imposed under this part.

(b) Assumption of full financial risk

The Medicare+Choice organization shall assume full financial risk on a prospective basis for the provision of the health care services for which benefits are required to be provided under section 1395w–22(a)(1) of this title, except that the organization—

(1) may obtain insurance or make other arrangements for the cost of providing to any enrolled member such services the aggregate value of which exceeds such aggregate level as the Secretary specifies from time to time,

(2) may obtain insurance or make other arrangements for the cost of such services provided to its enrolled members other than through the organization because medical necessity required their provision before they could be secured through the organization,

(3) may obtain insurance or make other arrangements for not more than 90 percent of the amount by which its costs for any of its fiscal years exceed 115 percent of its income for such fiscal year, and

(4) may make arrangements with physicians or other health care professionals, health care institutions, or any combination of such individuals or institutions to assume all or part of the financial risk on a prospective basis for the provision of basic health services by the physicians or other health professionals or through the institutions.

(c) Certification of provision against risk of insolvency for unlicensed PSOs

(1) In general

Each Medicare+Choice organization that is a provider-sponsored organization, that is not licensed by a State under subsection (a), and for which a waiver application has been approved under subsection (a)(2), shall meet standards established under section 1395w–26(a) of this title relating to the financial solvency and capital adequacy of the organization.

(2) Certification process for solvency standards for PSOs

The Secretary shall establish a process for the receipt and approval of applications of a provider-sponsored organization described in paragraph (1) for certification (and periodic recertification) of the organization as meeting such solvency standards. Under such process, the Secretary shall act upon such a certification application not later than 60 days after the date the application has been received.

(d) "Provider-sponsored organization" defined

(1) In general

In this part, the term ''provider-sponsored organization'' means a public or private entity—

(A) that is established or organized, and operated, by a health care provider, or group of affiliated health care providers,

(B) that provides a substantial proportion (as defined by the Secretary in accordance with paragraph (2)) of the health care items and services under the contract under this part directly through the provider or affiliated group of providers, and

(C) with respect to which the affiliated providers share, directly or indirectly, substantial financial risk with respect to the provision of such items and services and have at least a majority financial interest in the entity.

(2) Substantial proportion

In defining what is a ''substantial proportion'' for purposes of paragraph (1)(B), the Secretary—

(A) shall take into account the need for such an organization to assume responsibility for providing—

(i) significantly more than the majority of the items and services under the contract under this section through its own affiliated providers; and

(ii) most of the remainder of the items and services under the contract through providers with which the organization has an agreement to provide such items and services,

in order to assure financial stability and to address the practical considerations involved in integrating the delivery of a wide range of service providers;

(B) shall take into account the need for such an organization to provide a limited proportion of the items and services under the contract through providers that are neither affiliated with nor have an agreement with the organization; and

(C) may allow for variation in the definition of substantial proportion among such organizations based on relevant differences among the organizations, such as their location in an urban or rural area.

(3) Affiliation

For purposes of this subsection, a provider is ''affiliated'' with another provider if, through contract, ownership, or otherwise—

(A) one provider, directly or indirectly, controls, is controlled by, or is under common control with the other,

(B) both providers are part of a controlled group of corporations under section 1563 of the Internal Revenue Code of 1986,

(C) each provider is a participant in a lawful combination under which each provider shares substantial financial risk in connection with the organization's operations, or

(D) both providers are part of an affiliated service group under section 414 of such Code.

(4) Control

For purposes of paragraph (3), control is presumed to exist if one party, directly or indirectly, owns, controls, or holds the power to vote, or proxies for, not less than 51 percent of the voting rights or governance rights of another.

(5) "Health care provider" defined

In this subsection, the term ''health care provider'' means—

(A) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, and

(B) any entity that is engaged in the delivery of health care services in a State and that, if it is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, is so licensed.

(6) Regulations

The Secretary shall issue regulations to carry out this subsection.

(Aug. 14, 1935, ch. 531, title XVIII, § 1855, as added Pub. L. 105–33, title IV, § 4001, Aug. 5, 1997, 111 Stat. 312.)

Editorial Notes

REFERENCES IN TEXT

The Internal Revenue Code of 1986, referred to in subsec. (d)(3)(B), (D), is classified generally to Title 26, Internal Revenue Code.

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.

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

§ 1395w–26. Establishment of standards

(a) Establishment of solvency standards for provider-sponsored organizations

(1) Establishment

(A) In general

The Secretary shall establish, on an expedited basis and using a negotiated rulemaking process under subchapter III of chapter 5 of title 5, standards described in section 1395w–25(c)(1) of this title (relating to the financial solvency and capital adequacy of the organization) that entities must meet to qualify as provider-sponsored organizations under this part.

(B) Factors to consider for solvency standards

In establishing solvency standards under subparagraph (A) for provider-sponsored organizations, the Secretary shall consult with interested parties and shall take into account—

(i) the delivery system assets of such an organization and ability of such an organization to provide services directly to enrollees through affiliated providers,

(ii) alternative means of protecting against insolvency, including reinsurance, unrestricted surplus, letters of credit, guarantees, organizational insurance coverage, partnerships with other licensed entities, and valuation attributable to the ability of such an organization to meet its service obligations through direct delivery of care, and

(iii) any standards developed by the National Association of Insurance Commissioners specifically for risk-based health care delivery organizations.

(C) Enrollee protection against insolvency

Such standards shall include provisions to prevent enrollees from being held liable to any person or entity for the Medicare+Choice organization's debts in the event of the organization's insolvency.

(2) Publication of notice

In carrying out the rulemaking process under this subsection, the Secretary, after consultation with the National Association of Insurance Commissioners, the American Academy of Actuaries, organizations representative of medicare beneficiaries, and other interested parties, shall publish the notice provided for under section 564(a) of title 5 by not later than 45 days after August 5, 1997.

(3) Target date for publication of rule

As part of the notice under paragraph (2), and for purposes of this subsection, the ''target date for publication'' (referred to in section 564(a)(5) of such title) shall be April 1, 1998.

(4) Abbreviated period for submission of comments

In applying section 564(c) of such title under this subsection, ''15 days'' shall be substituted for ''30 days''.

(5) Appointment of negotiated rulemaking committee and facilitator

The Secretary shall provide for—