

cation 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.)

REFERENCES IN TEXT

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

CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate 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 rule-making 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—

(A) the appointment of a negotiated rulemaking committee under section 565(a) of such title by not later than 30 days after the end of the comment period provided for under section 564(c) of such title (as shortened under paragraph (4)), and

(B) the nomination of a facilitator under section 566(c) of such title by not later than 10 days after the date of appointment of the committee.

(6) Preliminary committee report

The negotiated rulemaking committee appointed under paragraph (5) shall report to the Secretary, by not later than January 1, 1998, regarding the committee's progress on achieving a consensus with regard to the rulemaking proceeding and whether such consensus is likely to occur before 1 month before the target date for publication of the rule. If the committee reports that the committee has failed

to make significant progress towards such consensus or is unlikely to reach such consensus by the target date, the Secretary may terminate such process and provide for the publication of a rule under this subsection through such other methods as the Secretary may provide.

(7) Final committee report

If the committee is not terminated under paragraph (6), the rulemaking committee shall submit a report containing a proposed rule by not later than 1 month before the target date of publication.

(8) Interim, final effect

The Secretary shall publish a rule under this subsection in the Federal Register by not later than the target date of publication. Such rule shall be effective and final immediately on an interim basis, but is subject to change and revision after public notice and opportunity for a period (of not less than 60 days) for public comment. In connection with such rule, the Secretary shall specify the process for the timely review and approval of applications of entities to be certified as provider-sponsored organizations pursuant to such rules and consistent with this subsection.

(9) Publication of rule after public comment

The Secretary shall provide for consideration of such comments and republication of such rule by not later than 1 year after the target date of publication.

(b) Establishment of other standards

(1) In general

The Secretary shall establish by regulation other standards (not described in subsection (a) of this section) for Medicare+Choice organizations and plans consistent with, and to carry out, this part. The Secretary shall publish such regulations by June 1, 1998. In order to carry out this requirement in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

(2) Use of current standards

Consistent with the requirements of this part, standards established under this subsection shall be based on standards established under section 1395mm of this title to carry out analogous provisions of such section.

(3) Relation to State laws

The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to MA plans which are offered by MA organizations under this part.

(4) Prohibition of midyear implementation of significant new regulatory requirements

The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a Medicare+Choice organization or plan.

(Aug. 14, 1935, ch. 531, title XVIII, § 1856, as added Pub. L. 105-33, title IV, § 4001, Aug. 5, 1997, 111

Stat. 317; amended Pub. L. 106-554, §1(a)(6) [title VI, §§612(a), 614(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A-560; Pub. L. 108-173, title II, §232(a), Dec. 8, 2003, 117 Stat. 2208.)

AMENDMENTS

2003—Subsec. (b)(3). Pub. L. 108-173 reenacted heading without change and amended text generally. Prior to amendment, text consisted of subpars. (A) and (B) stating general rule and listing standards specifically superseded.

2000—Subsec. (b)(3)(B)(i). Pub. L. 106-554, §1(a)(6) [title VI, §614(a)(1)], inserted “(including cost-sharing requirements)” after “Benefit requirements”.

Subsec. (b)(3)(B)(iv). Pub. L. 106-554, §1(a)(6) [title VI, §614(a)(2)], added cl. (iv).

Subsec. (b)(4). Pub. L. 106-554, §1(a)(6) [title VI, §612(a)], added par. (4).

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 2000 AMENDMENT

Pub. L. 106-554, §1(a)(6) [title VI, §612(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A-560, provided that: “The amendment made by subsection (a) [amending this section] takes effect on the date of the enactment of this Act [Dec. 21, 2000].”

Pub. L. 106-554, §1(a)(6) [title VI, §614(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A-561, provided that: “The amendments made by subsection (a) [amending this section] take effect on the date of the enactment of this Act [Dec. 21, 2000].”

§ 1395w-27. Contracts with Medicare+Choice organizations

(a) In general

The Secretary shall not permit the election under section 1395w-21 of this title of a Medicare+Choice plan offered by a Medicare+Choice organization under this part, and no payment shall be made under section 1395w-23 of this title to an organization, unless the Secretary has entered into a contract under this section with the organization with respect to the offering of such plan. Such a contract with an organization may cover more than 1 Medicare+Choice plan. Such contract shall provide that the organization agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(b) Minimum enrollment requirements

(1) In general

Subject to paragraph (2), the Secretary may not enter into a contract under this section with a Medicare+Choice organization unless the organization has—

(A) at least 5,000 individuals (or 1,500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the organization, or

(B) at least 1,500 individuals (or 500 individuals in the case of an organization that is a provider-sponsored organization) who are receiving health benefits through the orga-

nization if the organization primarily serves individuals residing outside of urbanized areas.

(2) Application to MSA plans

In applying paragraph (1) in the case of a Medicare+Choice organization that is offering an MSA plan, paragraph (1) shall be applied by substituting covered lives for individuals.

(3) Allowing transition

The Secretary may waive the requirement of paragraph (1) during the first 3 contract years with respect to an organization.

(c) Contract period and effectiveness

(1) Period

Each contract under this section shall be for a term of at least 1 year, as determined by the Secretary, and may be made automatically renewable from term to term in the absence of notice by either party of intention to terminate at the end of the current term.

(2) Termination authority

In accordance with procedures established under subsection (h) of this section, the Secretary may at any time terminate any such contract if the Secretary determines that the organization—

(A) has failed substantially to carry out the contract;

(B) is carrying out the contract in a manner inconsistent with the efficient and effective administration of this part; or

(C) no longer substantially meets the applicable conditions of this part.

(3) Effective date of contracts

The effective date of any contract executed pursuant to this section shall be specified in the contract, except that in no case shall a contract under this section which provides for coverage under an MSA plan be effective before January 1999 with respect to such coverage.

(4) Previous terminations

(A) In general

The Secretary may not enter into a contract with a Medicare+Choice organization if a previous contract with that organization under this section was terminated at the request of the organization within the preceding 2-year period, except as provided in subparagraph (B) and except in such other circumstances which warrant special consideration, as determined by the Secretary.

(B) Earlier re-entry permitted where change in payment policy

Subparagraph (A) shall not apply with respect to the offering by a Medicare+Choice organization of a Medicare+Choice plan in a Medicare+Choice payment area if during the 6-month period beginning on the date the organization notified the Secretary of the intention to terminate the most recent previous contract, there was a legislative change enacted (or a regulatory change adopted) that has the effect of increasing payment amounts under section 1395w-23 of this title for that Medicare+Choice payment area.