(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)) 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.)

Editorial Notes

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).

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 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 organization 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), the Secretary may at any time terminate any such contract if the Secretary determines that the organization—

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

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

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

(3) Effective date of contracts

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

(4) Previous terminations

(A) In general

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

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

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

(5) Contracting authority

The authority vested in the Secretary by this part may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this subchapter.

(d) Protections against fraud and beneficiary protections

(1) Periodic auditing

The Secretary shall provide for the annual auditing of the financial records (including data relating to medicare utilization and costs, including allowable costs under section 1395w–27a(c) of this title) of at least one-third of the Medicare+Choice organizations offering Medicare+Choice plans under this part. The Comptroller General shall monitor auditing activities conducted under this subsection.

(2) Inspection and audit

Each contract under this section shall provide that the Secretary, or any person or organization designated by the Secretary—

(A) shall have the right to timely inspect or otherwise evaluate (i) the quality, appropriateness, and timeliness of services performed under the contract, and (ii) the facilities of the organization when there is reasonable evidence of some need for such inspection, and

(B) shall have the right to timely audit and inspect any books and records of the Medicare+Choice organization that pertain (i) to the ability of the organization to bear the risk of potential financial losses, or (ii) to services performed or determinations of amounts payable under the contract.

(3) Enrollee notice at time of termination

Each contract under this section shall require the organization to provide (and pay for) written notice in advance of the contract's termination, as well as a description of alternatives for obtaining benefits under this sub-

chapter, to each individual enrolled with the organization under this part.

(4) Disclosure

(A) In general

Each Medicare+Choice organization shall, in accordance with regulations of the Secretary, report to the Secretary financial information which shall include the following:

(i) Such information as the Secretary may require demonstrating that the organization has a fiscally sound operation.

(ii) A copy of the report, if any, filed with the Secretary containing the information required to be reported under section 1320a–3 of this title by disclosing entities.

(iii) A description of transactions, as specified by the Secretary, between the organization and a party in interest. Such transactions shall include—

(I) any sale or exchange, or leasing of any property between the organization and a party in interest;

(II) any furnishing for consideration of goods, services (including management services), or facilities between the organization and a party in interest, but not including salaries paid to employees for services provided in the normal course of their employment and health services provided to members by hospitals and other providers and by staff, medical group (or groups), individual practice association (or associations), or any combination thereof; and

(III) any lending of money or other extension of credit between an organization and a party in interest.

The Secretary may require that information reported respecting an organization which controls, is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(B) "Party in interest" defined

For the purposes of this paragraph, the term ''party in interest'' means—

(i) any director, officer, partner, or employee responsible for management or administration of a Medicare+Choice organization, any person who is directly or indirectly the beneficial owner of more than 5 percent of the equity of the organization, any person who is the beneficial owner of a mortgage, deed of trust, note, or other interest secured by, and valuing more than 5 percent of the organization, and, in the case of a Medicare+Choice organization organized as a nonprofit corporation, an incorporator or member of such corporation under applicable State corporation law;

(ii) any entity in which a person described in clause (i)—

(I) is an officer or director;

(II) is a partner (if such entity is organized as a partnership);

(III) has directly or indirectly a beneficial interest of more than 5 percent of the equity; or

(IV) has a mortgage, deed of trust, note, or other interest valuing more than 5 percent of the assets of such entity;

(iii) any person directly or indirectly controlling, controlled by, or under common control with an organization; and

(iv) any spouse, child, or parent of an individual described in clause (i).

(C) Access to information

Each Medicare+Choice organization shall make the information reported pursuant to subparagraph (A) available to its enrollees upon reasonable request.

(5) Loan information

The contract shall require the organization to notify the Secretary of loans and other special financial arrangements which are made between the organization and subcontractors, affiliates, and related parties.

(6) Review to ensure compliance with care management requirements for specialized Medicare Advantage plans for special needs individuals

In conjunction with the periodic audit of a specialized Medicare Advantage plan for special needs individuals under paragraph (1), the Secretary shall conduct a review to ensure that such organization offering the plan meets the requirements described in section 1395w–28(f)(5) of this title.

(e) Additional contract terms

(1) In general

The contract shall contain such other terms and conditions not inconsistent with this part (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.

(2) Cost-sharing in enrollment-related costs

(A) In general

A Medicare+Choice organization and a PDP sponsor under part D shall pay the fee established by the Secretary under subparagraph (B).

(B) Authorization

The Secretary is authorized to charge a fee to each Medicare+Choice organization with a contract under this part and each PDP sponsor with a contract under part D that is equal to the organization's or sponsor's pro rata share (as determined by the Secretary) of the aggregate amount of fees which the Secretary is directed to collect in a fiscal year. Any amounts collected shall be available without further appropriation to the Secretary for the purpose of carrying out section 1395w–21 of this title (relating to enrollment and dissemination of information), section 1395w–101(c) of this title, and section 1395b–4 of this title (relating to the health insurance counseling and assistance program).

(C) Authorization of appropriations

There are authorized to be appropriated for the purposes described in subparagraph

(B) for each fiscal year beginning with fiscal year 2001 and ending with fiscal year 2005 an amount equal to $100,000,000, and for each fiscal year beginning with fiscal year 2006 an amount equal to $200,000,000, reduced by the amount of fees authorized to be collected under this paragraph and section 1395w–112(b)(3)(D) of this title for the fiscal year.

(D) Limitation

In any fiscal year the fees collected by the Secretary under subparagraph (B) shall not exceed the lesser of—

(i) the estimated costs to be incurred by the Secretary in the fiscal year in carrying out the activities described in section 1395w–21 of this title and section 1395w–101(c) of this title and section 1395b–4 of this title; or

(ii)(I) $200,000,000 in fiscal year 1998;

(II) $150,000,000 in fiscal year 1999;

(III) $100,000,000 in fiscal year 2000;

(IV) the Medicare+Choice portion (as defined in subparagraph (E)) of $100,000,000 in fiscal year 2001 and each succeeding fiscal year before fiscal year 2006; and

(V) the applicable portion (as defined in subparagraph (F)) of $200,000,000 in fiscal year 2006 and each succeeding fiscal year.

(E) Medicare+Choice portion defined

In this paragraph, the term ''Medicare+Choice portion'' means, for a fiscal year, the ratio, as estimated by the Secretary, of—

(i) the average number of individuals enrolled in Medicare+Choice plans during the fiscal year, to

(ii) the average number of individuals entitled to benefits under part A, and enrolled under part B, during the fiscal year.

(F) Applicable portion defined

In this paragraph, the term ''applicable portion'' means, for a fiscal year—

(i) with respect to MA organizations, the Secretary's estimate of the total proportion of expenditures under this subchapter that are attributable to expenditures made under this part (including payments under part D that are made to such organizations); or

(ii) with respect to PDP sponsors, the Secretary's estimate of the total proportion of expenditures under this subchapter that are attributable to expenditures made to such sponsors under part D.

(3) Agreements with federally qualified health centers

(A) Payment levels and amounts

A contract under this section with an MA organization shall require the organization to provide, in any written agreement described in section 1395w–23(a)(4) of this title between the organization and a federally qualified health center, for a level and amount of payment to the federally qualified health center for services provided by such health center that is not less than the level and amount of payment that the plan would make for such services if the services had been furnished by a entity providing similar services that was not a federally qualified health center.

(B) Cost-sharing

Under the written agreement referred to in subparagraph (A), a federally qualified health center must accept the payment amount referred to in such subparagraph plus the Federal payment provided for in section 1395*l*(a)(3)(B) of this title as payment in full for services covered by the agreement, except that such a health center may collect any amount of cost-sharing permitted under the contract under this section, so long as the amounts of any deductible, coinsurance, or copayment comply with the requirements under section 1395w–24(e) of this title.

(4) Requirement for minimum medical loss ratio

If the Secretary determines for a contract year (beginning with 2014) that an MA plan has failed to have a medical loss ratio of at least .85—

(A) the MA plan shall remit to the Secretary an amount equal to the product of—

(i) the total revenue of the MA plan under this part for the contract year; and

(ii) the difference between .85 and the medical loss ratio;

(B) for 3 consecutive contract years, the Secretary shall not permit the enrollment of new enrollees under the plan for coverage during the second succeeding contract year; and

(C) the Secretary shall terminate the plan contract if the plan fails to have such a medical loss ratio for 5 consecutive contract years.

(5) Communicating plan corrective actions against opioids over-prescribers

(A) In general

Beginning with plan years beginning on or after January 1, 2021, a contract under this section with an MA organization shall require the organization to submit to the Secretary, through the process established under subparagraph (B), information on the investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier related to fraud, and other actions taken by such plans related to inappropriate prescribing of opioids.

(B) Process

Not later than January 1, 2021, the Secretary shall, in consultation with stakeholders, establish a process under which MA plans and prescription drug plans shall submit to the Secretary information described in subparagraph (A).

(C) Regulations

For purposes of this paragraph, including as applied under section 1395w–112(b)(3)(D) of this title, the Secretary shall, pursuant to rulemaking—

(i) specify a definition for the term ''inappropriate prescribing'' and a method for determining if a provider of services prescribes inappropriate prescribing; and

(ii) establish the process described in subparagraph (B) and the types of information that shall be submitted through such process.

(f) Prompt payment by Medicare+Choice organization

(1) Requirement

A contract under this part shall require a Medicare+Choice organization to provide prompt payment (consistent with the provisions of sections 1395h(c)(2) and 1395u(c)(2) of this title) of claims submitted for services and supplies furnished to enrollees pursuant to the contract, if the services or supplies are not furnished under a contract between the organization and the provider or supplier (or in the case of a Medicare+Choice private fee-for-service plan, if a claim is submitted to such organization by an enrollee).

(2) Secretary's option to bypass noncomplying organization

In the case of a Medicare+Choice eligible organization which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with paragraph (1), the Secretary may provide for direct payment of the amounts owed to providers and suppliers (or, in the case of a Medicare+Choice private fee-for-service plan, amounts owed to the enrollees) for covered services and supplies furnished to individuals enrolled under this part under the contract. If the Secretary provides for the direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this part to reflect the amount of the Secretary's payments (and the Secretary's costs in making the payments).

(3) Incorporation of certain prescription drug plan contract requirements

The following provisions shall apply to contracts with a Medicare Advantage organization offering an MA–PD plan in the same manner as they apply to contracts with a PDP sponsor offering a prescription drug plan under part D:

(A) Prompt payment

Section 1395w–112(b)(4) of this title.

(B) Submission of claims by pharmacies located in or contracting with long-term care facilities

Section 1395w–112(b)(5) of this title.

(C) Regular update of prescription drug pricing standard

Section 1395w–112(b)(6) of this title.

(D) Suspension of payments pending investigation of credible allegations of fraud by pharmacies

Section 1395w–112(b)(7) of this title.

(E) Provision of information related to maximum fair prices

Section 1395w–112(b)(8) of this title.

(g) Intermediate sanctions

(1) In general

If the Secretary determines that a Medicare+Choice organization with a contract under this section—

(A) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(B) imposes premiums on individuals enrolled under this part in excess of the amount of the Medicare+Choice monthly basic and supplemental beneficiary premiums permitted under section 1395w–24 of this title;

(C) acts to expel or to refuse to re-enroll an individual in violation of the provisions of this part;

(D) engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this part) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(E) misrepresents or falsifies information that is furnished—

(i) to the Secretary under this part, or

(ii) to an individual or to any other entity under this part;

(F) fails to comply with the applicable requirements of section 1395w–22(j)(3) or 1395w–22(k)(2)(A)(ii) of this title;

(G) employs or contracts with any individual or entity that is excluded from participation under this subchapter under section 1320a–7 or 1320a–7a of this title for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services;

(H) except as provided under subparagraph (C) or (D) of section 1395w–101(b)(1) of this title, enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual;

(I) transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission;

(J) fails to comply with marketing restrictions described in subsections (h) and (j) of section 1395w–21 of this title or applicable implementing regulations or guidance; or

(K) employs or contracts with any individual or entity who engages in the conduct described in subparagraphs (A) through (J) of this paragraph;

the Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2). The Secretary may provide, in addition to any other remedies authorized by law, for any of

the remedies described in paragraph (2), if the Secretary determines that any employee or agent of such organization, or any provider or supplier who contracts with such organization, has engaged in any conduct described in subparagraphs (A) through (K) of this paragraph.

(2) Remedies

The remedies described in this paragraph are—

(A) civil money penalties of not more than $25,000 for each determination under paragraph (1) or, with respect to a determination under subparagraph (D) or (E)(i) of such paragraph, of not more than $100,000 for each such determination, except with respect to a determination under subparagraph (E),[1] an assessment of not more than the amount claimed by such plan or plan sponsor based upon the misrepresentation or falsified information involved, plus, with respect to a determination under paragraph (1)(B), double the excess amount charged in violation of such paragraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under paragraph (1)(D), $15,000 for each individual not enrolled as a result of the practice involved,

(B) suspension of enrollment of individuals under this part after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur, or

(C) suspension of payment to the organization under this part for individuals enrolled after the date the Secretary notifies the organization of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

(3) Other intermediate sanctions

In the case of a Medicare+Choice organization for which the Secretary makes a determination under subsection (c)(2) the basis of which is not described in paragraph (1), the Secretary may apply the following intermediate sanctions:

(A) Civil money penalties of not more than $25,000 for each determination under subsection (c)(2) if the deficiency that is the basis of the determination has directly adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.

(B) Civil money penalties of not more than $10,000 for each week beginning after the initiation of civil money penalty procedures by the Secretary during which the deficiency that is the basis of a determination under subsection (c)(2) exists.

(C) Suspension of enrollment of individuals under this part after the date the Secretary notifies the organization of a determination under subsection (c)(2) and until the Secretary is satisfied that the deficiency that is the basis for the determination has been corrected and is not likely to recur.

(D) Civil monetary penalties of not more than $100,000, or such higher amount as the Secretary may establish by regulation, where the finding under subsection (c)(2)(A) is based on the organization's termination of its contract under this section other than at a time and in a manner provided for under subsection (a).

(4) Civil money penalties

The provisions of section 1320a–7a (other than subsections (a) and (b)) of this title shall apply to a civil money penalty under paragraph (2) or (3) in the same manner as they apply to a civil money penalty or proceeding under section 1320a–7a(a) of this title.

(h) Procedures for termination

(1) In general

The Secretary may terminate a contract with a Medicare+Choice organization under this section in accordance with formal investigation and compliance procedures established by the Secretary under which—

(A) the Secretary provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Secretary's determination under subsection (c)(2); and

(B) the Secretary provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before terminating the contract.

(2) Exception for imminent and serious risk to health

Paragraph (1) shall not apply if the Secretary determines that a delay in termination, resulting from compliance with the procedures specified in such paragraph prior to termination, would pose an imminent and serious risk to the health of individuals enrolled under this part with the organization.

(3) Delay in contract termination authority for plans failing to achieve minimum quality rating

During the period beginning on December 13, 2016, and through the end of plan year 2018, the Secretary may not terminate a contract under this section with respect to the offering of an MA plan by a Medicare Advantage organization solely because the MA plan has failed to achieve a minimum quality rating under the 5-star rating system under section 1395w–23(*o*)(4) of this title.

(i) Medicare+Choice program compatibility with employer or union group health plans

(1) Contracts with MA organizations

To facilitate the offering of Medicare+Choice plans under contracts between Medicare+Choice organizations and employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination there-

[1] So in original. Probably means subpar. (E) of par. (1).

of) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such Medicare+Choice plans.

(2) Employer sponsored MA plans

To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such MA plans. Notwithstanding section 1395w–21(g) of this title, an MA plan described in the previous sentence may restrict the enrollment of individuals under this part to individuals who are beneficiaries and participants in such plan.

(Aug. 14, 1935, ch. 531, title XVIII, § 1857, as added Pub. L. 105–33, title IV, § 4001, Aug. 5, 1997, 111 Stat. 319; amended Pub. L. 106–113, div. B, § 1000(a)(6) [title V, §§ 513(a), (b)(1), 522(a)], Nov. 29, 1999, 113 Stat. 1536, 1501A–383, 1501A–387; Pub. L. 106–554, § 1(a)(6) [title VI, §§ 617(a), 623(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–561, 2763A–566; Pub. L. 108–173, title II, §§ 222(j), (k), (*l*)(3)(C), 237(c), title IX, § 900(e)(1)(I), Dec. 8, 2003, 117 Stat. 2205, 2207, 2213, 2372; Pub. L. 110–275, title I, §§ 164(d)(2), 171(b), 172(a)(2), 173(b), July 15, 2008, 122 Stat. 2574, 2580, 2581; Pub. L. 111–148, title VI, § 6408(b), Mar. 23, 2010, 124 Stat. 771; Pub. L. 111–152, title I, § 1103, Mar. 30, 2010, 124 Stat. 1047; Pub. L. 114–255, div. C, title XVII, § 17001(b), Dec. 13, 2016, 130 Stat. 1330; Pub. L. 115–271, title II, § 2008(b), title VI, § 6063(b), Oct. 24, 2018, 132 Stat. 3931, 3988; Pub. L. 117–169, title I, § 11001(b)(1)(F)(ii), Aug. 16, 2022, 136 Stat. 1853.)

Editorial Notes

AMENDMENTS

2022—Subsec. (f)(3)(E). Pub. L. 117–169 added subpar. (E).

2018—Subsec. (e)(5). Pub. L. 115–271, § 6063(b), added par. (5).

Subsec. (f)(3)(D). Pub. L. 115–271, § 2008(b), added subpar. (D).

2016—Subsec. (h)(3). Pub. L. 114–255 added par. (3).

2010—Subsec. (d)(2)(A). Pub. L. 111–148, § 6408(b)(1)(A), inserted ''timely'' before ''inspect''.

Subsec. (d)(2)(B). Pub. L. 111–148, § 6408(b)(1)(B), inserted ''timely'' before ''audit and inspect''.

Subsec. (e)(4). Pub. L. 111–152 added par. (4).

Subsec. (g)(1). Pub. L. 111–148, § 6408(b)(2)(C), inserted at end of concluding provisions ''The Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2), if the Secretary determines that any employee or agent of such organization, or any provider or supplier who contracts with such organization, has engaged in any conduct described in subparagraphs (A) through (K) of this paragraph.''

Subsec. (g)(1)(H) to (K). Pub. L. 111–148, § 6408(b)(2), added subpars. (H) to (K).

Subsec. (g)(2)(A). Pub. L. 111–148, § 6408(b)(3), inserted ''except with respect to a determination under subparagraph (E), an assessment of not more than the amount claimed by such plan or plan sponsor based upon the misrepresentation or falsified information involved,'' after ''for each such determination,''.

2008—Subsec. (d)(6). Pub. L. 110–275, § 164(d)(2), added par. (6).

Subsec. (f)(3). Pub. L. 110–275, § 171(b), added par. (3).

Subsec. (f)(3)(B). Pub. L. 110–275, § 172(a)(2), added subpar. (B).

Subsec. (f)(3)(C). Pub. L. 110–275, § 173(b), added subpar. (C).

2003—Subsec. (d)(1). Pub. L. 108–173, § 222(*l*)(3)(C), substituted ''and costs, including allowable costs under section 1395w–27a(c) of this title'' for '', costs, and computation of the adjusted community rate''.

Subsec. (d)(4)(A)(ii). Pub. L. 108–173, § 900(e)(1)(I), substituted ''Secretary'' for ''Health Care Financing Administration''.

Subsec. (e)(2)(A). Pub. L. 108–173, § 222(k)(1), inserted ''and a PDP sponsor under part D'' after ''organization''.

Subsec. (e)(2)(B). Pub. L. 108–173, § 222(k)(2), inserted ''and each PDP sponsor with a contract under part D'' after ''contract under this part'', ''or sponsor's'' after ''organization's'', and '', section 1395w–101(c) of this title,'' after ''information)''.

Subsec. (e)(2)(C). Pub. L. 108–173, § 222(k)(3), inserted ''and ending with fiscal year 2005'' after ''beginning with fiscal year 2001'', ''and for each fiscal year beginning with fiscal year 2006 an amount equal to $200,000,000,'' after ''$100,000,000,'', and ''and section 1395w–112(b)(3)(D) of this title'' after ''under this paragraph''.

Subsec. (e)(2)(D)(i). Pub. L. 108–173, § 222(k)(4)(A), inserted ''and section 1395w–101(c) of this title'' after ''section 1395w–21 of this title''.

Subsec. (e)(2)(D)(ii)(III). Pub. L. 108–173, § 222(k)(4)(B), struck out ''and'' at end.

Subsec. (e)(2)(D)(ii)(IV). Pub. L. 108–173, § 222(k)(4)(C), substituted ''each succeeding fiscal year before fiscal year 2006; and'' for ''each succeeding fiscal year.''

Subsec. (e)(2)(D)(ii)(V). Pub. L. 108–173, § 222(k)(4)(D), added subcl. (V).

Subsec. (e)(2)(F). Pub. L. 108–173, § 222(k)(5), added subpar. (F).

Subsec. (e)(3). Pub. L. 108–173, § 237(c), added par. (3).

Subsec. (i). Pub. L. 108–173, § 222(j), designated existing provisions as par. (1), inserted heading, and added par. (2).

2000—Subsec. (g)(3)(D). Pub. L. 106–554, § 1(a)(6) [title VI, § 623(a)], added subpar. (D).

Subsec. (i). Pub. L. 106–554, § 1(a)(6) [title VI, § 617(a)], added subsec. (i).

1999—Subsec. (c)(4). Pub. L. 106–113, § 1000(a)(6) [title V, § 513(b)(1)(B), (C)], designated existing provisions as subpar. (A), inserted heading, realigned margins, and added subpar. (B).

Pub. L. 106–113, § 1000(a)(6) [title V, § 513(a), (b)(1)(A)], substituted ''2-year period'' for ''5-year period'' and ''except as provided in subparagraph (B) and except in such other circumstances'' for ''except in circumstances''.

Subsec. (e)(2)(B). Pub. L. 106–113, § 1000(a)(6) [title V, § 522(a)(1)], substituted ''Any amounts collected shall be available without further appropriation to the Secretary for'' for ''Any amounts collected are authorized to be appropriated only for''.

Subsec. (e)(2)(C). Pub. L. 106–113, § 1000(a)(6) [title V, § 522(a)(2)], amended heading and text of subpar. (C) generally. Prior to amendment, text read as follows: ''For any fiscal year, the fees authorized under subparagraph (B) are contingent upon enactment in an appropriations act of a provision specifying the aggregate amount of fees the Secretary is directed to collect in a fiscal year. Fees collected during any fiscal year under this paragraph shall be deposited and credited as offsetting collections.''

Subsec. (e)(2)(D)(ii)(II). Pub. L. 106–113, § 1000(a)(6) [title V, § 522(a)(3)(A)], struck out ''and'' after semicolon.

Subsec. (e)(2)(D)(ii)(III). Pub. L. 106–113, § 1000(a)(6) [title V, § 522(a)(3)(B)], substituted ''; and'' for ''and each subsequent fiscal year.''

Subsec. (e)(2)(D)(ii)(IV). Pub. L. 106–113, §1000(a)(6) [title V, §522(a)(3)(C)], added subcl. (IV).

Subsec. (e)(2)(E). Pub. L. 106–113, §1000(a)(6) [title V, §522(a)(4)], added subpar. (E).

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 2018 AMENDMENT

Pub. L. 115–271, title II, §2008(e), Oct. 24, 2018, 132 Stat. 3931, provided that: ''The amendments made by this section [amending this section and sections 1395w–112 and 1395y of this title] shall apply with respect to plan years beginning on or after January 1, 2020.''

EFFECTIVE DATE OF 2010 AMENDMENT

Amendment by section 6408(b)(1) of Pub. L. 111–148 effective Mar. 23, 2010, and amendment by section 6408(b)(2), (3) of Pub. L. 111–148 applicable to acts committed on or after Jan. 1, 2010, see section 6408(d) of Pub. L. 111–148, set out as a note under section 1320a–7 of this title.

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–275, title I, §164(g), July 15, 2008, 122 Stat. 2575, provided that: ''The amendments made by subsections (c)(1), (d), and (e)(1) [amending this section and section 1395w–28 of this title] shall apply to plan years beginning on or after January 1, 2010, and shall apply to all specialized Medicare Advantage plans for special needs individuals regardless of when the plan first entered the Medicare Advantage program under part C of title XVIII of the Social Security Act [42 U.S.C. 1395w–21 et seq.].''

Pub. L. 110–275, title I, §171(c), July 15, 2008, 122 Stat. 2580, provided that: ''The amendments made by this section [amending this section and section 1395w–112 of this title] shall apply to plan years beginning on or after January 1, 2010.''

Pub. L. 110–275, title I, §172(b), July 15, 2008, 122 Stat. 2581, provided that: ''The amendments made by this section [amending this section and section 1395w–112 of this title] shall apply to plan years beginning on or after January 1, 2010.''

Pub. L. 110–275, title I, §173(c), July 15, 2008, 122 Stat. 2581, provided that: ''The amendments made by this section [amending this section and section 1395w–112 of this title] shall apply to plan years beginning on or after January 1, 2009.''

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 222(j), (k), (*l*)(3)(C) 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.

Amendment by section 237(c) of Pub. L. 108–173 applicable to services provided on or after Jan. 1, 2006, and contract years beginning on or after such date, see section 237(e) of Pub. L. 108–173, set out as a note under section 1320a–7b of this title.

EFFECTIVE DATE OF 2000 AMENDMENT

Pub. L. 106–554, §1(a)(6) [title VI, §617(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–562, provided that: ''The amendment made by subsection (a) [amending this section] shall apply with respect to years beginning with 2001.''

Pub. L. 106–554, §1(a)(6) [title VI, §623(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–566, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to terminations occurring after the date of the enactment of this Act [Dec. 21, 2000].''

EFFECTIVE DATE OF 1999 AMENDMENT

Pub. L. 106–113, div. B, §1000(a)(6) [title V, §513(c)], Nov. 29, 1999, 113 Stat. 1536, 1501A–383, provided that: ''The amendments made by this section [amending this section] apply to contract terminations occurring before, on, or after the date of the enactment of this Act [Nov. 29, 1999].''

Pub. L. 106–113, div. B, §1000(a)(6) [title V, §522(b)], Nov. 29, 1999, 113 Stat. 1536, 1501A–387, provided that: ''The amendments made by subsection (a) [amending this section] apply to fees charged on or after January 1, 2001. The Secretary of Health and Human Services may not increase the fees charged under section 1857(e)(2) of the Social Security Act (42 U.S.C. 1395w–27(e)(2)) for the 3-month period beginning with October 2000 above the level in effect during the previous 9-month period.''

CONSTRUCTION RELATING TO ADDITIONAL EXCEPTIONS

Pub. L. 106–113, div. B, §1000(a)(6) [title V, §513(b)(2)], Nov. 29, 1999, 113 Stat. 1536, 1501A–383, provided that: ''Nothing in the amendment made by paragraph (1)(C) [amending this section] shall be construed to affect the authority of the Secretary of Health and Human Services to provide for exceptions in addition to the exception provided in such amendment, including exceptions provided under Operational Policy Letter #103 (OPL99.103).''

DELAY IN AUTHORITY TO TERMINATE CONTRACTS FOR MEDICARE ADVANTAGE PLANS FAILING TO ACHIEVE MINIMUM QUALITY RATINGS

Pub. L. 114–255, div. C, title XVII, §17001(a), Dec. 13, 2016, 130 Stat. 1330, provided that: ''Consistent with the studies provided under the IMPACT Act of 2014 (Public Law 113–185) [see Tables for classification], it is the intent of Congress—

''(1) to continue to study and request input on the effects of socioeconomic status and dual-eligible populations on the Medicare Advantage STARS rating system before reforming such system with the input of stakeholders; and

''(2) pending the results of such studies and input, to provide for a temporary delay in authority of the Centers for Medicare & Medicaid Services (CMS) to terminate Medicare Advantage plan contracts solely on the basis of performance of plans under the STARS rating system.''

TECHNICAL CORRECTION TO MA PRIVATE FEE-FOR-SERVICE PLANS

Pub. L. 111–148, title III, §3207, Mar. 23, 2010, 124 Stat. 459, provided that: ''For plan year 2011 and subsequent plan years, to the extent that the Secretary of Health and Human Services is applying the 2008 service area extension waiver policy (as modified in the April 11, 2008, Centers for Medicare & Medicaid Services' memorandum with the subject '2009 Employer Group Waiver-Modification of the 2008 Service Area Extension Waiver Granted to Certain MA Local Coordinated Care Plans') to Medicare Advantage coordinated care plans, the Secretary shall extend the application of such waiver policy to employers who contract directly with the Secretary as a Medicare Advantage private fee-for-service plan under section 1857(i)(2) of the Social Security Act (42 U.S.C. 1395w–27(i)(2)) and that had enrollment as of October 1, 2009.''

STUDY OF MULTI-YEAR CONTRACTS

Pub. L. 108–173, title I, §107(d), Dec. 8, 2003, 117 Stat. 2171, directed the Secretary of Health and Human Services to provide for a study on the feasibility and advisability of providing for contracting with PDP sponsors and MA organizations under this part and part D of this subchapter on a multi-year basis, and to submit to Congress a report on such study not later than Jan. 1, 2007.

IMMEDIATE EFFECTIVE DATE FOR CERTAIN REQUIREMENTS FOR DEMONSTRATIONS

Pub. L. 105–33, title IV, § 4002(g), Aug. 5, 1997, 111 Stat. 330, provided that: ''Section 1857(e)(2) of the Social Security Act [42 U.S.C. 1395w–27(e)(2)] (requiring contribution to certain costs related to the enrollment process comparative materials) applies to demonstrations with respect to which enrollment is effected or coordinated under section 1851 of such Act [42 U.S.C. 1395w–21].''

§ 1395w–27a. Special rules for MA regional plans

(a) Regional service area; establishment of MA regions

(1) Coverage of entire MA region

The service area for an MA regional plan shall consist of an entire MA region established under paragraph (2) and the provisions of section 1395w–24(h) of this title shall not apply to such a plan.

(2) Establishment of MA regions

(A) MA region

For purposes of this subchapter, the term ''MA region'' means such a region within the 50 States and the District of Columbia as established by the Secretary under this paragraph.

(B) Establishment

####### (i) Initial establishment

Not later than January 1, 2005, the Secretary shall first establish and publish MA regions.

####### (ii) Periodic review and revision of service areas

The Secretary may periodically review MA regions under this paragraph and, based on such review, may revise such regions if the Secretary determines such revision to be appropriate.

(C) Requirements for MA regions

The Secretary shall establish, and may revise, MA regions under this paragraph in a manner consistent with the following:

####### (i) Number of regions

There shall be no fewer than 10 regions, and no more than 50 regions.

####### (ii) Maximizing availability of plans

The regions shall maximize the availability of MA regional plans to all MA eligible individuals without regard to health status, especially those residing in rural areas.

(D) Market survey and analysis

Before establishing MA regions, the Secretary shall conduct a market survey and analysis, including an examination of current insurance markets, to determine how the regions should be established.

(3) National plan

Nothing in this subsection shall be construed as preventing an MA regional plan from being offered in more than one MA region (including all regions).

(b) Application of single deductible and catastrophic limit on out-of-pocket expenses

An MA regional plan shall include the following:

(1) Single deductible

Any deductible for benefits under the original medicare fee-for-service program option shall be a single deductible (instead of a separate inpatient hospital deductible and a part B deductible) and may be applied differentially for in-network services and may be waived for preventive or other items and services.

(2) Catastrophic limit

(A) In-network

A catastrophic limit on out-of-pocket expenditures for in-network benefits under the original medicare fee-for-service program option.

(B) Total

A catastrophic limit on out-of-pocket expenditures for all benefits under the original medicare fee-for-service program option.

(c) Portion of total payments to an organization subject to risk for 2006 and 2007

(1) Application of risk corridors

(A) In general

This subsection shall only apply to MA regional plans offered during 2006 or 2007.

(B) Notification of allowable costs under the plan

In the case of an MA organization that offers an MA regional plan in an MA region in 2006 or 2007, the organization shall notify the Secretary, before such date in the succeeding year as the Secretary specifies, of—

(i) its total amount of costs that the organization incurred in providing benefits covered under the original medicare fee-for-service program option for all enrollees under the plan in the region in the year and the portion of such costs that is attributable to administrative expenses described in subparagraph (C); and

(ii) its total amount of costs that the organization incurred in providing rebatable integrated benefits (as defined in subparagraph (D)) and with respect to such benefits the portion of such costs that is attributable to administrative expenses described in subparagraph (C) and not described in clause (i) of this subparagraph.

(C) Allowable costs defined

For purposes of this subsection, the term ''allowable costs'' means, with respect to an MA regional plan for a year, the total amount of costs described in subparagraph (B) for the plan and year, reduced by the portion of such costs attributable to administrative expenses incurred in providing the benefits described in such subparagraph.

(D) Rebatable integrated benefits

For purposes of this subsection, the term ''rebatable integrated benefits'' means such non-drug supplemental benefits under subclause (I) of section 1395w–24(b)(1)(C)(ii) of this title pursuant to a rebate under such section that the Secretary determines are integrated with the benefits described in subparagraph (B)(i).