regional plan shall be, subject to the limitation of funds under paragraph (3), the amount (if any) by which—

(A) the amount of payment that would have been paid for such services under this subchapter if the enrollees were covered under the original medicare fee-for-service program option and the hospital were a critical access hospital; exceeds

(B) the amount of payment made for such services under paragraph (1)(A).

(3) Available amounts

There shall be available for payments under this subsection—

(A) in 2006, $25,000,000; and

(B) in each succeeding year the amount specified in this paragraph for the preceding year increased by the market basket percentage increase (as defined in section 1395ww(b)(3)(B)(iii) of this title) for the fiscal year ending in such succeeding year.

Payments under this subsection shall be made from the Federal Hospital Insurance Trust Fund.

(4) Essential hospital

In this subsection, the term ''essential hospital'' means, with respect to an MA regional plan offered by an MA organization, a subsection (d) hospital (as defined in section 1395ww(d) of this title) that the Secretary determines, based upon an application filed by the organization with the Secretary, is necessary to meet the requirements referred to in paragraph (1) for such plan.

(Aug. 14, 1935, ch. 531, title XVIII, § 1858, as added Pub. L. 108–173, title II, § 221(c), Dec. 8, 2003, 117 Stat. 2181; amended Pub. L. 109–432, div. B, title III, § 301, Dec. 20, 2006, 120 Stat. 2990; Pub. L. 110–48, § 3, July 18, 2007, 121 Stat. 244; Pub. L. 110–173, title I, § 110, Dec. 29, 2007, 121 Stat. 2497; Pub. L. 110–275, title I, § 166, July 15, 2008, 122 Stat. 2575; Pub. L. 111–8, div. G, title I, § 1301(f), Mar. 11, 2009, 123 Stat. 829; Pub. L. 111–148, title III, § 3201(a)(2)(C), (f)(2), title X, § 10327(c)(1), Mar. 23, 2010, 124 Stat. 444, 450, 964; Pub. L. 111–152, title I, § 1102(a), Mar. 30, 2010, 124 Stat. 1040.)

Editorial Notes

AMENDMENTS

2010—Subsec. (e). Pub. L. 111–148, § 10327(c)(1), struck out subsec. (e) which related to the MA Regional Plan Stabilization Fund.

Subsec. (f)(1). Pub. L. 111–148, § 3201(a)(2)(C)(i), (f)(2)(A), which directed substitution of ''1395w–23(j)(1)(B)'' for ''1395w–23(j)(2)'' and ''subsections (e) and (i)'' for ''subsection (e)'', respectively, was repealed by Pub. L. 111–152, § 1102(a). See Effective Date of 2010 Amendment note below.

Subsec. (f)(3)(A). Pub. L. 111–148, § 3201(a)(2)(C)(ii), which directed substitution of ''1395w–23(j)(1)(A)(i)'' for ''1395w–23(j)(1)(A)'', was repealed by Pub. L. 111–152, § 1102(a). See Effective Date of 2010 Amendment note below.

Subsec. (i). Pub. L. 111–148, § 3201(f)(2)(B), which directed addition of subsec. (i), was repealed by Pub. L. 111–152, § 1102(a). As enacted, text read as follows: ''For years beginning with 2014, the Secretary shall apply the performance bonuses under section 1395w–23(n) of this title (relating to bonuses for care coordination and management, quality performance, and new and low enrollment MA plans) to MA regional plans in a similar manner as such performance bonuses apply to MA plans under such subsection.'' See Effective Date of 2010 Amendment note below.

2009—Subsec. (e)(7). Pub. L. 111–8 struck out par. (7) which related to biennial GAO reports to be submitted by the Comptroller General to the Secretary and Congress.

2008—Subsec. (e)(2)(A)(i). Pub. L. 110–275 substituted ''2014'' for ''2013'' and ''$1'' for ''$1,790,000,000''.

2007—Subsec. (e)(2)(A)(i). Pub. L. 110–173, which directed substitution of ''the Fund during 2013, $1,790,000,000.'' for ''the Fund'' and all that follows, was executed by making the substitution for ''the Fund—

''(I) during 2012, $1,600,000,000; and

''(II) during 2013, $1,790,000,000.''

to reflect the probable intent of Congress.

Pub. L. 110–48 substituted ''the Fund—

''(I) during 2012, $1,600,000,000; and

''(II) during 2013, $1,790,000,000.''

for ''the Fund during the period beginning on January 1, 2012, and ending on December 31, 2013, a total of $3,500,000,000.''

2006—Subsec. (e)(2)(A)(i). Pub. L. 109–432 substituted ''2012'' for ''2007'' and ''$3,500,000,000'' for ''$10,000,000,000''.

Statutory Notes and Related Subsidiaries

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.

EFFECTIVE DATE

Section 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 an Effective Date of 2003 Amendment note under section 1395w–21 of this title.

ELIMINATION OF MA REGIONAL PLAN STABILIZATION FUND; TRANSITION

Pub. L. 111–148, title X, § 10327(c)(2), Mar. 23, 2010, 124 Stat. 964, provided that: ''Any amount contained in the MA Regional Plan Stabilization Fund as of the date of the enactment of this Act [Mar. 23, 2010] shall be transferred to the Federal Supplementary Medical Insurance Trust Fund.''

§ 1395w–28. Definitions; miscellaneous provisions

(a) Definitions relating to Medicare+Choice organizations

In this part—

(1) Medicare+Choice organization

The term ''Medicare+Choice organization'' means a public or private entity that is certified under section 1395w–26 of this title as meeting the requirements and standards of this part for such an organization.

(2) Provider-sponsored organization

The term ''provider-sponsored organization'' is defined in section 1395w–25(d)(1) of this title.

(b) Definitions relating to Medicare+Choice plans

(1) Medicare+Choice plan

The term ''Medicare+Choice plan'' means health benefits coverage offered under a policy, contract, or plan by a Medicare+Choice organization pursuant to and in accordance with a contract under section 1395w–27 of this title.

(2) Medicare+Choice private fee-for-service plan

The term ''Medicare+Choice private fee-for-service plan'' means a Medicare+Choice plan that—

(A) reimburses hospitals, physicians, and other providers at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

(B) does not vary such rates for such a provider based on utilization relating to such provider; and

(C) does not restrict the selection of providers among those who are lawfully authorized to provide the covered services and agree to accept the terms and conditions of payment established by the plan.

Nothing in subparagraph (B) shall be construed to preclude a plan from varying rates for such a provider based on the specialty of the provider, the location of the provider, or other factors related to such provider that are not related to utilization, or to preclude a plan from increasing rates for such a provider based on increased utilization of specified preventive or screening services.

(3) MSA plan

(A) In general

The term ''MSA plan'' means a Medicare+Choice plan that—

(i) provides reimbursement for at least the items and services described in section 1395w–22(a)(1) of this title in a year but only after the enrollee incurs countable expenses (as specified under the plan) equal to the amount of an annual deductible (described in subparagraph (B));

(ii) counts as such expenses (for purposes of such deductible) at least all amounts that would have been payable under parts A and B, and that would have been payable by the enrollee as deductibles, coinsurance, or copayments, if the enrollee had elected to receive benefits through the provisions of such parts; and

(iii) provides, after such deductible is met for a year and for all subsequent expenses for items and services referred to in clause (i) in the year, for a level of reimbursement that is not less than—

(I) 100 percent of such expenses, or

(II) 100 percent of the amounts that would have been paid (without regard to any deductibles or coinsurance) under parts A and B with respect to such expenses,

whichever is less.

(B) Deductible

The amount of annual deductible under an MSA plan—

(i) for contract year 1999 shall be not more than $6,000; and

(ii) for a subsequent contract year shall be not more than the maximum amount of such deductible for the previous contract year under this subparagraph increased by the national per capita Medicare+Choice growth percentage under section 1395w–23(c)(6) of this title for the year.

If the amount of the deductible under clause (ii) is not a multiple of $50, the amount shall be rounded to the nearest multiple of $50.

(4) MA regional plan

The term ''MA regional plan'' means an MA plan described in section 1395w–21(a)(2)(A)(i) of this title—

(A) that has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan;

(B) that provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers; and

(C) the service area of which is one or more entire MA regions.

(5) MA local plan

The term ''MA local plan'' means an MA plan that is not an MA regional plan.

(6) Specialized MA plans for special needs individuals

(A) In general

The term ''specialized MA plan for special needs individuals'' means an MA plan that exclusively serves special needs individuals (as defined in subparagraph (B)) and that, as of January 1, 2010, meets the applicable requirements of paragraph (2), (3), or (4) of subsection (f), as the case may be.

(B) Special needs individual

The term ''special needs individual'' means an MA eligible individual who—

(i) is institutionalized (as defined by the Secretary);

(ii) is entitled to medical assistance under a State plan under subchapter XIX; or

(iii) meets such requirements as the Secretary may determine would benefit from enrollment in such a specialized MA plan described in subparagraph (A) for individuals with severe or disabling chronic conditions who—

(I) before January 1, 2022, have one or more comorbid and medically complex chronic conditions that are substantially disabling or life threatening, have a high risk of hospitalization or other significant adverse health outcomes, and require specialized delivery systems across domains of care; and

(II) on or after January 1, 2022, have one or more comorbid and medically complex chronic conditions that is life threatening or significantly limits[1] overall health or function, have a high risk of hospitalization or other adverse health outcomes, and require intensive care coordination and that is listed under subsection (f)(9)(A).

The Secretary may apply rules similar to the rules of section 1395eee(c)(4) of this title for continued eligibility of special needs individuals.

[1] So in original. Probably should be ''that are life threatening or significantly limit''.

(c) Other references to other terms

(1) Medicare+Choice eligible individual

The term ''Medicare+Choice eligible individual'' is defined in section 1395w–21(a)(3) of this title.

(2) Medicare+Choice payment area

The term ''Medicare+Choice payment area'' is defined in section 1395w–23(d) of this title.

(3) National per capita Medicare+Choice growth percentage

The ''national per capita Medicare+Choice growth percentage'' is defined in section 1395w–23(c)(6) of this title.

(4) Medicare+Choice monthly basic beneficiary premium; Medicare+Choice monthly supplemental beneficiary premium

The terms ''Medicare+Choice monthly basic beneficiary premium'' and ''Medicare+Choice monthly supplemental beneficiary premium'' are defined in section 1395w–24(a)(2) of this title.

(5) MA local area

The term ''MA local area'' is defined in section 1395w–23(d)(2) of this title.

(d) Coordinated acute and long-term care benefits under Medicare+Choice plan

Nothing in this part shall be construed as preventing a State from coordinating benefits under a medicaid plan under subchapter XIX with those provided under a Medicare+Choice plan in a manner that assures continuity of a full-range of acute care and long-term care services to poor elderly or disabled individuals eligible for benefits under this subchapter and under such plan.

(e) Restriction on enrollment for certain Medicare+Choice plans

(1) In general

In the case of a Medicare+Choice religious fraternal benefit society plan described in paragraph (2), notwithstanding any other provision of this part to the contrary and in accordance with regulations of the Secretary, the society offering the plan may restrict the enrollment of individuals under this part to individuals who are members of the church, convention, or group described in paragraph (3)(B) with which the society is affiliated.

(2) Medicare+Choice religious fraternal benefit society plan described

For purposes of this subsection, a Medicare+Choice religious fraternal benefit society plan described in this paragraph is a Medicare+Choice plan described in section 1395w–21(a)(2) of this title that—

(A) is offered by a religious fraternal benefit society described in paragraph (3) only to members of the church, convention, or group described in paragraph (3)(B); and

(B) permits all such members to enroll under the plan without regard to health status-related factors.

Nothing in this subsection shall be construed as waiving any plan requirements relating to financial solvency.

(3) "Religious fraternal benefit society" defined

For purposes of paragraph (2)(A), a ''religious fraternal benefit society'' described in this section is an organization that—

(A) is described in section 501(c)(8) of the Internal Revenue Code of 1986 and is exempt from taxation under section 501(a) of such Act;

(B) is affiliated with, carries out the tenets of, and shares a religious bond with, a church or convention or association of churches or an affiliated group of churches;

(C) offers, in addition to a Medicare+Choice religious fraternal benefit society plan, health coverage to individuals not entitled to benefits under this subchapter who are members of such church, convention, or group; and

(D) does not impose any limitation on membership in the society based on any health status-related factor.

(4) Payment adjustment

Under regulations of the Secretary, in the case of individuals enrolled under this part under a Medicare+Choice religious fraternal benefit society plan described in paragraph (2), the Secretary shall provide for such adjustment to the payment amounts otherwise established under section 1395w–24 of this title as may be appropriate to assure an appropriate payment level, taking into account the actuarial characteristics and experience of such individuals.

(f) Requirements regarding enrollment in specialized MA plans for special needs individuals

(1) Requirements for enrollment

In the case of a specialized MA plan for special needs individuals (as defined in subsection (b)(6)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs individuals.

(2) Additional requirements for institutional SNPS

In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(i), the applicable requirements described in this paragraph are as follows:

(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individuals described in subsection (b)(6)(B)(i). In the case of an individual who is living in the community but requires an institutional level of care, such individual shall not be considered a special needs individual described in subsection (b)(6)(B)(i) unless the determination that the individual requires an institutional level of care was made—

(i) using a State assessment tool of the State in which the individual resides; and

(ii) by an entity other than the organization offering the plan.

(B) The plan meets the requirements described in paragraph (5).

(C) If applicable, the plan meets the requirement described in paragraph (7).

(3) Additional requirements for dual SNPS

In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii), the applicable requirements described in this paragraph are as follows:

(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individuals[2] described in subsection (b)(6)(B)(ii).

(B) The plan meets the requirements described in paragraph (5).

(C) The plan provides each prospective enrollee, prior to enrollment, with a comprehensive written statement (using standardized content and format established by the Secretary) that describes—

(i) the benefits and cost-sharing protections that the individual is entitled to under the State Medicaid program under subchapter XIX; and

(ii) which of such benefits and cost-sharing protections are covered under the plan.

Such statement shall be included with any description of benefits offered by the plan.

(D) The plan has a contract with the State Medicaid agency to provide benefits, or arrange for benefits to be provided, for which such individual is entitled to receive as medical assistance under subchapter XIX. Such benefits may include long-term care services consistent with State policy.

(E) If applicable, the plan meets the requirement described in paragraph (7).

(F) The plan meets the requirements applicable under paragraph (8).

(4) Additional requirements for severe or disabling chronic condition SNPS

In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(iii), the applicable requirements described in this paragraph are as follows:

(A) Each individual that enrolls in the plan on or after January 1, 2010, is a special needs individual described in subsection (b)(6)(B)(iii).

(B) The plan meets the requirements described in paragraph (5).

(C) If applicable, the plan meets the requirement described in paragraph (7).

(5) Care management requirements for all SNPs

(A) In general

Subject to subparagraph (B), the requirements described in this paragraph are that the organization offering a specialized MA plan for special needs individuals—

(i) have in place an evidenced-based model of care with appropriate networks of providers and specialists; and

(ii) with respect to each individual enrolled in the plan—

(I) conduct an initial assessment and an annual reassessment of the individual's physical, psychosocial, and functional needs;

(II) develop a plan, in consultation with the individual as feasible, that identifies goals and objectives, including measurable outcomes as well as specific services and benefits to be provided; and

(III) use an interdisciplinary team in the management of care.

(B) Improvements to care management requirements for severe or disabling chronic condition SNPs

For 2020 and subsequent years, in the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(iii), the requirements described in this paragraph include the following:

(i) The interdisciplinary team under subparagraph (A)(ii)(III) includes a team of providers with demonstrated expertise, including training in an applicable specialty, in treating individuals similar to the targeted population of the plan.

(ii) Requirements developed by the Secretary to provide face-to-face encounters with individuals enrolled in the plan not less frequently than on an annual basis.

(iii) As part of the model of care under clause (i) of subparagraph (A), the results of the initial assessment and annual reassessment under clause (ii)(I) of such subparagraph of each individual enrolled in the plan are addressed in the individual's individualized care plan under clause (ii)(II) of such subparagraph.

(iv) As part of the annual evaluation and approval of such model of care, the Secretary shall take into account whether the plan fulfilled the previous year's goals (as required under the model of care).

(v) The Secretary shall establish a minimum benchmark for each element of the model of care of a plan. The Secretary shall only approve a plan's model of care under this paragraph if each element of the model of care meets the minimum benchmark applicable under the preceding sentence.

(6) Transition and exception regarding restriction on enrollment

(A) In general

Subject to subparagraph (C), the Secretary shall establish procedures for the transition of applicable individuals to—

(i) a Medicare Advantage plan that is not a specialized MA plan for special needs individuals (as defined in subsection (b)(6)); or

(ii) the original medicare fee-for-service program under parts A and B.

(B) Applicable individuals

For purposes of clause (i), the term ''applicable individual'' means an individual who—

(i) is enrolled under a specialized MA plan for special needs individuals (as defined in subsection (b)(6)); and

(ii) is not within the 1 or more of the classes of special needs individuals to which enrollment under the plan is restricted to.

[2] So in original. Probably should be ''individual''.

(C) Exception

The Secretary shall provide for an exception to the transition described in subparagraph (A) for a limited period of time for individuals enrolled under a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii) who are no longer eligible for medical assistance under subchapter XIX.

(D) Timeline for initial transition

The Secretary shall ensure that applicable individuals enrolled in a specialized MA plan for special needs individuals (as defined in subsection (b)(6)) prior to January 1, 2010, are transitioned to a plan or the program described in subparagraph (A) by not later than January 1, 2013.

(7) Authority to require special needs plans be NCQA approved

For 2012 and subsequent years, the Secretary shall require that a Medicare Advantage organization offering a specialized MA plan for special needs individuals be approved by the National Committee for Quality Assurance (based on standards established by the Secretary).

(8) Increased integration of dual SNPs

(A) Designated contact

The Secretary, acting through the Federal Coordinated Health Care Office established under section 1315b of this title, shall serve as a dedicated point of contact for States to address misalignments that arise with the integration of specialized MA plans for special needs individuals described in subsection (b)(6)(B)(ii) under this paragraph and, consistent with such role, shall establish—

(i) a uniform process for disseminating to State Medicaid agencies information under this subchapter impacting contracts between such agencies and such plans under this subsection; and

(ii) basic resources for States interested in exploring such plans as a platform for integration, such as a model contract or other tools to achieve those goals.

(B) Unified grievances and appeals process

(i) In general

Not later than April 1, 2020, the Secretary shall establish procedures, to the extent feasible as determined by the Secretary, unifying grievances and appeals procedures under sections 1395w–22(f), 1395w–22(g), 1396a(a)(3), 1396a(a)(5), and 1396u–2(b)(4) of this title for items and services provided by specialized MA plans for special needs individuals described in subsection (b)(6)(B)(ii) under this subchapter and subchapter XIX. With respect to items and services described in the preceding sentence, procedures established under this clause shall apply in place of otherwise applicable grievances and appeals procedures. The Secretary shall solicit comment in developing such procedures from States, plans, beneficiaries and their representatives, and other relevant stakeholders.

(ii) Procedures

The procedures established under clause (i) shall be included in the plan contract under paragraph (3)(D) and shall—

(I) adopt the provisions for the enrollee that are most protective for the enrollee and, to the extent feasible as determined by the Secretary, are compatible with unified timeframes and consolidated access to external review under an integrated process;

(II) take into account differences in State plans under subchapter XIX to the extent necessary;

(III) be easily navigable by an enrollee; and

(IV) include the elements described in clause (iii), as applicable.

(iii) Elements described

Both unified appeals and unified grievance procedures shall include, as applicable, the following elements described in this clause:

(I) Single written notification of all applicable grievances and appeal rights under this subchapter and subchapter XIX. For purposes of this subparagraph, the Secretary may waive the requirements under section 1395w–22(g)(1)(B) of this title when the specialized MA plan covers items or services under this part or under subchapter XIX.

(II) Single pathways for resolution of any grievance or appeal related to a particular item or service provided by specialized MA plans for special needs individuals described in subsection (b)(6)(B)(ii) under this subchapter and subchapter XIX.

(III) Notices written in plain language and available in a language and format that is accessible to the enrollee, including in non-English languages that are prevalent in the service area of the specialized MA plan.

(IV) Unified timeframes for grievances and appeals processes, such as an individual's filing of a grievance or appeal, a plan's acknowledgment and resolution of a grievance or appeal, and notification of decisions with respect to a grievance or appeal.

(V) Requirements for how the plan must process, track, and resolve grievances and appeals, to ensure beneficiaries are notified on a timely basis of decisions that are made throughout the grievance or appeals process and are able to easily determine the status of a grievance or appeal.

(iv) Continuation of benefits pending appeal

The unified procedures under clause (i) shall, with respect to all benefits under parts A and B and subchapter XIX subject to appeal under such procedures, incorporate provisions under current law and

implementing regulations that provide continuation of benefits pending appeal under this subchapter and subchapter XIX.

(C) Requirement for unified grievances and appeals

For 2021 and subsequent years, the contract of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii) with a State Medicaid agency under paragraph (3)(D) shall require the use of unified grievances and appeals procedures as described in subparagraph (B).

(D) Requirements for integration

(i) In general

For 2021 and subsequent years, a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii) shall meet one or more of the following requirements, to the extent permitted under State law, for integration of benefits under this subchapter and subchapter XIX:

(I) The specialized MA plan must meet the requirements of contracting with the State Medicaid agency described in paragraph (3)(D) in addition to coordinating long-term services and supports or behavioral health services, or both, by meeting an additional minimum set of requirements determined by the Secretary through the Federal Coordinated Health Care Office established under section 1315b of this title based on input from stakeholders, such as notifying the State in a timely manner of hospitalizations, emergency room visits, and hospital or nursing home discharges of enrollees, assigning one primary care provider for each enrollee, or sharing data that would benefit the coordination of items and services under this subchapter and the State plan under subchapter XIX. Such minimum set of requirements must be included in the contract of the specialized MA plan with the State Medicaid agency under such paragraph.

(II) The specialized MA plan must meet the requirements of a fully integrated plan described in section 1395w–23(a)(1)(B)(iv)(II) of this title (other than the requirement that the plan have similar average levels of frailty, as determined by the Secretary, as the PACE program), or enter into a capitated contract with the State Medicaid agency to provide long-term services and supports or behavioral health services, or both.

(III) In the case of a specialized MA plan that is offered by a parent organization that is also the parent organization of a Medicaid managed care organization providing long term services and supports or behavioral services under a contract under section 1396b(m) of this title, the parent organization must assume clinical and financial responsibility for benefits provided under this subchapter and subchapter XIX with respect to any individual who is enrolled in both the specialized MA plan and the Medicaid managed care organization.

(ii) Suspension of enrollment for failure to meet requirements during initial period

During the period of plan years 2021 through 2025, if the Secretary determines that a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(ii) has failed to comply with clause (i), the Secretary may provide for the application against the Medicare Advantage organization offering the plan of the remedy described in section 1395w–27(g)(2)(B) of this title in the same manner as the Secretary may apply such remedy, and in accordance with the same procedures as would apply, in the case of an MA organization determined by the Secretary to have engaged in conduct described in section 1395w–27(g)(1) of this title. If the Secretary applies such remedy to a Medicare Advantage organization under the preceding sentence, the organization shall submit to the Secretary (at a time, and in a form and manner, specified by the Secretary) information describing how the plan will come into compliance with clause (i).

(E) Study and report to Congress

(i) In general

Not later than March 15, 2022, and, subject to clause (iii), biennially thereafter through 2032, the Medicare Payment Advisory Commission established under section 1395b–6 of this title, in consultation with the Medicaid and CHIP Payment and Access Commission established under section 1396 of this title, shall conduct (and submit to the Secretary and the Committees on Ways and Means and Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate a report on) a study to determine how specialized MA plans for special needs individuals described in subsection (b)(6)(B)(ii) perform among each other based on data from Healthcare Effectiveness Data and Information Set (HEDIS) quality measures, reported on the plan level, as required under section 1395w–22(e)(3) of this title (or such other measures or data sources that are available and appropriate, such as encounter data and Consumer Assessment of Healthcare Providers and Systems data, as specified by such Commissions as enabling an accurate evaluation under this subparagraph). Such study shall include, as feasible, the following comparison groups of specialized MA plans for special needs individuals described in subsection (b)(6)(B)(ii):

(I) A comparison group of such plans that are described in subparagraph (D)(i)(I).

(II) A comparison group of such plans that are described in subparagraph (D)(i)(II).

(III) A comparison group of such plans operating within the Financial Align-

ment Initiative demonstration for the period for which such plan is so operating and the demonstration is in effect, and, in the case that an integration option that is not with respect to specialized MA plans for special needs individuals is established after the conclusion of the demonstration involved.

(IV) A comparison group of such plans that are described in subparagraph (D)(i)(III).

(V) A comparison group of MA plans, as feasible, not described in a previous subclause of this clause, with respect to the performance of such plans for enrollees who are special needs individuals described in subsection (b)(6)(B)(ii).

(ii) Additional reports

Beginning with 2033 and every five years thereafter, the Medicare Payment Advisory Commission, in consultation with the Medicaid and CHIP Payment and Access Commission, shall conduct a study described in clause (i).

(9) List of conditions for clarification of the definition of a severe or disabling chronic conditions specialized needs individual

(A) In general

Not later than December 31, 2020, and every 5 years thereafter, subject to subparagraphs (B) and (C), the Secretary shall convene a panel of clinical advisors to establish and update a list of conditions that meet each of the following criteria:

(i) Conditions that meet the definition of a severe or disabling chronic condition under subsection (b)(6)(B)(iii) on or after January 1, 2022.

(ii) Conditions that require prescription drugs, providers, and models of care that are unique to the specific population of enrollees in a specialized MA plan for special needs individuals described in such subsection on or after such date and—

(I) as a result of access to, and enrollment in, such a specialized MA plan for special needs individuals, individuals with such condition would have a reasonable expectation of slowing or halting the progression of the disease, improving health outcomes and decreasing overall costs for individuals diagnosed with such condition compared to available options of care other than through such a specialized MA plan for special needs individuals; or

(II) have a low prevalence in the general population of beneficiaries under this subchapter or a disproportionally high per-beneficiary cost under this subchapter.

(B) Inclusion of certain conditions

The conditions listed under subparagraph (A) shall include HIV/AIDS, end stage renal disease, and chronic and disabling mental illness.

(C) Requirement

In establishing and updating the list under subparagraph (A), the panel shall take into account the availability of varied benefits, cost-sharing, and supplemental benefits under the model described in paragraph (2) of section 1395w–28(h) of this title, including the expansion under paragraph (1) of such section.

(g) Special rules for senior housing facility plans

(1) In general

In the case of a Medicare Advantage senior housing facility plan described in paragraph (2), notwithstanding any other provision of this part to the contrary and in accordance with regulations of the Secretary, the service area of such plan may be limited to a senior housing facility in a geographic area.

(2) Medicare Advantage senior housing facility plan described

For purposes of this subsection, a Medicare Advantage senior housing facility plan is a Medicare Advantage plan that—

(A) restricts enrollment of individuals under this part to individuals who reside in a continuing care retirement community (as defined in section 1395w–22(*l*)(4)(B) of this title);

(B) provides primary care services onsite and has a ratio of accessible physicians to beneficiaries that the Secretary determines is adequate;

(C) provides transportation services for beneficiaries to specialty providers outside of the facility; and

(D) has participated (as of December 31, 2009) in a demonstration project established by the Secretary under which such a plan was offered for not less than 1 year.

(h) National testing of Medicare Advantage Value-Based Insurance Design model

(1) In general

In implementing the Medicare Advantage Value-Based Insurance Design model that is being tested under section 1315a(b) of this title, the Secretary shall revise the testing of the model under such section to cover, effective not later than January 1, 2020, all States.

(2) Termination and modification provision not applicable until January 1, 2022

The provisions of section 1315a(b)(3)(B) of this title shall apply to the Medicare Advantage Value-Based Insurance Design model, including such model as revised under paragraph (1), beginning January 1, 2022, but shall not apply to such model, as so revised, prior to such date.

(3) Funding

The Secretary shall allocate funds made available under section 1315a(f)(1) of this title to design, implement, and evaluate the Medicare Advantage Value-Based Insurance Design model, as revised under paragraph (1).

(i) Program integrity transparency measures

(1) Program integrity portal

(A) In general

Not later than 2 years after October 24, 2018, the Secretary shall, after consultation with stakeholders, establish a secure inter-

net website portal (or other successor technology) that would allow a secure path for communication between the Secretary, MA plans under this part, prescription drug plans under part D, and an eligible entity with a contract under section 1395ddd of this title (such as a Medicare drug integrity contractor or an entity responsible for carrying out program integrity activities under this part and part D) for the purpose of enabling through such portal (or other successor technology)—

(i) the referral by such plans of substantiated or suspicious activities, as defined by the Secretary, of a provider of services (including a prescriber) or supplier related to fraud, waste, and abuse for initiating or assisting investigations conducted by the eligible entity; and

(ii) data sharing among such MA plans, prescription drug plans, and the Secretary.

(B) Required uses of portal

The Secretary shall disseminate the following information to MA plans under this part and prescription drug plans under part D through the secure internet website portal (or other successor technology) established under subparagraph (A):

(i) Providers of services and suppliers that have been referred pursuant to subparagraph (A)(i) during the previous 12-month period.

(ii) Providers of services and suppliers who are the subject of an active exclusion under section 1320a–7 of this title or who are subject to a suspension of payment under this subchapter pursuant to section 1395y(*o*) of this title or otherwise.

(iii) Providers of services and suppliers who are the subject of an active revocation of participation under this subchapter, including for not satisfying conditions of participation.

(iv) In the case of such a plan that makes a referral under subparagraph (A)(i) through the portal (or other successor technology) with respect to activities of substantiated or suspicious activities of fraud, waste, or abuse of a provider of services (including a prescriber) or supplier, if such provider (including a prescriber) or supplier has been the subject of an administrative action under this subchapter or subchapter XI with respect to similar activities, a notification to such plan of such action so taken.

(C) Rulemaking

For purposes of this paragraph, the Secretary shall, through rulemaking, specify what constitutes substantiated or suspicious activities of fraud, waste, and abuse, using guidance such as what is provided in the Medicare Program Integrity Manual 4.8. In carrying out this subsection, a fraud hotline tip (as defined by the Secretary) without further evidence shall not be treated as sufficient evidence for substantiated fraud, waste, or abuse.

(D) HIPAA compliant information only

For purposes of this subsection, communications may only occur if the communications are permitted under the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

(2) Quarterly reports

Beginning not later than 2 years after October 24, 2018, the Secretary shall make available to MA plans under this part and prescription drug plans under part D in a timely manner (but no less frequently than quarterly) and using information submitted to an entity described in paragraph (1) through the portal (or other successor technology) described in such paragraph or pursuant to section 1395ddd of this title, information on fraud, waste, and abuse schemes and trends in identifying suspicious activity. Information included in each such report shall—

(A) include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders; and

(B) be anonymized information submitted by plans without identifying the source of such information.

(3) Clarification

Nothing in this subsection shall preclude or otherwise affect referrals to the Inspector General of the Department of Health and Human Services or other law enforcement entities.

(Aug. 14, 1935, ch. 531, title XVIII, § 1859, as added Pub. L. 105–33, title IV, § 4001, Aug. 5, 1997, 111 Stat. 325; amended Pub. L. 106–113, div. B, § 1000(a)(6) [title V, § 523], Nov. 29, 1999, 113 Stat. 1536, 1501A–387; Pub. L. 108–173, title II, §§ 221(b)(1), (d)(2), 231(b), (c), Dec. 8, 2003, 117 Stat. 2180, 2193, 2207, 2208; Pub. L. 110–173, title I, § 108(a), Dec. 29, 2007, 121 Stat. 2496; Pub. L. 110–275, title I, §§ 162(b), 164(a), (c)(1), (d)(1), (e)(1), July 15, 2008, 122 Stat. 2571–2574; Pub. L. 111–148, title III, §§ 3205(a), (c), (e), (g), 3208(a), Mar. 23, 2010, 124 Stat. 457–459; Pub. L. 112–240, title VI, § 607, Jan. 2, 2013, 126 Stat. 2349; Pub. L. 113–67, div. B, title I, § 1107, Dec. 26, 2013, 127 Stat. 1197; Pub. L. 113–93, title I, § 107, Apr. 1, 2014, 128 Stat. 1043; Pub. L. 114–10, title II, § 206, Apr. 16, 2015, 129 Stat. 145; Pub. L. 114–255, div. C, title XVII, § 17006(a)(2)(B), Dec. 13, 2016, 130 Stat. 1334; Pub. L. 115–123, div. E, title III, §§ 50311(a), (b)(1), (c), 50321, Feb. 9, 2018, 132 Stat. 192, 196, 200; Pub. L. 115–271, title VI, § 6063(a), Oct. 24, 2018, 132 Stat. 3987.)

Editorial Notes

REFERENCES IN TEXT

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

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (i)(1)(D), is section 264(c) of Pub. L. 104–191, which is set out as a note under section 1320d–2 of this title.

AMENDMENTS

2018—Subsec. (b)(6)(B)(iii). Pub. L. 115–123, § 50311(c)(2)(A), substituted ''who—'' for ''who have'', in-

serted ''(I) before January 1, 2022, have'' before ''one or more comorbid and medically complex chronic conditions that are substantially disabling'', and added subcl. (II).

Subsec. (f)(1). Pub. L. 115–123, § 50311(a), struck out ''and for periods before January 1, 2019'' after ''the Secretary''.

Subsec. (f)(3)(F). Pub. L. 115–123, § 50311(b)(1)(A), added subpar. (F).

Subsec. (f)(5). Pub. L. 115–123, § 50311(c)(1), designated existing provisions as subpar. (A), inserted heading, substituted ''Subject to subparagraph (B), the requirements'' for ''The requirements'', redesignated former subpars. (A) and (B)(i) to (iii) as cls. (i) and (ii)(I) to (III), respectively, of subpar. (A), and added subpar. (B).

Subsec. (f)(8). Pub. L. 115–123, § 50311(b)(1)(B), added par. (8).

Subsec. (f)(9). Pub. L. 115–123, § 50311(c)(2)(B), added par. (9).

Subsec. (h). Pub. L. 115–123, § 50321, added subsec. (h).

Subsec. (i). Pub. L. 115–271 added subsec. (i).

2016—Subsec. (b)(6). Pub. L. 114–255 struck out ''may waive application of section 1395w–21(a)(3)(B) of this title in the case of an individual described in clause (i), (ii), or (iii) of this subparagraph and'' after ''The Secretary'' in concluding provisions.

2015—Subsec. (f)(1). Pub. L. 114–10 substituted ''2019'' for ''2017''.

2014—Subsec. (f)(1). Pub. L. 113–93 substituted ''2017'' for ''2016''.

2013—Subsec. (f)(1). Pub. L. 113–67 substituted ''2016'' for ''2015''.

Subsec. (f)(1). Pub. L. 112–240 substituted ''2015'' for ''2014''.

2010—Subsec. (f)(1). Pub. L. 111–148, § 3205(a), substituted ''2014'' for ''2011''.

Subsec. (f)(2)(C). Pub. L. 111–148, § 3205(e)(1), added subpar. (C).

Subsec. (f)(3)(E). Pub. L. 111–148, § 3205(e)(2), added subpar. (E).

Subsec. (f)(4)(C). Pub. L. 111–148, § 3205(e)(3), added subpar. (C).

Subsec. (f)(5). Pub. L. 111–148, § 3205(g), struck out ''described in subsection (b)(6)(B)(i)'' after ''individuals'' in introductory provisions.

Subsec. (f)(6), (7). Pub. L. 111–148, § 3205(c), (e)(4), added pars. (6) and (7).

Subsec. (g). Pub. L. 111–148, § 3208(a), added subsec. (g).

2008—Subsec. (b)(2). Pub. L. 110–275, § 162(b), inserted concluding provisions.

Subsec. (b)(6)(A). Pub. L. 110–275, § 164(c)(1)(A), inserted ''and that, as of January 1, 2010, meets the applicable requirements of paragraph (2), (3), or (4) of subsection (f), as the case may be'' before period at end.

Subsec. (b)(6)(B)(iii). Pub. L. 110–275, § 164(e)(1), inserted ''who have one or more comorbid and medically complex chronic conditions that are substantially disabling or life threatening, have a high risk of hospitalization or other significant adverse health outcomes, and require specialized delivery systems across domains of care'' before period at end.

Subsec. (f). Pub. L. 110–275, § 164(c)(1)(B)(ii), (iii), designated existing provisions as par. (1), inserted par. heading, and added pars. (2) to (4).

Pub. L. 110–275, § 164(c)(1)(B)(i), amended heading generally. Prior to amendment, heading read ''Restriction on enrollment for specialized MA plans for special needs individuals''.

Pub. L. 110–275, § 164(a), substituted ''2011'' for ''2010''.

Subsec. (f)(5). Pub. L. 110–275, § 164(d)(1), added par. (5).

2007—Subsec. (f). Pub. L. 110–173 substituted ''2010'' for ''2009''.

2003—Subsec. (b)(4), (5). Pub. L. 108–173, § 221(b)(1), added pars. (4) and (5).

Subsec. (b)(6). Pub. L. 108–173, § 231(b), added par. (6).

Subsec. (c)(5). Pub. L. 108–173, § 221(d)(2), added par. (5).

Subsec. (f). Pub. L. 108–173, § 231(c), added subsec. (f).

1999—Subsec. (e)(2). Pub. L. 106–113 substituted ''section 1395w–21(a)(2) of this title'' for ''section 1395w–21(a)(2)(A) of this title'' in introductory provisions.

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 2016 AMENDMENT

Amendment by Pub. L. 114–255 applicable with respect to plan years beginning on or after Jan. 1, 2021, see section 17006(a)(3) of Pub. L. 114–255, set out as a note under section 1395w–21 of this title.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, § 3208(b), Mar. 23, 2010, 124 Stat. 460, provided that: ''The amendment made by this section [amending this section] shall take effect on January 1, 2010, and shall apply to plan years beginning on or after such date.''

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 164(c)(1), (d)(1), (e)(1) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2010, and applicable to all specialized Medicare Advantage plans for special needs individuals regardless of when the plan first entered the Medicare Advantage program under this part, see section 164(g) of Pub. L. 110–275, set out as a note under section 1395w–27 of this title.

EFFECTIVE DATE OF 2003 AMENDMENT

Amendment by section 221(b)(1), (d)(2) 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 231(b), (c) of Pub. L. 108–173 effective Dec. 8, 2003, see section 231(f)(1) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

REGULATIONS

Pub. L. 108–173, title II, § 231(f)(2), Dec. 8, 2003, 117 Stat. 2208, provided that: ''No later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Secretary [of Health and Human Services] shall issue final regulations to establish requirements for special needs individuals under section 1859(b)(6)(B)(iii) of the Social Security Act [42 U.S.C. 1395w–28(b)(6)(B)(iii)], as added by subsection (b).''

AUTHORIZATION TO OPERATE; RESOURCES FOR STATE MEDICAID AGENCIES; CONTRACTING REQUIREMENTS

Pub. L. 110–275, title I, § 164(c)(2)–(4), July 15, 2008, 122 Stat. 2573, as amended by Pub. L. 111–148, title III, § 3205(d), Mar. 23, 2010, 124 Stat. 458, provided that:

''(2) AUTHORITY TO OPERATE BUT NO SERVICE AREA EXPANSION FOR DUAL SNPS THAT DO NOT MEET CERTAIN REQUIREMENTS.—Notwithstanding subsection (f) of section 1859 of the Social Security Act (42 U.S.C. 1395w–28), during the period beginning on January 1, 2010, and ending on December 31, 2012, in the case of a specialized Medicare Advantage plan for special needs individuals described in subsection (b)(6)(B)(ii) of such section, as amended by this section, that does not meet the requirement described in subsection (f)(3)(D) of such section, the Secretary of Health and Human Services—

''(A) shall permit such plan to be offered under part C of title XVIII of such Act [42 U.S.C. 1395w–21 et seq.]; and

''(B) shall not permit an expansion of the service area of the plan under such part C.

''(3) RESOURCES FOR STATE MEDICAID AGENCIES.—The Secretary of Health and Human Services shall provide for the designation of appropriate staff and resources that can address State inquiries with respect to the coordination of State and Federal policies for specialized MA plans for special needs individuals described in section 1859(b)(6)(B)(ii) of the Social Security Act (42 U.S.C. 1395w–28(b)(6)(B)(ii)), as amended by this section.

''(4) NO REQUIREMENT FOR CONTRACT.—Nothing in the provisions of, or amendments made by, this subsection [amending this section] shall require a State to enter into a contract with a Medicare Advantage organization with respect to a specialized MA plan for special needs individuals described in section 1859(b)(6)(B)(ii) of the Social Security Act (42 U.S.C. 1395w–28(b)(6)(B)(ii)), as amended by this section.''

PANEL OF CLINICAL ADVISORS TO DETERMINE CONDITIONS

Pub. L. 110–275, title I, §164(e)(2), July 15, 2008, 122 Stat. 2574, provided that: ''The Secretary of Health and Human Services shall convene a panel of clinical advisors to determine the conditions that meet the definition of severe and disabling chronic conditions under section 1859(b)(6)(B)(iii) of the Social Security Act (42 U.S.C. 1395w–28(b)(6)(B)(iii)), as amended by paragraph (1). The panel shall include the Director of the Agency for Healthcare Research and Quality (or the Director's designee).''

NO EFFECT ON MEDICAID BENEFITS FOR DUALS

Pub. L. 110–275, title I, §164(h), July 15, 2008, 122 Stat. 2575, provided that: ''Nothing in the provisions of, or amendments made by, this section [amending this section and sections 1395w–22 and 1395w–27 of this title and enacting provisions set out as notes under this section and sections 1395w–21, 1395w–22, and 1395w–27 of this title] shall affect the benefits available under the Medicaid program under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for special needs individuals described in section 1859(b)(6)(B)(ii) of such Act (42 U.S.C. 1395w–28(b)(6)(B)(ii)).''

AUTHORITY TO DESIGNATE OTHER PLANS AS SPECIALIZED MA PLANS

Secretary of Health and Human Services authorized, in promulgating regulations to carry out subsection (b)(6) of this section, to provide, notwithstanding subsection (b)(6)(A) of this section, for the offering of specialized MA plans for special needs individuals by MA plans that disproportionately serve special needs individuals, see section 231(d) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

§ 1395w–29. Repealed. Pub. L. 111–152, title I, § 1102(f), Mar. 30, 2010, 124 Stat. 1046

Section, act Aug. 14, 1935, ch. 531, title XVIII, §1860C–1, as added Pub. L. 108–173, title II, §241(a), Dec. 8, 2003, 117 Stat. 2214; amended Pub. L. 111–148, title III, §3201(a)(2)(D), Mar. 23, 2010, 124 Stat. 444; Pub. L. 111–152, title I, §1102(a), Mar. 30, 2010, 124 Stat. 1040, related to comparative cost adjustment program.

PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

Editorial Notes

PRIOR PROVISIONS

A prior part D of this subchapter, consisting of section 1395x et seq., was redesignated part E of this subchapter.

SUBPART 1—PART D ELIGIBLE INDIVIDUALS AND PRESCRIPTION DRUG BENEFITS

§ 1395w–101. Eligibility, enrollment, and information

(a) Provision of qualified prescription drug coverage through enrollment in plans

(1) In general

Subject to the succeeding provisions of this part, each part D eligible individual (as defined in paragraph (3)(A)) is entitled to obtain qualified prescription drug coverage (described in section 1395w–102(a) of this title) as follows:

(A) Fee-for-service enrollees may receive coverage through a prescription drug plan

A part D eligible individual who is not enrolled in an MA plan may obtain qualified prescription drug coverage through enrollment in a prescription drug plan (as defined in section 1395w–151(a)(14) of this title).

(B) Medicare Advantage enrollees

(i) Enrollees in a plan providing qualified prescription drug coverage receive coverage through the plan

A part D eligible individual who is enrolled in an MA–PD plan obtains such coverage through such plan.

(ii) Limitation on enrollment of MA plan enrollees in prescription drug plans

Except as provided in clauses (iii) and (iv), a part D eligible individual who is enrolled in an MA plan may not enroll in a prescription drug plan under this part.

(iii) Private fee-for-service enrollees in MA plans not providing qualified prescription drug coverage permitted to enroll in a prescription drug plan

A part D eligible individual who is enrolled in an MA private fee-for-service plan (as defined in section 1395w–28(b)(2) of this title) that does not provide qualified prescription drug coverage may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

(iv) Enrollees in MSA plans permitted to enroll in a prescription drug plan

A part D eligible individual who is enrolled in an MSA plan (as defined in section 1395w–28(b)(3) of this title) may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

(2) Coverage first effective January 1, 2006

Coverage under prescription drug plans and MA–PD plans shall first be effective on January 1, 2006.

(3) Definitions

For purposes of this part:

(A) Part D eligible individual

The term ''part D eligible individual'' means an individual who is entitled to benefits under part A or enrolled under part B (but not including an individual enrolled solely for coverage of immunosuppressive drugs under section 1395*o*(b) of this title).