

the Federal Hospital Insurance Trust Fund under section 1395i of this title and the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title (in proportions determined appropriate by the Secretary) \$5,000,000 for each of fiscal years 2010 through 2015 and \$9,000,000 for fiscal year 2021. Amounts transferred under this subsection for a fiscal year shall be available until expended.

(i) Termination

(1) Mandatory termination

The Secretary shall terminate an agreement with an independence at home medical practice if—

(A) the Secretary estimates or determines that such practice did not achieve savings for the third of 3 consecutive years under the demonstration program; or

(B) such practice fails to meet quality standards during any year of the demonstration program.

(2) Permissive termination

The Secretary may terminate an agreement with an independence at home medical practice for such other reasons determined appropriate by the Secretary.

(Aug. 14, 1935, ch. 531, title XVIII, §1866E, formerly §1866D, as added and renumbered §1866E, Pub. L. 111–148, title III, §3024, title X, §10308(b)(2), Mar. 23, 2010, 124 Stat. 404, 942; amended Pub. L. 114–39, §2, July 30, 2015, 129 Stat. 440; Pub. L. 115–123, div. E, title III, §50301(a), Feb. 9, 2018, 132 Stat. 190; Pub. L. 116–260, div. CC, title I, §105(a), Dec. 27, 2020, 134 Stat. 2944.)

Editorial Notes

REFERENCES IN TEXT

Parts A, B, and C, referred to in subsecs. (c) and (d)(1)(A), (B), are classified to sections 1395c et seq., 1395j et seq., and 1395w–21 et seq., respectively, of this title.

Section 50301(a)(1)(B)(i) of the Advancing Chronic Care, Extenders, and Social Services Act, referred to in subsec. (e)(5), probably means section 50301(a)(1)(B)(i) of the Advancing Chronic Care, Extenders, and Social Services (ACCESS) Act, div. E of Pub. L. 115–123, which amended this section.

Section 105 of division CC of the Consolidated Appropriations Act, 2021, referred to in subsec. (e)(5), is section 105 of div. CC of Pub. L. 116–260, which amended this section.

AMENDMENTS

2020—Subsec. (e)(1). Pub. L. 116–260, §105(a)(1)(A), substituted “10-year” for “7-year”.

Subsec. (e)(5). Pub. L. 116–260, §105(a)(1)(B), substituted “20,000” for “15,000” in first sentence and “sixth through tenth” for “sixth and seventh” in second sentence and inserted at end “An applicable beneficiary that participates in the demonstration program by reason of the increase from 15,000 to 20,000 in the first sentence of this paragraph pursuant to the amendment made by section 105 of division CC of the Consolidated Appropriations Act, 2021 shall be considered in the spending target estimates under paragraph (1) of subsection (c) and the incentive payment calculations under paragraph (2) of such subsection for the eighth through tenth years of such program.”

Subsec. (h). Pub. L. 116–260, §105(a)(2), inserted “and \$9,000,000 for fiscal year 2021” after “2015”.

2018—Subsec. (e)(1). Pub. L. 115–123, §50301(a)(1)(A), substituted “Agreements” for “An agreement” and “7-year” for “5-year”.

Subsec. (e)(5). Pub. L. 115–123, §50301(a)(1)(B), substituted “15,000” for “10,000” and inserted at end “An applicable beneficiary that participates in the demonstration program by reason of the increase from 10,000 to 15,000 in the preceding sentence pursuant to the amendment made by section 50301(a)(1)(B)(i) of the Advancing Chronic Care, Extenders, and Social Services Act shall be considered in the spending target estimates under paragraph (1) of subsection (c) and the incentive payment calculations under paragraph (2) of such subsection for the sixth and seventh years of such program.”

Subsec. (g). Pub. L. 115–123, §50301(a)(2), inserted “, including, to the extent practicable, with respect to the use of electronic health information systems, as described in subsection (b)(1)(A)(vi)” after “under the demonstration program”.

Subsec. (i)(1)(A). Pub. L. 115–123, §50301(a)(3), substituted “did not achieve savings for the third of 3” for “will not receive an incentive payment for the second of 2”.

2015—Subsec. (e)(1). Pub. L. 114–39 substituted “5-year” for “3-year”.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2020 AMENDMENT

Pub. L. 116–260, div. CC, title I, §105(b), Dec. 27, 2020, 134 Stat. 2944, provided that: “The amendments made by subsection (a) [amending this section] shall take effect as if included in the enactment of Public Law 111–148.”

EFFECTIVE DATE OF 2018 AMENDMENT

Pub. L. 115–123, div. E, title III, §50301(b), Feb. 9, 2018, 132 Stat. 190, provided that: “The amendment made by subsection (a)(3) [amending this section] shall take effect as if included in the enactment of Public Law 111–148.”

§ 1395cc–6. Opioid use disorder treatment demonstration program

(a) Implementation of 4-year demonstration program

(1) In general

Not later than January 1, 2021, the Secretary shall implement a 4-year demonstration program under this subchapter (in this section referred to as the “Program”) to increase access of applicable beneficiaries to opioid use disorder treatment services, improve physical and mental health outcomes for such beneficiaries, and to the extent possible, reduce expenditures under this subchapter. Under the Program, the Secretary shall make payments under subsection (e) to participants (as defined in subsection (c)(1)(A)) for furnishing opioid use disorder treatment services delivered through opioid use disorder care teams, or arranging for such services to be furnished, to applicable beneficiaries participating in the Program.

(2) Opioid use disorder treatment services

For purposes of this section, the term “opioid use disorder treatment services”—

(A) means, with respect to an applicable beneficiary, services that are furnished for the treatment of opioid use disorders and that utilize drugs approved under section 355 of title 21 for the treatment of opioid use disorders in an outpatient setting; and

(B) includes—

- (i) medication-assisted treatment;
- (ii) treatment planning;
- (iii) psychiatric, psychological, or counseling services (or any combination of such services), as appropriate;
- (iv) social support services, as appropriate; and
- (v) care management and care coordination services, including coordination with other providers of services and suppliers not on an opioid use disorder care team.

(b) Program design

(1) In general

The Secretary shall design the Program in such a manner to allow for the evaluation of the extent to which the Program accomplishes the following purposes:

- (A) Reduces hospitalizations and emergency department visits.
- (B) Increases use of medication-assisted treatment for opioid use disorders.
- (C) Improves health outcomes of individuals with opioid use disorders, including by reducing the incidence of infectious diseases (such as hepatitis C and HIV).
- (D) Does not increase the total spending on items and services under this subchapter.
- (E) Reduces deaths from opioid overdose.
- (F) Reduces the utilization of inpatient residential treatment.

(2) Consultation

In designing the Program, including the criteria under subsection (e)(2)(A), the Secretary shall, not later than 3 months after October 24, 2018, consult with specialists in the field of addiction, clinicians in the primary care community, and beneficiary groups.

(c) Participants; opioid use disorder care teams

(1) Participants

(A) Definition

In this section, the term “participant” means an entity or individual—

- (i) that is otherwise enrolled under this subchapter and that is—
 - (I) a physician (as defined in section 1395x(r)(1) of this title);
 - (II) a group practice comprised of at least one physician described in subclause (I);
 - (III) a hospital outpatient department;
 - (IV) a federally qualified health center (as defined in section 1395x(aa)(4) of this title);
 - (V) a rural health clinic (as defined in section 1395x(aa)(2) of this title);
 - (VI) a community mental health center (as defined in section 1395x(ff)(3)(B) of this title);
 - (VII) a clinic certified as a certified community behavioral health clinic pursuant to section 223 of the Protecting Access to Medicare Act of 2014; or
 - (VIII) any other individual or entity specified by the Secretary;
- (ii) that applied for and was selected to participate in the Program pursuant to an application and selection process established by the Secretary; and

- (iii) that establishes an opioid use disorder care team (as defined in paragraph (2)) through employing or contracting with health care practitioners described in paragraph (2)(A), and uses such team to furnish or arrange for opioid use disorder treatment services in the outpatient setting under the Program.

(B) Preference

In selecting participants for the Program, the Secretary shall give preference to individuals and entities that are located in areas with a prevalence of opioid use disorders that is higher than the national average prevalence.

(2) Opioid use disorder care teams

(A) In general

For purposes of this section, the term “opioid use disorder care team” means a team of health care practitioners established by a participant described in paragraph (1)(A) that—

- (i) shall include—
 - (I) at least one physician (as defined in section 1395x(r)(1) of this title) furnishing primary care services or addiction treatment services to an applicable beneficiary; and
 - (II) at least one eligible practitioner (as defined in paragraph (3)), who may be a physician who meets the criterion in subclause (I); and
- (ii) may include other practitioners licensed under State law to furnish psychiatric, psychological, counseling, and social services to applicable beneficiaries.

(B) Requirements for receipt of payment under program

In order to receive payments under subsection (e), each participant in the Program shall—

- (i) furnish opioid use disorder treatment services through opioid use disorder care teams to applicable beneficiaries who agree to receive the services;
- (ii) meet minimum criteria, as established by the Secretary; and
- (iii) submit to the Secretary, in such form, manner, and frequency as specified by the Secretary, with respect to each applicable beneficiary for whom opioid use disorder treatment services are furnished by the opioid use disorder care team, data and such other information as the Secretary determines appropriate to—
 - (I) monitor and evaluate the Program;
 - (II) determine if minimum criteria are met under clause (ii); and
 - (III) determine the incentive payment under subsection (e).

(3) Eligible practitioner defined

For purposes of this section, the term “eligible practitioner” means a physician or other health care practitioner, such as a nurse practitioner, that—

- (A) is enrolled under section 1395cc(j)(1) of this title; and
- (B) is authorized to prescribe or dispense narcotic drugs to individuals for mainte-

nance treatment or detoxification treatment.

(d) Participation of applicable beneficiaries

(1) Applicable beneficiary defined

In this section, the term “applicable beneficiary” means an individual who—

(A) is entitled to, or enrolled for, benefits under part A and enrolled for benefits under part B;

(B) is not enrolled in a Medicare Advantage plan under part C;

(C) has a current diagnosis for an opioid use disorder; and

(D) meets such other criteria as the Secretary determines appropriate.

Such term shall include an individual who is dually eligible for benefits under this subchapter and subchapter XIX if such individual satisfies the criteria described in subparagraphs (A) through (D).

(2) Voluntary beneficiary participation; limitation on number of beneficiaries

An applicable beneficiary may participate in the Program on a voluntary basis and may terminate participation in the Program at any time. Not more than 20,000 applicable beneficiaries may participate in the Program at any time.

(3) Services

In order to participate in the Program, an applicable beneficiary shall agree to receive opioid use disorder treatment services from a participant. Participation under the Program shall not affect coverage of or payment for any other item or service under this subchapter for the applicable beneficiary.

(4) Beneficiary access to services

Nothing in this section shall be construed as encouraging providers to limit applicable beneficiary access to services covered under this subchapter, and applicable beneficiaries shall not be required to relinquish access to any benefit under this subchapter as a condition of receiving services from a participant in the Program.

(e) Payments

(1) Per applicable beneficiary per month care management fee

(A) In general

The Secretary shall establish a schedule of per applicable beneficiary per month care management fees. Such a per applicable beneficiary per month care management fee shall be paid to a participant in addition to any other amount otherwise payable under this subchapter to the health care practitioners in the participant’s opioid use disorder care team or, if applicable, to the participant. A participant may use such per applicable beneficiary per month care management fee to deliver additional services to applicable beneficiaries, including services not otherwise eligible for payment under this subchapter.

(B) Payment amounts

In carrying out subparagraph (A), the Secretary may—

(i) consider payments otherwise payable under this subchapter for opioid use disorder treatment services and the needs of applicable beneficiaries;

(ii) pay a higher per applicable beneficiary per month care management fee for an applicable beneficiary who receives more intensive treatment services from a participant and for whom those services are appropriate based on clinical guidelines for opioid use disorder care;

(iii) pay a higher per applicable beneficiary per month care management fee for the month in which the applicable beneficiary begins treatment with a participant than in subsequent months, to reflect the greater time and costs required for the planning and initiation of treatment, as compared to maintenance of treatment; and

(iv) take into account whether a participant’s opioid use disorder care team refers applicable beneficiaries to other suppliers or providers for any opioid use disorder treatment services.

(C) No duplicate payment

The Secretary shall make payments under this paragraph to only one participant for services furnished to an applicable beneficiary during a calendar month.

(2) Incentive payments

(A) In general

Under the Program, the Secretary shall establish a performance-based incentive payment, which shall be paid (using a methodology established and at a time determined appropriate by the Secretary) to participants based on the performance of participants with respect to criteria, as determined appropriate by the Secretary, in accordance with subparagraph (B).

(B) Criteria

(i) In general

Criteria described in subparagraph (A) may include consideration of the following:

(I) Patient engagement and retention in treatment.

(II) Evidence-based medication-assisted treatment.

(III) Other criteria established by the Secretary.

(ii) Required consultation and consideration

In determining criteria described in subparagraph (A), the Secretary shall—

(I) consult with stakeholders, including clinicians in the primary care community and in the field of addiction medicine; and

(II) consider existing clinical guidelines for the treatment of opioid use disorders.

(C) No duplicate payment

The Secretary shall ensure that no duplicate payments under this paragraph are made with respect to an applicable beneficiary.

(f) Multipayer strategy

In carrying out the Program, the Secretary shall encourage other payers to provide similar payments and to use similar criteria as applied under the Program under subsection (e)(2)(C). The Secretary may enter into a memorandum of understanding with other payers to align the methodology for payment provided by such a payer related to opioid use disorder treatment services with such methodology for payment under the Program.

(g) Evaluation**(1) In general**

The Secretary shall conduct an intermediate and final evaluation of the program. Each such evaluation shall determine the extent to which each of the purposes described in subsection (b) have been accomplished under the Program.

(2) Reports

The Secretary shall submit to Congress—

(A) a report with respect to the intermediate evaluation under paragraph (1) not later than 3 years after the date of the implementation of the Program; and

(B) a report with respect to the final evaluation under paragraph (1) not later than 6 years after such date.

(h) Funding**(1) Administrative funding**

For the purposes of implementing, administering, and carrying out the Program (other than for purposes described in paragraph (2)), \$5,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title.

(2) Care management fees and incentives

For the purposes of making payments under subsection (e), \$10,000,000 shall be available from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title for each of fiscal years 2021 through 2024.

(3) Availability

Amounts transferred under this subsection for a fiscal year shall be available until expended.

(i) Waivers

The Secretary may waive any provision of this subchapter as may be necessary to carry out the Program under this section.

(Aug. 14, 1935, ch. 531, title XVIII, §1866F, as added Pub. L. 115–271, title VI, §6042, Oct. 24, 2018, 132 Stat. 3979; amended Pub. L. 117–215, title I, §103(b)(4)(C), Dec. 2, 2022, 136 Stat. 2263; Pub. L. 117–328, div. FF, title I, §1262(b)(7), Dec. 29, 2022, 136 Stat. 5682.)

Editorial Notes**REFERENCES IN TEXT**

Section 223 of the Protecting Access to Medicare Act of 2014, referred to in subsec. (c)(1)(A)(i)(VII), is section 223 of Pub. L. 113–93, which is set out as a note under section 1396a of this title.

AMENDMENTS

2022—Subsec. (c)(3)(C). Pub. L. 117–328 struck out subpar. (C) which read as follows: “has in effect a waiver

in accordance with section 823(h) of title 21 for such purpose and is otherwise in compliance with regulations promulgated by the Substance Abuse and Mental Health Services Administration to carry out such section.”

Pub. L. 117–215 substituted “823(h)” for “823(g)”.

§ 1395cc–7. Extension of Acute Hospital Care at Home initiative**(a) In general****(1) Extension**

With respect to inpatient hospital admissions occurring during the period beginning on the first day after the end of the emergency period described in section 1320b–5(g)(1)(B) of this title and ending on March 31, 2025, the Secretary of Health and Human Services shall grant waivers and flexibilities (as described in paragraph (2)) to an individual hospital that submits a request for such waivers and flexibilities and meets specified criteria (as described in paragraph (3)) in order to participate in the Acute Hospital Care at Home initiative of the Secretary.

(2) Acute Hospital Care at Home waivers and flexibilities

For the purposes of paragraph (1), the waivers and flexibilities described in this paragraph are the following waivers and flexibilities that were made available to individual hospitals under the Acute Hospital Care at Home initiative of the Secretary during the emergency period described in section 1320b–5(g)(1)(B) of this title:

(A) Subject to paragraph (3)(D), waiver of the requirements to provide 24-hour nursing services on premises and for the immediate availability of a registered nurse under section 482.23(b) of title 42, Code of Federal Regulations (or any successor regulation), and the waivers of the physical environment and Life Safety Code requirements under section 482.41 of title 42, Code of Federal Regulations (or any successor regulation).

(B) Flexibility to allow a hospital to furnish inpatient services, including routine services, outside the hospital under arrangements, as described in Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals; Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID–19 (87 Fed. Reg. 71748 et seq.).

(C) Waiver of the telehealth requirements under clause (i)¹ of section 1395m(m)(4)(C) of this title, as amended by section 4113(a) of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022, such that the originating sites described in clause (ii) of such section shall include the

¹So in original. Probably should be “clause (iii)”. See References in Text note below.