onstrated the ability to meet patient care and patient safety standards and that provides under common management the medical and rehabilitation services provided in inpatient rehabilitation hospitals and units (as defined in section 1395 ww(d)(1)(B)(ii) of this title), long term care hospitals (as defined in section $1395 \text{ww}(d)(1)(B)(iv)(I)^2$ of this title), and skilled nursing facilities (as defined in section 1395 i-3(a) of this title) that are located in a hospital described in section 1395 ww(d) of this title.

(h) Administration

Chapter 35 of title 44 shall not apply to the selection, testing, and evaluation of models or the expansion of such models under this section.

(Aug. 14, 1935, ch. 531, title XVIII, §1866D, as added and amended Pub. L. 111–148, title III, §3023, title X, §10308(a), (b)(1), Mar. 23, 2010, 124 Stat. 399, 941, 942.)

Editorial Notes

References in Text

Parts A, B, and C, referred to in subsec. (a)(2)(A)(i), are classified to sections 1395c et seq., 1395j et seq., and 1395w-21 et seq., respectively, of this title.

Section 1395ww(d)(1)(B)(iv)(I) of this title, referred to in subsec. (g)(3), was redesignated section 1395ww(d)(1)(B)(iv) of this title by Pub. L. 114-255, div. C, title XV, $\S15008(a)(3)$, Dec. 13, 2016, 130 Stat. 1321.

CODIFICATION

Another section 1866D of act Aug. 14, 1935, was renumbered section 1866E and is classified to section 1395cc–5 of this title.

AMENDMENTS

2010—Pub. L. 111–148, \$10308(b)(1), made technical correction to directory language of Pub. L. 111–148, \$3023, which enacted this section.

Subsec. (a)(2)(B). Pub. L. 111–148, $\S 10308(a)(1)$, substituted "10 conditions" for "8 conditions".

Subsec. (c)(1)(B). Pub. L. 111–148, §10308(a)(2), added subpar. (B) and struck out former subpar. (B). Prior to amendment, text read as follows: "The Secretary may extend the duration of the pilot program for providers of services and suppliers participating in the pilot program as of the day before the end of the 5-year period described in subparagraph (A), for a period determined appropriate by the Secretary, if the Secretary determines that such extension will result in improving or not reducing the quality of patient care and reducing spending under this subchapter."

Subsec. (g). Pub. L. 111–148, §10308(a)(3), added subsec. (g) and struck out former subsec. (g). Prior to amendment, text read as follows: "Not later than January 1, 2016, the Secretary shall submit a plan for the implementation of an expansion of the pilot program if the Secretary determines that such expansion will result in improving or not reducing the quality of patient care and reducing spending under this subchapter."

§ 1395cc-5. Independence at home medical practice demonstration program

(a) Establishment

(1) In general

The Secretary shall conduct a demonstration program (in this section referred to as the "demonstration program") to test a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams designed to reduce expenditures and improve health outcomes in the provision of items and services under this subchapter to applicable beneficiaries (as defined in subsection (d)).

(2) Requirement

The demonstration program shall test whether a model described in paragraph (1), which is accountable for providing comprehensive, coordinated, continuous, and accessible care to high-need populations at home and coordinating health care across all treatment settings, results in—

- (A) reducing preventable hospitalizations;
- (B) preventing hospital readmissions;
- (C) reducing emergency room visits;
- (D) improving health outcomes commensurate with the beneficiaries' stage of chronic illness;
- (E) improving the efficiency of care, such as by reducing duplicative diagnostic and laboratory tests;
- (F) reducing the cost of health care services covered under this subchapter; and
- (G) achieving beneficiary and family caregiver satisfaction.

(b) Independence at home medical practice

(1) Independence at home medical practice defined

In this section:

(A) In general

The term "independence at home medical practice" means a legal entity that—

- (i) is comprised of an individual physician or nurse practitioner or group of physicians and nurse practitioners that provides care as part of a team that includes physicians, nurses, physician assistants, pharmacists, and other health and social services staff as appropriate who have experience providing home-based primary care to applicable beneficiaries, make inhome visits, and are available 24 hours per day, 7 days per week to carry out plans of care that are tailored to the individual beneficiary's chronic conditions and designed to achieve the results in subsection
- (ii) is organized at least in part for the purpose of providing physicians' services;
- (iii) has documented experience in providing home-based primary care services to high-cost chronically ill beneficiaries, as determined appropriate by the Secretary;
- (iv) furnishes services to at least 200 applicable beneficiaries (as defined in subsection (d)) during each year of the demonstration program;
- (v) has entered into an agreement with the Secretary;
- (vi) uses electronic health information systems, remote monitoring, and mobile diagnostic technology; and
- (vii) meets such other criteria as the Secretary determines to be appropriate to participate in the demonstration program.

The entity shall report on quality measures (in such form, manner, and frequency as

² See References in Text note below.

specified by the Secretary, which may be for the group, for providers of services and suppliers, or both) and report to the Secretary (in a form, manner, and frequency as specified by the Secretary) such data as the Secretary determines appropriate to monitor and evaluate the demonstration program.

(B) Physician

The term "physician" includes, except as the Secretary may otherwise provide, any individual who furnishes services for which payment may be made as physicians' services and has the medical training or experience to fulfill the physician's role described in subparagraph (A)(i).

(2) Participation of nurse practitioners and physician assistants

Nothing in this section shall be construed to prevent a nurse practitioner or physician assistant from participating in, or leading, a home-based primary care team as part of an independence at home medical practice if—

- (A) all the requirements of this section are met;
- (B) the nurse practitioner or physician assistant, as the case may be, is acting consistent with State law; and
- (C) the nurse practitioner or physician assistant has the medical training or experience to fulfill the nurse practitioner or physician assistant role described in paragraph (1)(A)(i).

(3) Inclusion of providers and practitioners

Nothing in this subsection shall be construed as preventing an independence at home medical practice from including a provider of services or a participating practitioner described in section 1395u(b)(18)(C) of this title that is affiliated with the practice under an arrangement structured so that such provider of services or practitioner participates in the demonstration program and shares in any savings under the demonstration program.

(4) Quality and performance standards

The Secretary shall develop quality performance standards for independence at home medical practices participating in the demonstration program.

(c) Payment methodology

(1) Establishment of target spending level

The Secretary shall establish an estimated annual spending target, for the amount the Secretary estimates would have been spent in the absence of the demonstration, for items and services covered under parts A and B furnished to applicable beneficiaries for each qualifying independence at home medical practice under this section. Such spending targets shall be determined on a per capita basis. Such spending targets shall include a risk corridor that takes into account normal variation in expenditures for items and services covered under parts A and B furnished to such beneficiaries with the size of the corridor being related to the number of applicable beneficiaries furnished services by each independence at home medical practice. The

spending targets may also be adjusted for other factors as the Secretary determines appropriate.

(2) Incentive payments

Subject to performance on quality measures, a qualifying independence at home medical practice is eligible to receive an incentive payment under this section if actual expenditures for a year for the applicable beneficiaries it enrolls are less than the estimated spending target established under paragraph (1) for such year. An incentive payment for such year shall be equal to a portion (as determined by the Secretary) of the amount by which actual expenditures (including incentive payments under this paragraph) for applicable beneficiaries under parts A and B for such year are estimated to be less than 5 percent less than the estimated spending target for such year, as determined under paragraph (1).

(d) Applicable beneficiaries

(1) Definition

In this section, the term "applicable beneficiary" means, with respect to a qualifying independence at home medical practice, an individual who the practice has determined—

- (A) is entitled to benefits under part A and enrolled for benefits under part B;
- (B) is not enrolled in a Medicare Advantage plan under part C or a PACE program under section 1395eee of this title;
- (C) has 2 or more chronic illnesses, such as congestive heart failure, diabetes, other dementias designated by the Secretary, chronic obstructive pulmonary disease, ischemic heart disease, stroke, Alzheimer's Disease and neurodegenerative diseases, and other diseases and conditions designated by the Secretary which result in high costs under this subchapter;
- (D) within the past 12 months has had a nonelective hospital admission;
- (E) within the past 12 months has received acute or subacute rehabilitation services;
- (F) has 2 or more functional dependencies requiring the assistance of another person (such as bathing, dressing, toileting, walking, or feeding); and
- (G) meets such other criteria as the Secretary determines appropriate.

(2) Patient election to participate

The Secretary shall determine an appropriate method of ensuring that applicable beneficiaries have agreed to enroll in an independence at home medical practice under the demonstration program. Enrollment in the demonstration program shall be voluntary.

(3) Beneficiary access to services

Nothing in this section shall be construed as encouraging physicians or nurse practitioners 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 an independence at home medical practice

(e) Implementation

(1) Starting date

The demonstration program shall begin no later than January 1, 2012. Agreements with an independence at home medical practice under the demonstration program may cover not more than a 10-year period.

(2) No physician duplication in demonstration participation

The Secretary shall not pay an independence at home medical practice under this section that participates in section 1395jjj of this title.

(3) No beneficiary duplication in demonstration participation

The Secretary shall ensure that no applicable beneficiary enrolled in an independence at home medical practice under this section is participating in the programs under section 1395jjj of this title.

(4) Preference

In approving an independence at home medical practice, the Secretary shall give preference to practices that are—

- (A) located in high-cost areas of the country:
- (B) have experience in furnishing health care services to applicable beneficiaries in the home; and
- (C) use electronic medical records, health information technology, and individualized plans of care.

(5) Limitation on number of practices

In selecting qualified independence at home medical practices to participate under the demonstration program, the Secretary shall limit the number of such practices so that the number of applicable beneficiaries that may participate in the demonstration program does not exceed 20,000. 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 bv 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 through tenth years of such program. 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.

(6) Waiver

The Secretary may waive such provisions of this subchapter and subchapter XI as the Secretary determines necessary in order to implement the demonstration program.

(7) Administration

Chapter 35 of title 44 shall not apply to this section.

(f) Evaluation and monitoring

(1) In general

The Secretary shall evaluate each independence at home medical practice under the demonstration program to assess whether the practice achieved the results described in subsection (a).

(2) Monitoring applicable beneficiaries

The Secretary may monitor data on expenditures and quality of services under this subchapter after an applicable beneficiary discontinues receiving services under this subchapter through a qualifying independence at home medical practice.

(g) Reports to Congress

The Secretary shall conduct an independent evaluation of the demonstration program and submit to Congress a final report, including best practices under the demonstration program, including, to the extent practicable, with respect to the use of electronic health information systems, as described in subsection (b)(1)(A)(vi). Such report shall include an analysis of the demonstration program on coordination of care, expenditures under this subchapter, applicable beneficiary access to services, and the quality of health care services provided to applicable beneficiaries.

(h) Funding

For purposes of administering and carrying out the demonstration program, other than for payments for items and services furnished under this subchapter and incentive payments under subsection (c), in addition to funds otherwise appropriated, there shall be transferred to the Secretary for the Center for Medicare & Medicaid Services Program Management Account from 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"

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.