(B) streamline documentation and reporting requirements otherwise required under this subchapter.

(3) Benefits

A health care group that receives assistance under this section may, with respect to the demonstration project to be carried out with such assistance, include modifications to the package of benefits available under the original medicare fee-for-service program under parts A and B or the package of benefits available through a Medicare Advantage plan under part C. The criteria employed under the demonstration program under this section to evaluate outcomes and determine best practice guidelines and incentives shall not be used as a basis for the denial of medicare benefits under the demonstration program to patients against their wishes (or if the patient is incompetent, against the wishes of the patient's surrogate) on the basis of the patient's age or expected length of life or of the patient's present or predicted disability, degree of medical dependency, or quality of life.

(d) Eligibility criteria

To be eligible to receive assistance under this section, an entity shall—

(1) be a health care group;

(2) meet quality standards established by the Secretary, including—

(A) the implementation of continuous quality improvement mechanisms that are aimed at integrating community-based support services, primary care, and referral care;

(B) the implementation of activities to increase the delivery of effective care to beneficiaries;

(C) encouraging patient participation in preference-based decisions;

(D) the implementation of activities to encourage the coordination and integration of medical service delivery; and

(E) the implementation of activities to measure and document the financial impact on the health care marketplace of altering the incentives of health care delivery and changing the allocation of resources; and

(3) meet such other requirements as the Secretary may establish.

(e) Waiver authority

The Secretary may waive such requirements of this subchapter and subchapter XI as may be necessary to carry out the purposes of the demonstration program established under this section.

(f) Budget neutrality

With respect to the period of the demonstration program under subsection (b), the aggregate expenditures under this subchapter for such period shall not exceed the aggregate expenditures that would have been expended under this subchapter if the program established under this section had not been implemented.

(g) Notice requirements

In the case of an individual that receives health care items or services under a demonstration program carried out under this section, the Secretary shall ensure that such individual is notified of any waivers of coverage or payment rules that are applicable to such individual under this subchapter as a result of the participation of the individual in such program.

(h) Participation and support by Federal agencies

In carrying out the demonstration program under this section, the Secretary may direct—

(1) the Director of the National Institutes of Health to expand the efforts of the Institutes to evaluate current medical technologies and improve the foundation for evidence-based practice;

(2) the Administrator of the Agency for Healthcare Research and Quality to, where possible and appropriate, use the program under this section as a laboratory for the study of quality improvement strategies and to evaluate, monitor, and disseminate information relevant to such program; and

(3) the Administrator of the Centers for Medicare & Medicaid Services and the Administrator of the Center for Medicare Choices to support linkages of relevant medicare data to registry information from participating health care groups for the beneficiary populations served by the participating groups, for analysis supporting the purposes of the demonstration program, consistent with the applicable provisions of the Health Insurance Portability and Accountability Act of 1996.

(Aug. 14, 1935, ch. 531, title XVIII, § 1866C, as added Pub. L. 108–173, title VI, § 646, Dec. 8, 2003, 117 Stat. 2324; amended Pub. L. 111–148, title III, § 3021(c), Mar. 23, 2010, 124 Stat. 395.)

REFERENCES IN TEXT

The Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (h)(3), is Pub. L. 104–191, Aug. 21, 1996, 110 Stat. 1936. For complete classification of this Act to the Code, see section 1(a) of Pub. L. 104–191, set out as a Short Title of 1996 Amendments note under section 201 of this title and Tables.

AMENDMENTS

2010—Subsec. (b). Pub. L. 111–148 struck out ''5-year'' before ''demonstration program'' in introductory provisions.

Subsec. (f). Pub. L. 111–148 struck out ''5-year'' before ''period of the demonstration program''.

§ 1395cc–4. National pilot program on payment bundling

(a) Implementation

(1) In general

The Secretary shall establish a pilot program for integrated care during an episode of care provided to an applicable beneficiary around a hospitalization in order to improve the coordination, quality, and efficiency of health care services under this subchapter.

(2) Definitions

In this section:

(A) Applicable beneficiary

The term ''applicable beneficiary'' means an individual who—

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

under part B of such subchapter, but not enrolled under part C or a PACE program under section 1395eee of this title; and

(ii) is admitted to a hospital for an applicable condition.

(B) Applicable condition

The term ''applicable condition'' means 1 or more of 10 conditions selected by the Secretary. In selecting conditions under the preceding sentence, the Secretary shall take into consideration the following factors:

(i) Whether the conditions selected include a mix of chronic and acute conditions.

(ii) Whether the conditions selected include a mix of surgical and medical conditions.

(iii) Whether a condition is one for which there is evidence of an opportunity for providers of services and suppliers to improve the quality of care furnished while reducing total expenditures under this subchapter.

(iv) Whether a condition has significant variation in—

(I) the number of readmissions; and

(II) the amount of expenditures for post-acute care spending under this subchapter.

(v) Whether a condition is high-volume and has high post-acute care expenditures under this subchapter.

(vi) Which conditions the Secretary determines are most amenable to bundling across the spectrum of care given practice patterns under this subchapter.

(C) Applicable services

The term ''applicable services'' means the following:

(i) Acute care inpatient services.

(ii) Physicians' services delivered in and outside of an acute care hospital setting.

(iii) Outpatient hospital services, including emergency department services.

(iv) Post-acute care services, including home health services, skilled nursing services, inpatient rehabilitation services, and inpatient hospital services furnished by a long-term care hospital.

(v) Other services the Secretary determines appropriate.

(D) Episode of care

(i) In general

Subject to clause (ii), the term ''episode of care'' means, with respect to an applicable condition and an applicable beneficiary, the period that includes—

(I) the 3 days prior to the admission of the applicable beneficiary to a hospital for the applicable condition;

(II) the length of stay of the applicable beneficiary in such hospital; and

(III) the 30 days following the discharge of the applicable beneficiary from such hospital.

(ii) Establishment of period by the Secretary

The Secretary, as appropriate, may establish a period (other than the period described in clause (i)) for an episode of care under the pilot program.

(E) Physicians' services

The term ''physicians' services'' has the meaning given such term in section 1395x(q) of this title.

(F) Pilot program

The term ''pilot program'' means the pilot program under this section.

(G) Provider of services

The term ''provider of services'' has the meaning given such term in section 1395x(u) of this title.

(H) Readmission

The term ''readmission'' has the meaning given such term in section 1395ww(q)(5)(E) of this title.

(I) Supplier

The term ''supplier'' has the meaning given such term in section 1395x(d) of this title.

(3) Deadline for implementation

The Secretary shall establish the pilot program not later than January 1, 2013.

(b) Developmental phase

(1) Determination of patient assessment instrument

The Secretary shall determine which patient assessment instrument (such as the Continuity Assessment Record and Evaluation (CARE) tool) shall be used under the pilot program to evaluate the applicable condition of an applicable beneficiary for purposes of determining the most clinically appropriate site for the provision of post-acute care to the applicable beneficiary.

(2) Development of quality measures for an episode of care and for post-acute care

(A) In general

The Secretary, in consultation with the Agency for Healthcare Research and Quality and the entity with a contract under section 1395aaa(a) of this title, shall develop quality measures for use in the pilot program—

(i) for episodes of care; and

(ii) for post-acute care.

(B) Site-neutral post-acute care quality measures

Any quality measures developed under subparagraph (A)(ii) shall be site-neutral.

(C) Coordination with quality measure development and endorsement procedures

The Secretary shall ensure that the development of quality measures under subparagraph (A) is done in a manner that is consistent with the measures developed and endorsed under section [1] 1395aaa and 1395aaa–1 of this title that are applicable to all post-acute care settings.

[1] So in original. Probably should be ''sections''.

(c) Details

(1) Duration

(A) In general

Subject to subparagraph (B), the pilot program shall be conducted for a period of 5 years.

(B) Expansion

The Secretary may, at any point after January 1, 2016, expand the duration and scope of the pilot program, to the extent determined appropriate by the Secretary, if—

(i) the Secretary determines that such expansion is expected to—

(I) reduce spending under this subchapter without reducing the quality of care; or

(II) improve the quality of care and reduce spending;

(ii) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce program spending under this subchapter; and

(iii) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under this subchapter for individuals.

(2) Participating providers of services and suppliers

(A) In general

An entity comprised of providers of services and suppliers, including a hospital, a physician group, a skilled nursing facility, and a home health agency, who are otherwise participating under this subchapter, may submit an application to the Secretary to provide applicable services to applicable individuals under this section.

(B) Requirements

The Secretary shall develop requirements for entities to participate in the pilot program under this section. Such requirements shall ensure that applicable beneficiaries have an adequate choice of providers of services and suppliers under the pilot program.

(3) Payment methodology

(A) In general

(i) Establishment of payment methods

The Secretary shall develop payment methods for the pilot program for entities participating in the pilot program. Such payment methods may include bundled payments and bids from entities for episodes of care. The Secretary shall make payments to the entity for services covered under this section.

(ii) No additional program expenditures

Payments under this section for applicable items and services under this subchapter (including payment for services described in subparagraph (B)) for applicable beneficiaries for a year shall be established in a manner that does not result in spending more for such entity for such beneficiaries than would otherwise be expended for such entity for such beneficiaries for such year if the pilot program were not implemented, as estimated by the Secretary.

(B) Inclusion of certain services

A payment methodology tested under the pilot program shall include payment for the furnishing of applicable services and other appropriate services, such as care coordination, medication reconciliation, discharge planning, transitional care services, and other patient-centered activities as determined appropriate by the Secretary.

(C) Bundled payments

(i) In general

A bundled payment under the pilot program shall—

(I) be comprehensive, covering the costs of applicable services and other appropriate services furnished to an individual during an episode of care (as determined by the Secretary); and

(II) be made to the entity which is participating in the pilot program.

(ii) Requirement for provision of applicable services and other appropriate services

Applicable services and other appropriate services for which payment is made under this subparagraph shall be furnished or directed by the entity which is participating in the pilot program.

(D) Payment for post-acute care services after the episode of care

The Secretary shall establish procedures, in the case where an applicable beneficiary requires continued post-acute care services after the last day of the episode of care, under which payment for such services shall be made.

(4) Quality measures

(A) In general

The Secretary shall establish quality measures (including quality measures of process, outcome, and structure) related to care provided by entities participating in the pilot program. Quality measures established under the preceding sentence shall include measures of the following:

(i) Functional status improvement.

(ii) Reducing rates of avoidable hospital readmissions.

(iii) Rates of discharge to the community.

(iv) Rates of admission to an emergency room after a hospitalization.

(v) Incidence of health care acquired infections.

(vi) Efficiency measures.

(vii) Measures of patient-centeredness of care.

(viii) Measures of patient perception of care.

(ix) Other measures, including measures of patient outcomes, determined appropriate by the Secretary.

(B) Reporting on quality measures

(i) In general

A entity shall submit data to the Secretary on quality measures established

under subparagraph (A) during each year of the pilot program (in a form and manner, subject to clause (iii), specified by the Secretary).

(ii) Submission of data through electronic health record

To the extent practicable, the Secretary shall specify that data on measures be submitted under clause (i) through the use of an qualified electronic health record (as defined in section 300jj(13) of this title) in a manner specified by the Secretary.

(d) Waiver

The Secretary may waive such provisions of this subchapter and subchapter XI as may be necessary to carry out the pilot program.

(e) Independent evaluation and reports on pilot program

(1) Independent evaluation

The Secretary shall conduct an independent evaluation of the pilot program, including the extent to which the pilot program has—

(A) improved quality measures established under subsection (c)(4)(A);

(B) improved health outcomes;

(C) improved applicable beneficiary access to care; and

(D) reduced spending under this subchapter.

(2) Reports

(A) Interim report

Not later than 2 years after the implementation of the pilot program, the Secretary shall submit to Congress a report on the initial results of the independent evaluation conducted under paragraph (1).

(B) Final report

Not later than 3 years after the implementation of the pilot program, the Secretary shall submit to Congress a report on the final results of the independent evaluation conducted under paragraph (1).

(f) Consultation

The Secretary shall consult with representatives of small rural hospitals, including critical access hospitals (as defined in section 1395x(mm)(1) of this title), regarding their participation in the pilot program. Such consultation shall include consideration of innovative methods of implementing bundled payments in hospitals described in the preceding sentence, taking into consideration any difficulties in doing so as a result of the low volume of services provided by such hospitals.

(g) Application of pilot program to continuing care hospitals

(1) In general

In conducting the pilot program, the Secretary shall apply the provisions of the program so as to separately pilot test the continuing care hospital model.

(2) Special rules

In pilot testing the continuing care hospital model under paragraph (1), the following rules shall apply:

(A) Such model shall be tested without the limitation to the conditions selected under subsection (a)(2)(B).

(B) Notwithstanding subsection (a)(2)(D), an episode of care shall be defined as the full period that a patient stays in the continuing care hospital plus the first 30 days following discharge from such hospital.

(3) Continuing care hospital defined

In this subsection, the term ''continuing care hospital'' means an entity that has demonstrated 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 1395ww(d)(1)(B)(ii) of this title), long term care hospitals (as defined in section 1395ww(d)(1)(B)(iv)(I)[2] of this title), and skilled nursing facilities (as defined in section 1395i–3(a) of this title) that are located in a hospital described in section 1395ww(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.)

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, § 15008(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, § 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.''

[2] See References in Text note below.

§ 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 in-home 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 (a);

(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 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