TITLE 42 - THE PUBLIC HEALTH AND WELFARE
CHAPTER 7 - SOCIAL SECURITY
SUBCHAPTER XVIII - HEALTH INSURANCE FOR AGED AND DISABLED

§ 1395b–8. Chronic care improvement

(a) Implementation of chronic care improvement programs

(1) In general

The Secretary shall provide for the phased-in development, testing, evaluation, and implementation of chronic care improvement programs in accordance with this section. Each such program shall be designed to improve clinical quality and beneficiary satisfaction and achieve spending targets with respect to expenditures under this subchapter for targeted beneficiaries with one or more threshold conditions.

(2) Definitions

For purposes of this section:

(A) Chronic care improvement program

The term "chronic care improvement program" means a program described in paragraph (1) that is offered under an agreement under subsection (b) or (c) of this section.

(B) Chronic care improvement organization

The term "chronic care improvement organization" means an entity that has entered into an agreement under subsection (b) or (c) of this section to provide, directly or through contracts with subcontractors, a chronic care improvement program under this section. Such an entity may be a disease management organization, health insurer, integrated delivery system, physician group practice, a consortium of such entities, or any other legal entity that the Secretary determines appropriate to carry out a chronic care improvement program under this section.

(C) Care management plan

The term "care management plan" means a plan established under subsection (d) of this section for a participant in a chronic care improvement program.

(D) Threshold condition

The term "threshold condition" means a chronic condition, such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), or other diseases or conditions, as selected by the Secretary as appropriate for the establishment of a chronic care improvement program.

(E) Targeted beneficiary

The term "targeted beneficiary" means, with respect to a chronic care improvement program, an individual who—

(i) is entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter, but not enrolled in a plan under part C of this subchapter;

(ii) has one or more threshold conditions covered under such program; and

(iii) has been identified under subsection (d)(1) of this section as a potential participant in such program.

(3) Construction

Nothing in this section shall be construed as—

(A) expanding the amount, duration, or scope of benefits under this subchapter;

(B) providing an entitlement to participate in a chronic care improvement program under this section;

(C) providing for any hearing or appeal rights under section 1395ff, 1395oo of this title, or otherwise, with respect to a chronic care improvement program under this section; or

(D) providing benefits under a chronic care improvement program for which a claim may be submitted to the Secretary by any provider of services or supplier (as defined in section 1395x (d) of this title).

(b) Developmental phase (Phase I)

(1) In general

In carrying out this section, the Secretary shall enter into agreements consistent with subsection (f) of this section with chronic care improvement organizations for the development, testing, and evaluation of chronic care improvement programs using randomized controlled trials. The first such agreement shall be entered into not later than 12 months after December 8, 2003.

(2) Agreement period

The period of an agreement under this subsection shall be for 3 years.

(3) Minimum participation

(A) In general

The Secretary shall enter into agreements under this subsection in a manner so that chronic care improvement programs offered under this section are offered in geographic areas that, in the aggregate, consist of areas in which at least 10 percent of the aggregate number of medicare beneficiaries reside.

(B) Medicare beneficiary defined

In this paragraph, the term "medicare beneficiary" means an individual who is entitled to benefits under part A of this subchapter, enrolled under part B of this subchapter, or both, and who resides in the United States.

(4) Site selection

In selecting geographic areas in which agreements are entered into under this subsection, the Secretary shall ensure that each chronic care improvement program is conducted in a geographic area in which at least 10,000 targeted beneficiaries reside among other individuals entitled to benefits under part A of this subchapter, enrolled under part B of this subchapter, or both to serve as a control population.

(5) Independent evaluations of Phase I programs

The Secretary shall contract for an independent evaluation of the programs conducted under this subsection. Such evaluation shall be done by a contractor with knowledge of chronic care management programs and demonstrated experience in the evaluation of such programs. Each evaluation shall include an assessment of the following factors of the programs:

(A) Quality improvement measures, such as adherence to evidence-based guidelines and rehospitalization rates.

(B) Beneficiary and provider satisfaction.

(C) Health outcomes.

(D) Financial outcomes, including any cost savings to the program under this subchapter.

(c) Expanded implementation phase (Phase II)

(1) In general

With respect to chronic care improvement programs conducted under subsection (b) of this section, if the Secretary finds that the results of the independent evaluation conducted under subsection (b)(6) of this section indicate that the conditions specified in paragraph (2) have been met by a

program (or components of such program), the Secretary shall enter into agreements consistent with subsection (f) of this section to expand the implementation of the program (or components) to additional geographic areas not covered under the program as conducted under subsection (b) of this section, which may include the implementation of the program on a national basis. Such expansion shall begin not earlier than 2 years after the program is implemented under subsection (b) of this section and not later than 6 months after the date of completion of such program.

(2) Conditions for expansion of programs

The conditions specified in this paragraph are, with respect to a chronic care improvement program conducted under subsection (b) of this section for a threshold condition, that the program is expected to—

(A) improve the clinical quality of care;

(B) improve beneficiary satisfaction; and

(C) achieve targets for savings to the program under this subchapter specified by the Secretary in the agreement within a range determined to be appropriate by the Secretary, subject to the application of budget neutrality with respect to the program and not taking into account any payments by the organization under the agreement under the program for risk under subsection (f)(3)(B) of this section.

(3) Independent evaluations of Phase II programs

The Secretary shall carry out evaluations of programs expanded under this subsection as the Secretary determines appropriate. Such evaluations shall be carried out in the similar manner as is provided under subsection (b)(5) of this section.

(d) Identification and enrollment of prospective program participants

(1) Identification of prospective program participants

The Secretary shall establish a method for identifying targeted beneficiaries who may benefit from participation in a chronic care improvement program.

(2) Initial contact by Secretary

The Secretary shall communicate with each targeted beneficiary concerning participation in a chronic care improvement program. Such communication may be made by the Secretary and shall include information on the following:

(A) A description of the advantages to the beneficiary in participating in a program.

(B) Notification that the organization offering a program may contact the beneficiary directly concerning such participation.

(C) Notification that participation in a program is voluntary.

(D) A description of the method for the beneficiary to participate or for declining to participate and the method for obtaining additional information concerning such participation.

(3) Voluntary participation

A targeted beneficiary may participate in a chronic care improvement program on a voluntary basis and may terminate participation at any time.

(e) Chronic care improvement programs

(1) In general

Each chronic care improvement program shall—

(A) have a process to screen each targeted beneficiary for conditions other than threshold conditions, such as impaired cognitive ability and co-morbidities, for the purposes of developing an individualized, goal-oriented care management plan under paragraph (2);

(B) provide each targeted beneficiary participating in the program with such plan; and

(C) carry out such plan and other chronic care improvement activities in accordance with paragraph (3).

(2) Elements of care management plans

A care management plan for a targeted beneficiary shall be developed with the beneficiary and shall, to the extent appropriate, include the following:

(A) A designated point of contact responsible for communications with the beneficiary and for facilitating communications with other health care providers under the plan.

(B) Self-care education for the beneficiary (through approaches such as disease management or medical nutrition therapy) and education for primary caregivers and family members.

(C) Education for physicians and other providers and collaboration to enhance communication of relevant clinical information.

(D) The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment.

(E) The provision of information about hospice care, pain and palliative care, and end-of-life care.

(3) Conduct of programs

In carrying out paragraph (1)(C) with respect to a participant, the chronic care improvement organization shall—

(A) guide the participant in managing the participant's health (including all co-morbidities, relevant health care services, and pharmaceutical needs) and in performing activities as specified under the elements of the care management plan of the participant;

(B) use decision-support tools such as evidence-based practice guidelines or other criteria as determined by the Secretary; and

(C) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

(4) Additional responsibilities

(A) Outcomes report

Each chronic care improvement organization offering a chronic care improvement program shall monitor and report to the Secretary, in a manner specified by the Secretary, on health care quality, cost, and outcomes.

(B) Additional requirements

Each such organization and program shall comply with such additional requirements as the Secretary may specify.

(5) Accreditation

The Secretary may provide that chronic care improvement programs and chronic care improvement organizations that are accredited by qualified organizations (as defined by the Secretary) may be deemed to meet such requirements under this section as the Secretary may specify.

(f) Terms of agreements

(1) Terms and conditions

(A) In general

An agreement under this section with a chronic care improvement organization shall contain such terms and conditions as the Secretary may specify consistent with this section.

(B) Clinical, quality improvement, and financial requirements

The Secretary may not enter into an agreement with such an organization under this section for the operation of a chronic care improvement program unless—

(i) the program and organization meet the requirements of subsection (e) of this section and such clinical, quality improvement, financial, and other requirements as the Secretary deems to be appropriate for the targeted beneficiaries to be served; and

(ii) the organization demonstrates to the satisfaction of the Secretary that the organization is able to assume financial risk for performance under the agreement (as applied under paragraph (3)(B)) with respect to payments made to the organization under such agreement through available reserves, reinsurance, withholds, or such other means as the Secretary determines appropriate.

(2) Manner of payment

Subject to paragraph (3)(B), the payment under an agreement under—

(A) subsection (b) of this section shall be computed on a per-member per-month basis; or

(B) subsection (c) of this section may be on a per-member per-month basis or such other basis as the Secretary and organization may agree.

(3) Application of performance standards

(A) Specification of performance standards

Each agreement under this section with a chronic care improvement organization shall specify performance standards for each of the factors specified in subsection (c)(2) of this section, including clinical quality and spending targets under this subchapter, against which the performance of the chronic care improvement organization under the agreement is measured.

(B) Adjustment of payment based on performance

(i) In general

Each such agreement shall provide for adjustments in payment rates to an organization under the agreement insofar as the Secretary determines that the organization failed to meet the performance standards specified in the agreement under subparagraph (A).

(ii) Financial risk for performance

In the case of an agreement under subsection (b) or (c) of this section, the agreement shall provide for a full recovery for any amount by which the fees paid to the organization under the agreement exceed the estimated savings to the programs under this subchapter attributable to implementation of such agreement.

(4) Budget neutral payment condition

Under this section, the Secretary shall ensure that the aggregate sum of medicare program benefit expenditures for beneficiaries participating in chronic care improvement programs and funds paid to chronic care improvement organizations under this section, shall not exceed the medicare program benefit expenditures that the Secretary estimates would have been made for such targeted beneficiaries in the absence of such programs.

(g) Funding

(1) Subject to paragraph (2), there are appropriated to the Secretary, in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund, such sums as may be necessary to provide for agreements with chronic care improvement programs under this section.

(2) In no case shall the funding under this section exceed $100,000,000 in aggregate increased expenditures under this subchapter (after taking into account any savings attributable to the operation of this section) over the 3-fiscal-year period beginning on October 1, 2003.

(Aug. 14, 1935, ch. 531, title XVIII, § 1807, as added Pub. L. 108–173, title VII, § 721(a), Dec. 8, 2003, 117 Stat. 2341.)

References in Text

Parts A, B, and C of this subchapter, referred to in subsecs. (a)(2)(E)(i) and (b)(3)(B), (4), are classified to sections 1395c et seq., 1395j et seq., and 1395w–21 et seq., respectively, of this title.

Demonstration Project for Consumer-Directed Chronic Outpatient Services

Pub. L. 108–173, title VI, § 648, Dec. 8, 2003, 117 Stat. 2327, provided that:

"(a) Establishment.—

"(1) In general.—Subject to the succeeding provisions of this section, the Secretary [of Health and Human Services] shall establish demonstration projects (in this section referred to as 'demonstration projects') under which the Secretary shall evaluate methods that improve the quality of care provided to individuals with chronic conditions and that reduce expenditures that would otherwise be made under the medicare program on behalf of such individuals for such chronic conditions, such methods to include permitting those beneficiaries to direct their own health care needs and services.

"(2) Individuals with chronic conditions defined.—In this section, the term 'individuals with chronic conditions' means an individual entitled to benefits under part A of title XVIII of the Social Security Act [part A of this subchapter], and enrolled under part B of such title [part B of this subchapter], but who is not enrolled under part C of such title [part C of this subchapter] who is diagnosed as having one or more chronic conditions (as defined by the Secretary), such as diabetes.

"(b) Design of Projects.—

"(1) Evaluation before implementation of project.—

"(A) In general.—In establishing the demonstration projects under this section, the Secretary shall evaluate best practices employed by group health plans and practices under State plans for medical assistance under the medicaid program under title XIX of the Social Security Act [subchapter XIX of this chapter], as well as best practices in the private sector or other areas, of methods that permit patients to self-direct the provision of personal care services. The Secretary shall evaluate such practices for a 1-year period and, based on such evaluation, shall design the demonstration project.

"(B) Requirement for estimate of budget neutral costs.—As part of the evaluation under subparagraph (A), the Secretary shall evaluate the costs of furnishing care under the projects. The Secretary may not implement the demonstration projects under this section unless the Secretary determines that the costs of providing care to individuals with chronic conditions under the project will not exceed the costs, in the aggregate, of furnishing care to such individuals under title XVIII of the Social Security Act [this subchapter], that would otherwise be paid without regard to the demonstration projects for the period of the project.

"(2) Scope of services.—The Secretary shall determine the appropriate scope of personal care services that would apply under the demonstration projects.

"(c) Voluntary Participation.—Participation of providers of services and suppliers, and of individuals with chronic conditions, in the demonstration projects shall be voluntary.

"(d) Demonstration Projects Sites.—Not later than 2 years after the date of the enactment of this Act [Dec. 8, 2003], the Secretary shall conduct a demonstration project in at least one area that the Secretary determines has a population of individuals entitled to benefits under part A of title XVIII of the Social Security Act [part A of this subchapter], and enrolled under part B of such title [part B of this subchapter], with a rate of incidence of diabetes that significantly exceeds the national average rate of all areas.

"(e) Evaluation and Report.—

"(1) Evaluations.—The Secretary shall conduct evaluations of the clinical and cost effectiveness of the demonstration projects.

"(2) Reports.—Not later than 2 years after the commencement of the demonstration projects, and biannually thereafter, the Secretary shall submit to Congress a report on the evaluation, and shall include in the report the following:

"(A) An analysis of the patient outcomes and costs of furnishing care to the individuals with chronic conditions participating in the projects as compared to such outcomes and costs to other individuals for the same health conditions.

"(B) Evaluation of patient satisfaction under the demonstration projects.

"(C) Such recommendations regarding the extension, expansion, or termination of the projects as the Secretary determines appropriate.

"(f) Waiver Authority.—The Secretary shall waive compliance with the requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) to such extent and for such period as the Secretary determines is necessary to conduct demonstration projects.

"(g) Authorization of Appropriations.—(1) Payments for the costs of carrying out the demonstration project under this section shall be made from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t).

"(2) There are authorized to be appropriated from such Trust Fund such sums as may be necessary for the Secretary to enter into contracts with appropriate organizations for the deign [sic], implementation, and evaluation of the demonstration project.

"(3) In no case may expenditures under this section exceed the aggregate expenditures that would otherwise have been made for the provision of personal care services."

Reports

Pub. L. 108–173, title VII, § 721(b), Dec. 8, 2003, 117 Stat. 2346, provided that: "The Secretary [of Health and Human Services] shall submit to Congress reports on the operation of section 1807 of the Social Security Act [this section], as added by subsection (a), as follows:

"(1) Not later than 2 years after the date of the implementation of such section, the Secretary shall submit to Congress an interim report on the scope of implementation of the programs under subsection (b) of such section, the design of the programs, and preliminary cost and quality findings with respect to those programs based on the following measures of the programs:

"(A) Quality improvement measures, such as adherence to evidence-based guidelines and rehospitalization rates.

"(B) Beneficiary and provider satisfaction.

"(C) Health outcomes.

"(D) Financial outcomes.

"(2) Not later than 3 years and 6 months after the date of the implementation of such section the Secretary shall submit to Congress an update to the report required under paragraph (1) on the results of such programs.

"(3) The Secretary shall submit to Congress 2 additional biennial reports on the chronic care improvement programs conducted under such section. The first such report shall be submitted not later than 2 years after the report is submitted under paragraph (2). Each such report shall include information on—

"(A) the scope of implementation (in terms of both regions and chronic conditions) of the chronic care improvement programs;

"(B) the design of the programs; and

"(C) the improvements in health outcomes and financial efficiencies that result from such implementation."

Chronically Ill Medicare Beneficiary Research, Data, Demonstration Strategy

Pub. L. 108–173, title VII, § 723, Dec. 8, 2003, 117 Stat. 2348, provided that:

"(a) Development of Plan.—Not later than 6 months after the date of the enactment of this Act [Dec. 8, 2003], the Secretary [of Health and Human Services] shall develop a plan to improve quality of care and reduce the cost of care for chronically ill medicare beneficiaries.

"(b) Plan Requirements.—The plan will utilize existing data and identify data gaps, develop research initiatives, and propose intervention demonstration programs to provide better health care for chronically ill medicare beneficiaries. The plan shall—

"(1) integrate existing data sets including, the Medicare Current Beneficiary Survey (MCBS), Minimum Data Set (MDS), Outcome and Assessment Information Set (OASIS), data from Quality Improvement Organizations (QIO), and claims data;

"(2) identify any new data needs and a methodology to address new data needs;

"(3) plan for the collection of such data in a data warehouse; and

"(4) develop a research agenda using such data.

"(c) Consultation.—In developing the plan under this section, the Secretary shall consult with experts in the fields of care for the chronically ill (including clinicians).

"(d) Implementation.—Not later than 2 years after the date of the enactment of this Act [Dec. 8, 2003], the Secretary shall implement the plan developed under this section. The Secretary may contract with appropriate entities to implement such plan.

"(e) Authorization of Appropriations.—There are authorized to be appropriated to the Secretary such sums as may be necessary in fiscal years 2004 and 2005 to carry out this section."