

“(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 design [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 [42 U.S.C. 1395b-8], 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.”

#### § 1395b-9. Provisions relating to administration

##### (a) Coordinated administration of medicare prescription drug and Medicare Advantage programs

###### (1) In general

There is within the Centers for Medicare & Medicaid Services a center to carry out the duties described in paragraph (3).

###### (2) Director

Such center shall be headed by a director who shall report directly to the Administrator of the Centers for Medicare & Medicaid Services.

###### (3) Duties

The duties described in this paragraph are the following:

(A) The administration of parts C and D.

(B) The provision of notice and information under section 1395b-2 of this title.

(C) Such other duties as the Secretary may specify.

###### (4) Deadline

The Secretary shall ensure that the center is carrying out the duties described in paragraph (3) by not later than January 1, 2008.

##### (b) Employment of management staff

###### (1) In general

The Secretary may employ, within the Centers for Medicare & Medicaid Services, such individuals as management staff as the Secretary determines to be appropriate. With respect to the administration of parts C and D, such individuals shall include individuals with private sector expertise in negotiations with health benefits plans.

###### (2) Eligibility

To be eligible for employment under paragraph (1) an individual shall be required to

have demonstrated, by their education and experience (either in the public or private sector), superior expertise in at least one of the following areas:

- (A) The review, negotiation, and administration of health care contracts.
- (B) The design of health care benefit plans.
- (C) Actuarial sciences.
- (D) Compliance with health plan contracts.
- (E) Consumer education and decision making.
- (F) Any other area specified by the Secretary that requires specialized management or other expertise.

### (3) Rates of payment

#### (A) Performance-related pay

Subject to subparagraph (B), the Secretary shall establish the rate of pay for an individual employed under paragraph (1). Such rate shall take into account expertise, experience, and performance.

#### (B) Limitation

In no case may the rate of compensation determined under subparagraph (A) exceed the highest rate of basic pay for the Senior Executive Service under section 5382(b) of title 5.

### (c) Medicare Beneficiary Ombudsman

#### (1) In general

The Secretary shall appoint within the Department of Health and Human Services a Medicare Beneficiary Ombudsman who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under this subchapter.

#### (2) Duties

The Medicare Beneficiary Ombudsman shall—

- (A) receive complaints, grievances, and requests for information submitted by individuals entitled to benefits under part A or enrolled under part B, or both, with respect to any aspect of the medicare program;
- (B) provide assistance with respect to complaints, grievances, and requests referred to in subparagraph (A), including—
  - (i) assistance in collecting relevant information for such individuals, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, MA organization, or the Secretary;
  - (ii) assistance to such individuals with any problems arising from disenrollment from an MA plan under part C; and
  - (iii) assistance to such individuals in presenting information under section 1395r(i)(4)(C) of this title (relating to income-related premium adjustment;<sup>1</sup> and
- (C) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such recommendations for improvement in the adminis-

tration of this subchapter as the Ombudsman determines appropriate.

The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

### (3) Working with health insurance counseling programs

To the extent possible, the Ombudsman shall work with health insurance counseling programs (receiving funding under section 1395b-4 of this title) to facilitate the provision of information to individuals entitled to benefits under part A or enrolled under part B, or both regarding MA plans and changes to those plans. Nothing in this paragraph shall preclude further collaboration between the Ombudsman and such programs.

### (d) Pharmaceutical and technology ombudsman

#### (1) In general

Not later than 12 months after December 13, 2016, the Secretary shall provide for a pharmaceutical and technology ombudsman within the Centers for Medicare & Medicaid Services who shall receive and respond to complaints, grievances, and requests that—

- (A) are from entities that manufacture pharmaceutical, biotechnology, medical device, or diagnostic products that are covered or for which coverage is being sought under this subchapter; and
- (B) are with respect to coverage, coding, or payment under this subchapter for such products.

#### (2) Application

The second sentence of subsection (c)(2) shall apply to the ombudsman under subparagraph (A) in the same manner as such sentence applies to the Medicare Beneficiary Ombudsman under subsection (c).

(Aug. 14, 1935, ch. 531, title XVIII, § 1808, as added and amended Pub. L. 108-173, title IX, §§ 900(a), (b), 923(a), Dec. 8, 2003, 117 Stat. 2369, 2393; Pub. L. 114-255, div. A, title IV, § 4010, Dec. 13, 2016, 130 Stat. 1185.)

#### AMENDMENTS

- 2016—Subsec. (d). Pub. L. 114-255 added subsec. (d).
- 2003—Subsec. (b). Pub. L. 108-173, § 900(b), added subsec. (b).
- Subsec. (c). Pub. L. 108-173, § 923(a), added subsec. (c).

#### DEADLINE FOR APPOINTMENT

Pub. L. 108-173, title IX, § 923(b), Dec. 8, 2003, 117 Stat. 2394, provided that: “By not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003], the Secretary [of Health and Human Services] shall appoint the Medicare Beneficiary Ombudsman under section 1808(c) of the Social Security Act [42 U.S.C. 1395b-9(c)], as added by subsection (a).”

### § 1395b-10. Addressing health care disparities

#### (a) Evaluating data collection approaches

The Secretary shall evaluate approaches for the collection of data under this subchapter, to be performed in conjunction with existing quality reporting requirements and programs under this subchapter, that allow for the ongoing, ac-

<sup>1</sup> So in original. A closing parenthesis probably should precede the semicolon.