so that such individual or entity participates in a demonstration under this section and will share in any bonus earned under subsection (d) of this section.

### (b) Eligibility criteria

#### (1) In general

The Secretary is authorized to establish criteria for health care groups eligible to participate in a demonstration under this section, including criteria relating to numbers of health care professionals in, and of patients served by, the group, scope of services provided, and quality of care.

#### (2) Payment method

A health care group participating in the demonstration under this section shall agree with respect to services furnished to beneficiaries within the scope of the demonstration (as determined under subsection (c) of this section)—

- (A) to be paid on a fee-for-service basis; and
- (B) that payment with respect to all such services furnished by members of the health care group to such beneficiaries shall (where determined appropriate by the Secretary) be made to a single entity.

#### (3) Data reporting

A health care group participating in a demonstration under this section shall report to the Secretary such data, at such times and in such format as the Secretary requires, for purposes of monitoring and evaluation of the demonstration under this section.

## (c) Patients within scope of demonstration

## (1) In general

The Secretary shall specify, in accordance with this subsection, the criteria for identifying those patients of a health care group who shall be considered within the scope of the demonstration under this section for purposes of application of subsection (d) of this section and for assessment of the effectiveness of the group in achieving the objectives of this section.

#### (2) Other criteria

The Secretary may establish additional criteria for inclusion of beneficiaries within a demonstration under this section, which may include frequency of contact with physicians in the group or other factors or criteria that the Secretary finds to be appropriate.

### (3) Notice requirements

In the case of each beneficiary determined to be within the scope of a demonstration under this section with respect to a specific health care group, the Secretary shall ensure that such beneficiary is notified of the incentives, and of any waivers of coverage or payment rules, applicable to such group under such demonstration.

#### (d) Incentives

### (1) Performance target

The Secretary shall establish for each health care group participating in a demonstration under this section—

(A) a base expenditure amount, equal to the average total payments under parts A and B of this subchapter for patients served by the health care group on a fee-for-service basis in a base period determined by the Secretary; and

(B) an annual per capita expenditure target for patients determined to be within the scope of the demonstration, reflecting the base expenditure amount adjusted for risk and expected growth rates.

#### (2) Incentive bonus

The Secretary shall pay to each participating health care group (subject to paragraph (4)) a bonus for each year under the demonstration equal to a portion of the medicare savings realized for such year relative to the performance target.

# (3) Additional bonus for process and outcome improvements

At such time as the Secretary has established appropriate criteria based on evidence the Secretary determines to be sufficient, the Secretary shall also pay to a participating health care group (subject to paragraph (4)) an additional bonus for a year, equal to such portion as the Secretary may designate of the saving to the program under this subchapter resulting from process improvements made by and patient outcome improvements attributable to activities of the group.

#### (4) Limitation

The Secretary shall limit bonus payments under this section as necessary to ensure that the aggregate expenditures under this subchapter (inclusive of bonus payments) with respect to patients within the scope of the demonstration do not exceed the amount which the Secretary estimates would be expended if the demonstration projects under this section were not implemented.

(Aug. 14, 1935, ch. 531, title XVIII, \$1866A, as added Pub. L. 106-554, \$1(a)(6) [title IV, \$412(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A-509.)

#### GAO REPORT

Pub. L. 106–554, §1(a)(6) [title IV, §412(b)], Dec. 21, 2000, 114 Stat. 2763, 2763A–515, provided that: "Not later than 2 years after the date on which the demonstration project under section 1866A of the Social Security Act [42 U.S.C. 1395cc–1], as added by subsection (a), is implemented, the Comptroller General of the United States shall submit to Congress a report on such demonstration project. The report shall include such recommendations with respect to changes to the demonstration project that the Comptroller General determines appropriate."

#### § 1395cc-2. Provisions for administration of demonstration program

## (a) General administrative authority

## (1) Beneficiary eligibility

Except as otherwise provided by the Secretary, an individual shall only be eligible to receive benefits under the program under section 1395cc-1 of this title (in this section referred to as the "demonstration program") if such individual—

(A) is enrolled under the program under part B of this subchapter and entitled to benefits under part A of this subchapter; and (B) is not enrolled in a Medicare+Choice plan under part C of this subchapter, an eligible organization under a contract under section 1395mm of this title (or a similar organization operating under a demonstration project authority), an organization with an agreement under section 1395l(a)(1)(A) of this title, or a PACE program under section 1395eee of this title.

## (2) Secretary's discretion as to scope of program

The Secretary may limit the implementation of the demonstration program to—

- (A) a geographic area (or areas) that the Secretary designates for purposes of the program, based upon such criteria as the Secretary finds appropriate;
- (B) a subgroup (or subgroups) of beneficiaries or individuals and entities furnishing items or services (otherwise eligible to participate in the program), selected on the basis of the number of such participants that the Secretary finds consistent with the effective and efficient implementation of the program;
- (C) an element (or elements) of the program that the Secretary determines to be suitable for implementation; or
- (D) any combination of any of the limits described in subparagraphs (A) through (C).

## (3) Voluntary receipt of items and services

Items and services shall be furnished to an individual under the demonstration program only at the individual's election.

#### (4) Agreements

The Secretary is authorized to enter into agreements with individuals and entities to furnish health care items and services to beneficiaries under the demonstration program.

#### (5) Program standards and criteria

The Secretary shall establish performance standards for the demonstration program including, as applicable, standards for quality of health care items and services, cost-effectiveness, beneficiary satisfaction, and such other factors as the Secretary finds appropriate. The eligibility of individuals or entities for the initial award, continuation, and renewal of agreements to provide health care items and services under the program shall be conditioned, at a minimum, on performance that meets or exceeds such standards.

# (6) Administrative review of decisions affecting individuals and entities furnishing services

An individual or entity furnishing services under the demonstration program shall be entitled to a review by the program administrator (or, if the Secretary has not contracted with a program administrator, by the Secretary) of a decision not to enter into, or to terminate, or not to renew, an agreement with the entity to provide health care items or services under the program.

### (7) Secretary's review of marketing materials

An agreement with an individual or entity furnishing services under the demonstration program shall require the individual or entity to guarantee that it will not distribute materials that market items or services under the program without the Secretary's prior review and approval.

#### (8) Payment in full

#### (A) In general

Except as provided in subparagraph (B), an individual or entity receiving payment from the Secretary under a contract or agreement under the demonstration program shall agree to accept such payment as payment in full, and such payment shall be in lieu of any payments to which the individual or entity would otherwise be entitled under this subchapter.

#### (B) Collection of deductibles and coinsurance

Such individual or entity may collect any applicable deductible or coinsurance amount from a beneficiary.

#### (b) Contracts for program administration

#### (1) In general

The Secretary may administer the demonstration program through a contract with a program administrator in accordance with the provisions of this subsection.

#### (2) Scope of program administrator contracts

The Secretary may enter into such contracts for a limited geographic area, or on a regional or national basis.

#### (3) Eligible contractors

The Secretary may contract for the administration of the program with—

- (A) an entity that, under a contract under section 1395h or 1395u of this title, determines the amount of and makes payments for health care items and services furnished under this subchapter; or
- (B) any other entity with substantial experience in managing the type of program concerned.

## (4) Contract award, duration, and renewal

#### (A) In general

A contract under this subsection shall be for an initial term of up to three years, renewable for additional terms of up to three years.

#### (B) Noncompetitive award and renewal for entities administering part A or part B payments

The Secretary may enter or renew a contract under this subsection with an entity described in paragraph (3)(A) without regard to the requirements of section 6101 of title 41

## (5) Applicability of Federal Acquisition Regula-

The Federal Acquisition Regulation shall apply to program administration contracts under this subsection.

## (6) Performance standards

The Secretary shall establish performance standards for the program administrator including, as applicable, standards for the quality and cost-effectiveness of the program administered, and such other factors as the Secretary finds appropriate. The eligibility of entities for the initial award, continuation, and renewal of program administration contracts shall be conditioned, at a minimum, on performance that meets or exceeds such standards.

### (7) Functions of program administrator

A program administrator shall perform any or all of the following functions, as specified by the Secretary:

# (A) Agreements with entities furnishing health care items and services

Determine the qualifications of entities seeking to enter or renew agreements to provide services under the demonstration program, and as appropriate enter or renew (or refuse to enter or renew) such agreements on behalf of the Secretary.

#### (B) Establishment of payment rates

Negotiate or otherwise establish, subject to the Secretary's approval, payment rates for covered health care items and services.

#### (C) Payment of claims or fees

Administer payments for health care items or services furnished under the program

#### (D) Payment of bonuses

Using such guidelines as the Secretary shall establish, and subject to the approval of the Secretary, make bonus payments as described in subsection (c)(2)(B) of this section to entities furnishing items or services for which payment may be made under the program.

## (E) Oversight

Monitor the compliance of individuals and entities with agreements under the program with the conditions of participation.

#### (F) Administrative review

Conduct reviews of adverse determinations specified in subsection (a)(6) of this section.

## (G) Review of marketing materials

Conduct a review of marketing materials proposed by an entity furnishing services under the program.

#### (H) Additional functions

Perform such other functions as the Secretary may specify.

#### (8) Limitation of liability

The provisions of section 1320c-6(b) of this title shall apply with respect to activities of contractors and their officers, employees, and agents under a contract under this subsection.

### (9) Information sharing

Notwithstanding section 1306 of this title and section 552a of title 5, the Secretary is authorized to disclose to an entity with a program administration contract under this subsection such information (including medical information) on individuals receiving health care items and services under the program as the entity may require to carry out its responsibilities under the contract.

# (c) Rules applicable to both program agreements and program administration contracts

#### (1) Records, reports, and audits

The Secretary is authorized to require entities with agreements to provide health care items or services under the demonstration program, and entities with program administration contracts under subsection (b) of this section, to maintain adequate records, to afford the Secretary access to such records (including for audit purposes), and to furnish such reports and other materials (including audited financial statements and performance data) as the Secretary may require for purposes of implementation, oversight, and evaluation of the program and of individuals' and entities' effectiveness in performance of such agreements or contracts.

#### (2) Bonuses

Notwithstanding any other provision of law, but subject to subparagraph (B)(ii), the Secretary may make bonus payments under the demonstration program from the Federal Health Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in amounts that do not exceed the amounts authorized under the program in accordance with the following:

#### (A) Payments to program administrators

The Secretary may make bonus payments under the program to program administrators

## (B) Payments to entities furnishing services

#### (i) In general

Subject to clause (ii), the Secretary may make bonus payments to individuals or entities furnishing items or services for which payment may be made under the demonstration program, or may authorize the program administrator to make such bonus payments in accordance with such guidelines as the Secretary shall establish and subject to the Secretary's approval.

#### (ii) Limitations

The Secretary may condition such payments on the achievement of such standards related to efficiency, improvement in processes or outcomes of care, or such other factors as the Secretary determines to be appropriate.

### (3) Antidiscrimination limitation

The Secretary shall not enter into an agreement with an entity to provide health care items or services under the demonstration program, or with an entity to administer the program, unless such entity guarantees that it will not deny, limit, or condition the coverage or provision of benefits under the program, for individuals eligible to be enrolled under such program, based on any health status-related factor described in section 2702(a)(1)<sup>1</sup> of the Public Health Service Act.

#### (d) Limitations on judicial review

The following actions and determinations with respect to the demonstration program shall not

<sup>&</sup>lt;sup>1</sup> See References in Text note below.

be subject to review by a judicial or administrative tribunal:

- (1) Limiting the implementation of the program under subsection (a)(2) of this section.
- (2) Establishment of program participation standards under subsection (a)(5) of this section or the denial or termination of, or refusal to renew, an agreement with an entity to provide health care items and services under the program.
- (3) Establishment of program administration contract performance standards under subsection (b)(6) of this section, the refusal to renew a program administration contract, or the noncompetitive award or renewal of a program administration contract under subsection (b)(4)(B) of this section.
- (4) Establishment of payment rates, through negotiation or otherwise, under a program agreement or a program administration contract.
- (5) A determination with respect to the program (where specifically authorized by the program authority or by subsection (c)(2) of this section)—
  - (A) as to whether cost savings have been achieved, and the amount of savings; or
  - (B) as to whether, to whom, and in what amounts bonuses will be paid.

#### (e) Application limited to parts A and B

None of the provisions of this section or of the demonstration program shall apply to the programs under part C of this subchapter.

#### (f) Reports to Congress

Not later than two years after December 21, 2000, and biennially thereafter for six years, the Secretary shall report to Congress on the use of authorities under the demonstration program. Each report shall address the impact of the use of those authorities on expenditures, access, and quality under the programs under this subchapter.

(Aug. 14, 1935, ch. 531, title XVIII, §1866B, as added Pub. L. 106–554, §1(a)(6) [title IV, §412(a)], Dec. 21, 2000, 114 Stat. 2763, 2763A–511; amended Pub. L. 108–173, title VII, §736(c)(5), Dec. 8, 2003, 117 Stat. 2356.)

#### REFERENCES IN TEXT

Section 2702 of the Public Health Service Act, referred to in subsec. (c)(3), is section 2702 of act July 1, 1944, which was classified to section 300gg-1 of this title, was amended by Pub. L. 111-148, title I, §1201(3), Mar. 23, 2010, 124 Stat. 154, and was transferred to subsecs. (d) to (f) of section 300gg-4 of this title, effective for plan years beginning on or after Jan. 1, 2014. A new section 2702 of act July 1, 1944, related to guaranteed availability of coverage, was added by Pub. L. 111-148, title I, §1201(4), Mar. 23, 2010, 124 Stat. 156, effective for plan years beginning on or after Jan. 1, 2014, and is classified to section 300gg-1 of this title.

### CODIFICATION

In subsec. (b)(4)(B), "section 6101 of title 41" substituted for "section 5 of title 41, United States Code" on authority of Pub. L. 111–350,  $\S6(c)$ , Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

#### AMENDMENTS

2003—Subsec. (b)(7)(D). Pub. L. 108–173 substituted ''(c)(2)(B)'' for ''(c)(2)(A)(ii)''.

#### CHANGE OF NAME

References to Medicare+Choice deemed to refer to Medicare Advantage or MA, subject to an appropriate transition provided by the Secretary of Health and Human Services in the use of those terms, see section 201 of Pub. L. 108-173, set out as a note under section 1395w-21 of this title.

# §1395cc-3. Health care quality demonstration program

#### (a) Definitions

In this section:

#### (1) Beneficiary

The term "beneficiary" means an individual who is entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter, including any individual who is enrolled in a Medicare Advantage plan under part C of this subchapter.

#### (2) Health care group

#### (A) In general

The term "health care group" means-

- (i) a group of physicians that is organized at least in part for the purpose of providing physician's services under this subchapter;
- (ii) an integrated health care delivery system that delivers care through coordinated hospitals, clinics, home health agencies, ambulatory surgery centers, skilled nursing facilities, rehabilitation facilities and clinics, and employed, independent, or contracted physicians; or
- (iii) an organization representing regional coalitions of groups or systems described in clause (i) or (ii).

#### (B) Inclusion

As the Secretary determines appropriate, a health care group may include a hospital or any other individual or entity furnishing items or services for which payment may be made under this subchapter that is affiliated with the health care group under an arrangement structured so that such hospital, individual, or entity participates in a demonstration project under this section.

#### (3) Physician

Except as otherwise provided for by the Secretary, the term "physician" means any individual who furnishes services that may be paid for as physicians' services under this subchapter.

## (b) Demonstration projects

The Secretary shall establish a demonstration program under which the Secretary shall approve demonstration projects that examine health delivery factors that encourage the delivery of improved quality in patient care, including—

- (1) the provision of incentives to improve the safety of care provided to beneficiaries;
- (2) the appropriate use of best practice guidelines by providers and services by beneficiaries;
- (3) reduced scientific uncertainty in the delivery of care through the examination of variations in the utilization and allocation of