

(j) Demonstration authority

The Secretary may make demonstration awards under this section to historically black health professions schools for the purposes of—

(1) developing patient-based research infrastructure at historically black health professions schools, which have an affiliation, or affiliations, with any of the providers identified in subsection (b)(1)(B) of this section;

(2) establishment of joint and collaborative programs of medical research and data collection between historically black health professions schools and such providers, whose goal is to improve the health status of medically underserved populations; or

(3) supporting the research-related costs of patient care, data collection, and academic training resulting from such affiliations.

(k) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2002 through 2006.

(l) Date certain for termination of program

Funds may not be appropriated to carry out this section after September 30, 2006.

(July 1, 1944, ch. 373, title III, § 340, as added Pub. L. 107-251, title IV, § 402, Oct. 26, 2002, 116 Stat. 1655.)

PRIOR PROVISIONS

A prior section 256, act July 1, 1944, ch. 373, title III, § 340, as added July 22, 1987, Pub. L. 100-77, title VI, § 601, 101 Stat. 511; amended Nov. 4, 1988, Pub. L. 100-607, title VIII, §§ 801(a), (c), 802(a), (b)(1), 803, 804, 102 Stat. 3168, 3169; Nov. 7, 1988, Pub. L. 100-628, title VI, §§ 601(a), (c), 602(a), (b)(1), 603, 604, 102 Stat. 3241, 3242; Aug. 16, 1989, Pub. L. 101-93, § 5(t)(1), (3), 103 Stat. 615; Nov. 29, 1990, Pub. L. 101-645, title V, §§ 501-503, 104 Stat. 4724; Oct. 27, 1992, Pub. L. 102-531, title III, § 309(c), 106 Stat. 3501, related to grant program for certain health services for the homeless, prior to repeal by Pub. L. 104-299, § 4(a)(3), Oct. 11, 1996, 110 Stat. 3645, eff. Oct. 1, 1996.

Another prior section 256, act July 1, 1944, ch. 373, title III, § 340, as added Nov. 10, 1978, Pub. L. 95-626, title I, § 115(2), 92 Stat. 3567; amended Dec. 12, 1979, Pub. L. 96-142, title III, § 301(a), 93 Stat. 1073; Aug. 13, 1981, Pub. L. 97-35, title IX, § 903(b)(1), 95 Stat. 561; Jan. 4, 1983, Pub. L. 97-414, § 8(h), 96 Stat. 2061, related to primary care research and demonstration projects to serve medically underserved population, prior to repeal by Pub. L. 97-35, title IX, § 903(c), Aug. 13, 1981, 95 Stat. 561, eff. Oct. 1, 1982.

Another prior section 256, act July 1, 1944, ch. 373, title III, § 340, formerly § 332, 58 Stat. 698; renumbered § 340, Oct. 12, 1976, Pub. L. 94-484, title IV, § 407(b)(2), 90 Stat. 2268, related to apprehension, detention, treatment, and release of persons being treated for leprosy, prior to repeal by Pub. L. 95-626, title I, § 105(b), Nov. 10, 1978, 92 Stat. 3560.

PURPOSE

Pub. L. 107-251, title IV, § 401, Oct. 26, 2002, 116 Stat. 1655, provided that: "The purpose of this title [enacting this subpart and subpart X (§ 256f et seq.) of this part and provisions set out as a note under section 1396a of this title] is to provide assistance to communities and consortia of health care providers and others, to develop or strengthen integrated community health care delivery systems that coordinate health care services for individuals who are uninsured or underinsured and to develop or strengthen activities related to providing coordinated care for individuals with chronic conditions who are uninsured or underinsured, through the—

"(1) coordination of services to allow individuals to receive efficient and higher quality care and to gain entry into and receive services from a comprehensive system of care;

"(2) development of the infrastructure for a health care delivery system characterized by effective collaboration, information sharing, and clinical and financial coordination among all providers of care in the community; and

"(3) provision of new Federal resources that do not supplant funding for existing Federal categorical programs that support entities providing services to low-income populations."

§ 256a. Patient navigator grants**(a) Grants**

The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make grants to eligible entities for the development and operation of demonstration programs to provide patient navigator services to improve health care outcomes. The Secretary shall coordinate with, and ensure the participation of, the Indian Health Service, the National Cancer Institute, the Office of Rural Health Policy, and such other offices and agencies as deemed appropriate by the Secretary, regarding the design and evaluation of the demonstration programs.

(b) Use of funds

The Secretary shall require each recipient of a grant under this section to use the grant to recruit, assign, train, and employ patient navigators who have direct knowledge of the communities they serve to facilitate the care of individuals, including by performing each of the following duties:

(1) Acting as contacts, including by assisting in the coordination of health care services and provider referrals, for individuals who are seeking prevention or early detection services for, or who following a screening or early detection service are found to have a symptom, abnormal finding, or diagnosis of, cancer or other chronic disease.

(2) Facilitating the involvement of community organizations in assisting individuals who are at risk for or who have cancer or other chronic diseases to receive better access to high-quality health care services (such as by creating partnerships with patient advocacy groups, charities, health care centers, community hospice centers, other health care providers, or other organizations in the targeted community).

(3) Notifying individuals of clinical trials and, on request, facilitating enrollment of eligible individuals in these trials.

(4) Anticipating, identifying, and helping patients to overcome barriers within the health care system to ensure prompt diagnostic and treatment resolution of an abnormal finding of cancer or other chronic disease.

(5) Coordinating with the relevant health insurance ombudsman programs to provide information to individuals who are at risk for or who have cancer or other chronic diseases about health coverage, including private insurance, health care savings accounts, and other publicly funded programs (such as Medicare, Medicaid, health programs operated by

the Department of Veterans Affairs or the Department of Defense, the State children's health insurance program, and any private or governmental prescription assistance programs).

(6) Conducting ongoing outreach to health disparity populations, including the uninsured, rural populations, and other medically underserved populations, in addition to assisting other individuals who are at risk for or who have cancer or other chronic diseases to seek preventative care.

(c) Prohibitions

(1) Referral fees

The Secretary shall require each recipient of a grant under this section to prohibit any patient navigator providing services under the grant from accepting any referral fee, kick-back, or other thing of value in return for referring an individual to a particular health care provider.

(2) Legal fees and costs

The Secretary shall prohibit the use of any grant funds received under this section to pay any fees or costs resulting from any litigation, arbitration, mediation, or other proceeding to resolve a legal dispute.

(d) Grant period

(1) In general

Subject to paragraphs (2) and (3), the Secretary may award grants under this section for periods of not more than 3 years.

(2) Extensions

Subject to paragraph (3), the Secretary may extend the period of a grant under this section. Each such extension shall be for a period of not more than 1 year.

(3) Limitations on grant period

In carrying out this section, the Secretary—

(A) shall ensure that the total period of a grant does not exceed 4 years; and

(B) may not authorize any grant period ending after September 30, 2010.

(e) Application

(1) In general

To seek a grant under this section, an eligible entity shall submit an application to the Secretary in such form, in such manner, and containing such information as the Secretary may require.

(2) Contents

At a minimum, the Secretary shall require each such application to outline how the eligible entity will establish baseline measures and benchmarks that meet the Secretary's requirements to evaluate program outcomes.

(f) Uniform baseline measures

The Secretary shall establish uniform baseline measures in order to properly evaluate the impact of the demonstration projects under this section.

(g) Preference

In making grants under this section, the Secretary shall give preference to eligible entities

that demonstrate in their applications plans to utilize patient navigator services to overcome significant barriers in order to improve health care outcomes in their respective communities.

(h) Duplication of services

An eligible entity that is receiving Federal funds for activities described in subsection (b) of this section on the date on which the entity submits an application under subsection (e) of this section may not receive a grant under this section unless the entity can demonstrate that amounts received under the grant will be utilized to expand services or provide new services to individuals who would not otherwise be served.

(i) Coordination with other programs

The Secretary shall ensure coordination of the demonstration grant program under this section with existing authorized programs in order to facilitate access to high-quality health care services.

(j) Study; reports

(1) Final report by Secretary

Not later than 6 months after the completion of the demonstration grant program under this section, the Secretary shall conduct a study of the results of the program and submit to the Congress a report on such results that includes the following:

(A) An evaluation of the program outcomes, including—

(i) quantitative analysis of baseline and benchmark measures; and

(ii) aggregate information about the patients served and program activities.

(B) Recommendations on whether patient navigator programs could be used to improve patient outcomes in other public health areas.

(2) Interim reports by Secretary

The Secretary may provide interim reports to the Congress on the demonstration grant program under this section at such intervals as the Secretary determines to be appropriate.

(3) Reports by grantees

The Secretary may require grant recipients under this section to submit interim and final reports on grant program outcomes.

(k) Rule of construction

This section shall not be construed to authorize funding for the delivery of health care services (other than the patient navigator duties listed in subsection (b) of this section).

(l) Definitions

In this section:

(1) The term "eligible entity" means a public or nonprofit private health center (including a Federally qualified health center (as that term is defined in section 1395x(aa)(4) of this title)), a health facility operated by or pursuant to a contract with the Indian Health Service, a hospital, a cancer center, a rural health clinic, an academic health center, or a nonprofit entity that enters into a partnership or coordinates referrals with such a center, clinic, facility, or hospital to provide patient navigator services.

(2) The term “health disparity population” means a population that, as determined by the Secretary, has a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates as compared to the health status of the general population.

(3) The term “patient navigator” means an individual who has completed a training program approved by the Secretary to perform the duties listed in subsection (b) of this section.

(m) Authorization of appropriations

(1) In general

To carry out this section, there are authorized to be appropriated \$2,000,000 for fiscal year 2006, \$5,000,000 for fiscal year 2007, \$8,000,000 for fiscal year 2008, \$6,500,000 for fiscal year 2009, and \$3,500,000 for fiscal year 2010.

(2) Availability

The amounts appropriated pursuant to paragraph (1) shall remain available for obligation through the end of fiscal year 2010.

(July 1, 1944, ch. 373, title III, § 340A, as added Pub. L. 109-18, § 2, June 29, 2005, 119 Stat. 340.)

PRIOR PROVISIONS

A prior section 256a, act July 1, 1944, ch. 373, title III, § 340A, as added Nov. 6, 1990, Pub. L. 101-527, § 3, 104 Stat. 2314; amended Oct. 27, 1992, Pub. L. 102-531, title III, § 309(d), 106 Stat. 3502, related to health services for residents of public housing, prior to repeal by Pub. L. 104-299, §§ 4(a)(3), 5, Oct. 11, 1996, 110 Stat. 3645, effective Oct. 1, 1996.

Another prior section 256a, act July 1, 1944, ch. 373, title III, § 340A, as added Nov. 10, 1978, Pub. L. 95-626, title I, § 106(a), 92 Stat. 3560, related to technical assistance demonstration grants and contracts, prior to repeal by Pub. L. 100-77, title VI, § 601, July 22, 1987, 101 Stat. 511.

SUBPART VII—DRUG PRICING AGREEMENTS

§ 256b. Limitation on prices of drugs purchased by covered entities

(a) Requirements for agreement with Secretary

(1) In general

The Secretary shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2).

(2) “Rebate percentage” defined

(A) In general

For a covered outpatient drug purchased in a calendar quarter, the “rebate percentage” is the amount (expressed as a percentage) equal to—

(i) the average total rebate required under section 1927(c) of the Social Security

Act [42 U.S.C. 1396r-8(c)] with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

(B) Over the counter drugs

(i) In general

For purposes of subparagraph (A), in the case of over the counter drugs, the “rebate percentage” shall be determined as if the rebate required under section 1927(c) of the Social Security Act [42 U.S.C. 1396r-8(c)] is based on the applicable percentage provided under section 1927(c)(4) of such Act.

(ii) “Over the counter drug” defined

The term “over the counter drug” means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

(3) Drugs provided under State Medicaid plans

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(4) “Covered entity” defined

In this section, the term “covered entity” means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act [42 U.S.C. 1396d(l)(2)(B)]).

(B) An entity receiving a grant under section 256a¹ of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II¹ of part C of subchapter XXIV of this chapter (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV of this chapter.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act [42 U.S.C. 701(a)(2)].

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].

(J) Any entity receiving assistance under subchapter XXIV of this chapter (other than a State or unit of local government or an entity described in subparagraph (D)), but only

¹ See References in Text note below.