

654, § 4, 62 Stat. 1018; June 25, 1952, ch. 460, 66 Stat. 157; July 12, 1960, Pub. L. 86-624, § 29(b), 74 Stat. 419; renumbered § 339, Oct. 12, 1976, Pub. L. 94-484, title IV, § 407(b)(2), 90 Stat. 2268, which related to reception of persons suffering from leprosy in any hospital, was renumbered section 320 of act July 1, 1944, and transferred to section 247e of this title.

AMENDMENTS

1984—Subsecs. (a)(5), (b)(5). Pub. L. 98-555 inserted provisions authorizing appropriations for fiscal years ending Sept. 30, 1985, 1986, and 1987.

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104-14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

REPORT TO CONGRESS CONCERNING RESULTS OF STUDIES EVALUATING HOME AND COMMUNITY BASED HEALTH SERVICES; STUDIES OF REIMBURSEMENT METHODOLOGIES; INVESTIGATION OF FRAUD; DEMONSTRATION PROJECTS; HOME HEALTH SERVICES, DEFINED

Section 6(b)-(f) of Pub. L. 97-414 directed Secretary of Health and Human Services to report results of studies evaluating home and community based health services, and any recommendations for legislative action which might improve the provision of such services, to Congress prior to Jan. 1, 1985, to compile and analyze results of significant public or private studies relating to reimbursement methodologies for home health services and to report recommendations to Congress within 180 days after Jan. 4, 1983, to investigate methods available to stem medicare and medicaid fraud and abuse and extent to which such methods are applied and to report results to Congress within 18 months of Jan. 4, 1983, and to develop and carry out demonstration projects commencing no later than Jan. 1, 1984, to test methods for identifying patients at risk of institutionalization who could be treated more cost-effectively with home health services, and to test alternative reimbursement methodologies for home health agencies in order to determine most cost-effective way of providing home health services, and to report to Congress with regard to the demonstrations no later than Jan. 1, 1985; and defined "home health services" for purposes of this section.

SUBPART V—HEALTHY COMMUNITIES ACCESS PROGRAM

PRIOR PROVISIONS

A prior subpart VI, consisting of section 256a, related to health services for residents of public housing, prior to repeal by Pub. L. 104-299, § 4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

§ 256. Grants to strengthen the effectiveness, efficiency, and coordination of services for the uninsured and underinsured

(a) In general

The Secretary may award grants to eligible entities to assist in the development of inte-

grated health care delivery systems to serve communities of individuals who are uninsured and individuals who are underinsured—

(1) to improve the efficiency of, and coordination among, the providers providing services through such systems;

(2) to assist communities in developing programs targeted toward preventing and managing chronic diseases; and

(3) to expand and enhance the services provided through such systems.

(b) Eligible entities

To be eligible to receive a grant under this section, an entity shall be an entity that—

(1) represents a consortium—

(A) whose principal purpose is to provide a broad range of coordinated health care services for a community defined in the entity's grant application as described in paragraph (2); and

(B) that includes at least one of each of the following providers that serve the community (unless such provider does not exist within the community, declines or refuses to participate, or places unreasonable conditions on their participation)—

(i) a Federally qualified health center (as defined in section 1395x(aa) of this title);

(ii) a hospital with a low-income utilization rate (as defined in section 1396r-4(b)(3) of this title), that is greater than 25 percent;

(iii) a public health department; and

(iv) an interested public or private sector health care provider or an organization that has traditionally served the medically uninsured and underserved; and

(2) submits to the Secretary an application, in such form and manner as the Secretary shall prescribe, that—

(A) defines a community or geographic area of uninsured and underinsured individuals;

(B) identifies the providers who will participate in the consortium's program under the grant, and specifies each provider's contribution to the care of uninsured and underinsured individuals in the community, including the volume of care the provider provides to beneficiaries under the medicare, medicaid, and State child health insurance programs and to patients who pay privately for services;

(C) describes the activities that the applicant and the consortium propose to perform under the grant to further the objectives of this section;

(D) demonstrates the consortium's ability to build on the current system (as of the date of submission of the application) for serving a community or geographic area of uninsured and underinsured individuals by involving providers who have traditionally provided a significant volume of care for that community;

(E) demonstrates the consortium's ability to develop coordinated systems of care that either directly provide or ensure the prompt provision of a broad range of high-quality, accessible services, including, as appro-

appropriate, primary, secondary, and tertiary services, as well as substance abuse treatment and mental health services in a manner that assures continuity of care in the community or geographic area;

(F) provides evidence of community involvement in the development, implementation, and direction of the program that the entity proposes to operate;

(G) demonstrates the consortium's ability to ensure that individuals participating in the program are enrolled in public insurance programs for which the individuals are eligible or know of private insurance programs where available;

(H) presents a plan for leveraging other sources of revenue, which may include State and local sources and private grant funds, and integrating current and proposed new funding sources in a way to assure long-term sustainability of the program;

(I) describes a plan for evaluation of the activities carried out under the grant, including measurement of progress toward the goals and objectives of the program and the use of evaluation findings to improve program performance;

(J) demonstrates fiscal responsibility through the use of appropriate accounting procedures and appropriate management systems;

(K) demonstrates the consortium's commitment to serve the community without regard to the ability of an individual or family to pay by arranging for or providing free or reduced charge care for the poor; and

(L) includes such other information as the Secretary may prescribe.

(c) Limitations

(1) Number of awards

(A) In general

For each of fiscal years 2003, 2004, 2005, and 2006, the Secretary may not make more than 35 new awards under subsection (a) of this section (excluding renewals of such awards).

(B) Rule of construction

This paragraph shall not be construed to affect awards made before fiscal year 2003.

(2) In general

An eligible entity may not receive a grant under this section (including with respect to any such grant made before fiscal year 2003) for more than 3 consecutive fiscal years, except that such entity may receive such a grant award for not more than 1 additional fiscal year if—

(A) the eligible entity submits to the Secretary a request for a grant for such an additional fiscal year;

(B) the Secretary determines that extraordinary circumstances (as defined in paragraph (3)) justify the granting of such request; and

(C) the Secretary determines that granting such request is necessary to further the objectives described in subsection (a) of this section.

(3) Extraordinary circumstances

(A) In general

In paragraph (2), the term "extraordinary circumstances" means an event (or events) that is outside of the control of the eligible entity that has prevented the eligible entity from fulfilling the objectives described by such entity in the application submitted under subsection (b)(2) of this section.

(B) Examples

Extraordinary circumstances include—

(i) natural disasters or other major disruptions to the security or health of the community or geographic area served by the eligible entity; or

(ii) a significant economic deterioration in the community or geographic area served by such eligible entity, that directly and adversely affects the entity receiving an award under subsection (a) of this section.

(d) Priorities

In awarding grants under this section, the Secretary—

(1) shall accord priority to applicants that demonstrate the extent of unmet need in the community involved for a more coordinated system of care; and

(2) may accord priority to applicants that best promote the objectives of this section, taking into consideration the extent to which the application involved—

(A) identifies a community whose geographical area has a high or increasing percentage of individuals who are uninsured;

(B) demonstrates that the applicant has included in its consortium providers, support systems, and programs that have a tradition of serving uninsured individuals and underinsured individuals in the community;

(C) shows evidence that the program would expand utilization of preventive and primary care services for uninsured and underinsured individuals and families in the community, including behavioral and mental health services, oral health services, or substance abuse services;

(D) proposes a program that would improve coordination between health care providers and appropriate social service providers;

(E) demonstrates collaboration with State and local governments;

(F) demonstrates that the applicant makes use of non-Federal contributions to the greatest extent possible; or

(G) demonstrates a likelihood that the proposed program will continue after support under this section ceases.

(e) Use of funds

(1) Use by grantees

(A) In general

Except as provided in paragraphs (2) and (3), a grantee may use amounts provided under this section only for—

(i) direct expenses associated with achieving the greater integration of a health care delivery system so that the

system either directly provides or ensures the provision of a broad range of culturally competent services, as appropriate, including primary, secondary, and tertiary services, as well as substance abuse treatment and mental health services; and

(ii) direct patient care and service expansions to fill identified or documented gaps within an integrated delivery system.

(B) Specific uses

The following are examples of purposes for which a grantee may use grant funds under this section, when such use meets the conditions stated in subparagraph (A):

(i) Increases in outreach activities and closing gaps in health care service.

(ii) Improvements to case management.

(iii) Improvements to coordination of transportation to health care facilities.

(iv) Development of provider networks and other innovative models to engage physicians in voluntary efforts to serve the medically underserved within a community.

(v) Recruitment, training, and compensation of necessary personnel.

(vi) Acquisition of technology for the purpose of coordinating care.

(vii) Improvements to provider communication, including implementation of shared information systems or shared clinical systems.

(viii) Development of common processes for determining eligibility for the programs provided through the system, including creating common identification cards and single sliding scale discounts.

(ix) Development of specific prevention and disease management tools and processes.

(x) Translation services.

(xi) Carrying out other activities that may be appropriate to a community and that would increase access by the uninsured to health care, such as access initiatives for which private entities provide non-Federal contributions to supplement the Federal funds provided through the grants for the initiatives.

(2) Direct patient care limitation

Not more than 15 percent of the funds provided under a grant awarded under this section may be used for providing direct patient care and services.

(3) Reservation of funds for national program purposes

The Secretary may use not more than 3 percent of funds appropriated to carry out this section for providing technical assistance to grantees, obtaining assistance of experts and consultants, holding meetings, developing of tools, disseminating of information, evaluation, and carrying out activities that will extend the benefits of programs funded under this section to communities other than the community served by the program funded.

(f) Grantee requirements

(1) Evaluation of effectiveness

A grantee under this section shall—

(A) report to the Secretary annually regarding—

(i) progress in meeting the goals and measurable objectives set forth in the grant application submitted by the grantee under subsection (b) of this section; and

(ii) the extent to which activities conducted by such grantee have—

(I) improved the effectiveness, efficiency, and coordination of services for uninsured and underinsured individuals in the communities or geographic areas served by such grantee;

(II) resulted in the provision of better quality health care for such individuals; and

(III) resulted in the provision of health care to such individuals at lower cost than would have been possible in the absence of the activities conducted by such grantee; and

(B) provide for an independent annual financial audit of all records that relate to the disposition of funds received through the grant.

(2) Progress

The Secretary may not renew an annual grant under this section for an entity for a fiscal year unless the Secretary is satisfied that the consortium represented by the entity has made reasonable and demonstrable progress in meeting the goals and measurable objectives set forth in the entity's grant application for the preceding fiscal year.

(g) Maintenance of effort

With respect to activities for which a grant under this section is authorized, the Secretary may award such a grant only if the applicant for the grant, and each of the participating providers, agree that the grantee and each such provider will maintain its expenditures of non-Federal funds for such activities at a level that is not less than the level of such expenditures during the fiscal year immediately preceding the fiscal year for which the applicant is applying to receive such grant.

(h) Technical assistance

The Secretary may, either directly or by grant or contract, provide any entity that receives a grant under this section with technical and other nonfinancial assistance necessary to meet the requirements of this section.

(i) Evaluation of program

Not later than September 30, 2005, the Secretary shall prepare and submit to the appropriate committees of Congress a report that describes the extent to which projects funded under this section have been successful in improving the effectiveness, efficiency, and coordination of services for uninsured and underinsured individuals in the communities or geographic areas served by such projects, including whether the projects resulted in the provision of better quality health care for such individuals, and whether such care was provided at lower costs, than would have been provided in the absence of such projects.

(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.