

PATIENT NAVIGATOR OUTREACH AND CHRONIC DISEASE
PREVENTION ACT OF 2004

OCTOBER 5, 2004.—Ordered to be printed

Mr. BARTON of Texas, from the Committee on Energy and
Commerce, submitted the following

R E P O R T

[To accompany H.R. 918]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 918) to authorize the Health Resources and Services Administration, the National Cancer Institute, and the Indian Health Service to make grants for model programs to provide to individuals of health disparity populations prevention, early detection, treatment, and appropriate follow-up care services for cancer and chronic diseases, and to make grants regarding patient navigators to assist individuals of health disparity populations in receiving such services, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

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AMENDMENT

The amendments are as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Patient Navigator Outreach and Chronic Disease Prevention Act of 2004”.

SEC. 2. PATIENT NAVIGATOR GRANTS.

Subpart V of part D of title III of the Public Health Service Act (42 U.S.C. 256) is amended by adding at the end the following:

“SEC. 340A. 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.—A condition on the receipt of a grant under this section is that the grantee agree 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 providing assistance to 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 facilitating enrollment in these trials if requested and eligible.

“(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, and the State children’s health insurance program).

“(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) 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, except that—

“(A) each such extension shall be for a period of not more than 1 year; and

“(B) the Secretary may make not more than 4 such extensions with respect to any grant.

“(3) END OF GRANT PERIOD.—In carrying out this section, the Secretary may not authorize any grant period ending after September 30, 2010.

“(d) 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.

"(e) UNIFORM BASELINE MEASURES.—The Secretary shall establish uniform baseline measures in order to properly evaluate the impact of the demonstration projects under this section.

"(f) 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.

"(g) 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.

"(h) 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) INTERIM REPORTS BY GRANTEEES.—The Secretary may require grant recipients under this section to submit interim reports on grant program outcomes.

"(i) 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)).

"(j) 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 1861(aa)(4) of the Social Security Act)), 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).

"(k) 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."

Amend the title so as to read:

A bill to amend the Public Health Service Act to authorize a demonstration grant program to provide patient navigator services to reduce barriers and improve health care outcomes, and for other purposes.

PURPOSE AND SUMMARY

The purpose of H.R. 918 is to authorize the Secretary of the Department of Health and Human Services to conduct a demonstration program to promote model "patient navigator" programs to improve health care outcomes for individuals with cancer or other chronic diseases, with a specific emphasis on health disparity populations.

BACKGROUND AND NEED FOR LEGISLATION

Improving health care outcomes for all Americans requires substantial improvement in health disparity populations, populations—not defined solely by race and ethnicity—that have 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. Patient navigator programs provide outreach to communities to seek preventative care and coordinate health care services for individuals who are at risk for or who have a chronic disease. For example, the Ralph Lauren Center for Cancer Care and Prevention, a partnership between Memorial Sloan-Kettering and North General Hospital in Harlem, New York, operates a patient navigator program to help patients and family members deal with the complexities of the health care system. By coordinating health care services through a patient navigator, the patient navigator programs strive to shorten the period of time when a patient is screened for cancer or other chronic diseases and further diagnosis and treatment, if needed.

H.R. 918 authorizes the Secretary of Health and Human Services to conduct a demonstration program to evaluate the impact of patient navigator programs on improving health care outcomes.

HEARINGS

The Committee on Energy and Commerce has not held hearings on the legislation.

COMMITTEE CONSIDERATION

On Thursday, September 30, 2004 the Full Committee met in open markup session and ordered H.R. 918 favorably reported to the House, as amended, by a voice vote, a quorum being present.

COMMITTEE VOTES

There were no record votes taken in connection with ordering H.R. 918 reported. A motion by Mr. Barton to order H.R. 918 reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has not held oversight or legislative hearings on this legislation.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of H.R. 918 is to establish a demonstration program to evaluate the impact of “patient navigator” programs on improving health care outcomes for individuals with cancer or other chronic diseases.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 918, the Patient Navigator Outreach and Chronic Disease Prevention Act of

2004, would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, the following is the cost estimate provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, October 4, 2003.

Hon. JOE BARTON,
*Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 918, the Patient Navigator Outreach and Chronic Disease Prevention Act of 2004.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Margaret Nowak.

Sincerely,

DOUGLAS HOLTZ-EAKIN,
Director.

Enclosure.

H.R. 918—Patient Navigator Outreach and Chronic Disease Prevention Act of 2004

H.R. 918 would amend the Public Health Service Act to authorize the Secretary of Health and Human Services to make grants for the development and operation of programs that provide “patient navigator” services. Patient navigators assist patients in overcoming obstacles to the prompt diagnosis and treatment of health problems, in part by identifying sources of care and insurance, coordinating referrals, and facilitating enrollment in clinical trials. The bill also would require the Secretary to conduct a study and report to the Congress within six months of completion of the grant program.

The bill would authorize the appropriation of \$2 million in 2006, \$5 million in 2007, \$8 million in 2008, \$6.5 million in 2009, and \$3.5 million in 2010. Based on spending patterns for similar programs, and assuming appropriation of the authorized amounts, CBO estimates that implementing H.R. 918 would cost \$18 million from 2005 through 2009. The legislation would not affect direct spending or receipts.

H.R. 918 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act; state, local, and tribal governments would be eligible to apply for grants authorized by the bill.

The CBO staff contact for this estimate is Margaret Nowak. This estimate was approved by Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

This section provides the short title of the bill, the “Patient Navigator Outreach and Chronic Disease Prevention Act of 2004.”

Section 2. Patient navigator grants

Section 2 authorizes the Secretary of the Department of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration (“HRSA”), to make grants to eligible entities for the development and operation of demonstration programs to provide patient navigator services to improve health care outcomes. Eligible entities include a public or nonprofit private health center, a community health center, a health facility operated with the Indian Health Services, 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 health care facilities. With respect to a nonprofit entity, the Committee does not intend the term “coordinates referrals with” to imply that a nonprofit entity must jointly file a grant application with a health care facility. Instead, the Committee fully expects the Administrator of HRSA to evaluate nonprofit entity applications by the strength of the nonprofit entity’s ability to provide all of the requirements of patient navigator services, including referrals to specific facilities, as well as the ability of the nonprofit organization to conduct outreach activities for prevention services and treatment programs.

The Committee recognizes the challenges of some communities in overcoming significant barriers to high quality health care services, including geographic isolation, cultural and linguistic barriers, limited transportation services, lack of health insurance and information about health options, and socioeconomic status. Therefore, section 2 requires the Administrator of HRSA to give preference to grant applicants who target populations in greatest need and utilize patient navigators to help overcome these and other barriers in order to reduce health care disparities and improve health care outcomes.

Eligible entities may use the grant to recruit, assign, train, and employ patient navigators who have a direct knowledge of the communities they serve. The term “patient navigator” is defined to mean an individual who has completed a training program approved by the Secretary to perform the duties outlined in the legislation. The Committee recognizes that there will be grant applicants with varying levels of experience in patient navigation. Some may have existing, trained patient navigators who want to expand their services; others may have no trained navigators but are well positioned to begin providing patient navigator services with appropriate training. An allowable use of part of the funds under this grant would be to provide navigator training, a plan for which should be included in the grant application.

Patient navigators must coordinate health care services and provider referrals, facilitate the involvement of community organizations to provide assistance to patients, facilitate enrollment in clinical trials, anticipate barriers within the health care system and help ensure prompt diagnostic care and treatment, coordinate with appropriate health insurance ombudsman programs, and conduct ongoing outreach to health disparity populations and other individuals to seek preventative care. Section 2 includes a rule of construction to clarify that the bill does not authorize funding for the delivery of health care services other than the patient navigator duties outlined in the legislation. The Committee fully expects that patient navigators will assist the uninsured individuals in enrolling in appropriate health coverage programs, including private insurance, publicly funded programs like Medicaid, as well as health care savings accounts.

The Administrator of HRSA must coordinate and ensure the participation of the Indian Health Service, the National Cancer Institute, the Office of Rural Health Policy, and other such office and agencies deemed appropriate by the Secretary, regarding the design and evaluation of the demonstration program. To facilitate the operation of the program, the Committee has assigned primary responsibility to the Administrator of HRSA. However, the Committee recognizes the distinct role of each of these offices and agencies within the Department of Health and Human Services, and therefore requires close coordination to maximize the impact of the patient navigator demonstration program. Section 2 also requires the Secretary to ensure coordination of the demonstration program with existing authorized programs in order to facilitate access to high-quality health care services, for example, the Community Access Program administered by HRSA and the breast and cervical cancer screening programs administered by the Centers for Disease Control and Prevention.

An eligible entity may receive a grant for a period of not more than 3 years. The Secretary may, based on extenuating circumstances, approve an extension of the grant period for up to one-year. The demonstration program expires on September 30, 2010.

Grant recipients must establish baseline measures and benchmarks to evaluate program outcomes. The Secretary may require grant recipients to submit interim reports on grant program outcomes, as well as provide Congress with interim reports on the progress of the demonstration program. The Secretary is required to conduct an evaluation of the results of the program no later than 6 months after the completion of the demonstration grant program. To effectively measure program outcomes, the Committee recommends that the Secretary collect and include the following data in the final report to Congress: the patient's insurance status, income, education level, gender, age, race and ethnicity, the number of patients navigated, demographic coverage area, screening location and date, type and stage of diagnosis, point at which the navigator was brought into the process, type of navigator (lay or professional), barriers the patient encountered and how they were resolved, compliance rate for appointments and follow-up exams, number of patients referred (e.g., to treatment, pharmaceutical assistance programs, ombudsman programs/other health insurance programs, community organizations) and follow-up outcomes (e.g., number of uninsured who get health coverage, etc.), time interval between diagnosis or referral and resolution date, and the final outcome or result. For applicants who are providing training for patient navigators, the report should also include the plan for such training and the outcomes.

Finally, section 2 authorizes to be appropriated \$2 million in fiscal year 2006, \$5 million in fiscal year 2007, \$8 million in fiscal year 2008, \$6.5 million in fiscal year 2009, and \$3.5 million in fiscal year 2010 to carry out the patient navigator demonstration program. Amounts appropriated will be available through the end of fiscal year 2010.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * *

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

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PART D—PRIMARY HEALTH CARE

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Subpart V—Healthy Communities Access Program

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SEC. 340A. 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.*—A condition on the receipt of a grant under this section is that the grantee agree 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 providing assistance to 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 facilitating enrollment in these trials if requested and eligible.

(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, and the State children's health insurance program).

(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) *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, except that—

(A) each such extension shall be for a period of not more than 1 year; and

(B) the Secretary may make not more than 4 such extensions with respect to any grant.

(3) *END OF GRANT PERIOD.*—In carrying out this section, the Secretary may not authorize any grant period ending after September 30, 2010.

(d) *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.

(e) *UNIFORM BASELINE MEASURES.*—The Secretary shall establish uniform baseline measures in order to properly evaluate the impact of the demonstration projects under this section.

(f) *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.

(g) *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.

(h) *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) *INTERIM REPORTS BY GRANTEEES.*—The Secretary may require grant recipients under this section to submit interim reports on grant program outcomes.

(i) *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)).

(j) *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 1861(aa)(4) of the Social Security Act)), 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).*

(k) *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.*

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