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PATIENT NAVIGATOR OUTREACH AND CHRONIC DISEASE
PREVENTION ACT OF 2005

MAY 25, 2005.—Ordered to be printed

Mr. ENZI, from the Committee on Health, Education, Labor, and
Pensions, submitted the following

R E P O R T

[To accompany S. 898]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 898) 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, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

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I. PURPOSE AND SUMMARY

The purpose of S. 898, the “Patient Navigator Outreach and Chronic Disease Prevention Act of 2005” 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.

II. 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 preventive 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.

S. 898 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.

III. LEGISLATIVE HISTORY AND COMMITTEE ACTION

On April 25, 2005, Sen. Hutchison, Bingaman, Brownback, Kennedy, and Cochran introduced S. 898, the “Patient Navigator, Outreach and Chronic Disease Prevention Act of 2005.” On April 27, 2005, the committee held an executive session to consider S. 898. After accepting a manager’s amendment by unanimous voice vote, the committee approved S. 898 by unanimous voice vote.

IV. EXPLANATION OF BILL AND COMMITTEE VIEWS

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 by the Indian Health Services providers or tribal organizations, 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 required 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, a lack of quality health care pro-

viders, 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.

It is the committee's intent that the Secretary would develop specific requirements related to the patient navigator training programs to ensure the quality of services provided to patients by patient navigators. Such requirements may include minimum qualification requirements, such as education requirements, prior work experience, appropriate background checks, specified levels of expertise in health care or the community, and oversight or supervision requirements by licensed professionals. 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.

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. It is the committee's view that this provision would prohibit a patient navigator from directly providing health care or treatment to a patient funded by the demonstration program, even if the patient navigator is a licensed medical provider.

The committee fully expects that patient navigators will assist the uninsured individuals in enrolling in appropriate health coverage programs.

Maintaining the confidentiality of patient medical information is a concern, given that patient navigators will likely receive sensitive health information during the performance of their activities. It is the committee's view that most, if not all eligible entities would be covered health care providers under, and thus subject to, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. Besides health care providers, other nonprofit entities are also eligible entities under this program but only if they enter into a "partnership or coordinates referrals" with one of these health care providers. It is the committee's view that these nonprofit entities would be considered to be "business associates" of the covered entities under HIPAA and thus also subject to the requirements of HIPAA.

To the extent the patient navigator services are provided through an eligible entity that is a covered entity for HIPAA purposes, the patient navigator is likely to be a workforce member of the covered entity or of a business associate of a covered entity. Thus, the committee expects that the majority, if not all patient navigators will need to abide by the Privacy Rule in using or disclosing protected health information about the patients to whom they provide services. The Privacy Rule allows protected health information to be used and disclosed by a covered entity for the core functions of

treatment, payment, and health care operations, and they do not need patient authorization for these uses or disclosures. In reviewing the types of functions that a patient navigator is likely to perform and that the purposes for these services is to facilitate the patient's access to quality care, it appears that most of the services would fit within one or more of the HIPAA core functions.

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, the Office of Minority Health and other such office and agencies deemed appropriate by the Secretary, regarding the design and evaluation of the demonstration program. The committee strongly encourages the Administrator of HRSA to also coordinate with the Office of Minority Health and Health Disparities and the Bureau of Primary Health Care at HRSA, as well as other similar offices throughout the Department of Health and Human Services. 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 (e.g., the Healthy Communities Access Program administered by HRSA and the breast and cervical cancer screening programs administered by the Centers for Disease Control and Prevention). Additionally, if grant recipients are already receiving federal funds for activities similar to those described under this program, at the time of the grant application, the applicant must describe how amounts received under this grant will be utilized to provide new services, or to serve new classes of individuals who would not otherwise be served. In including this provision, the committee wants to ensure that the patient navigator grants provided for under this section provide added value or new community services without duplicating programs or efforts that would qualify for funding under current law.

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, 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.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, May 5, 2005.

Hon. MICHAEL B. ENZI,
*Chairman, Committee on Health, Education, Labor, and Pensions,
U.S. Senate, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 898, Patient Navigator Outreach and Chronic Disease Prevention Act of 2005.

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

Sincerely,

ELIZABETH M. ROBINSON
(For Douglas Holtz-Eakin, Director).

Enclosure.

S. 898—Patient Navigator Outreach and Chronic Disease Prevention Act of 2005

S. 898 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 6 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 S. 898 would cost \$23 million from 2006 through 2010. The legislation would not affect direct spending or receipts.

S. 898 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act. If state, local, or tribal governments choose to participate in the grant program as authorized by the bill, any costs resulting from grant conditions would be incurred voluntarily.

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

VI. APPLICATION OF LAW TO THE 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.

VII. REGULATORY IMPACT STATEMENT

The committee has determined that there will be de minimus changes to the regulatory burden due to this bill.

VIII. 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 2005.”

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 by the Indian Health Services providers or tribal organizations, 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.

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. Health disparity populations are defined as 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.

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.

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 culturally competent and linguistically appropriate outreach to health disparity populations and other individuals to seek preventive 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.

Section 2 further clarifies that the grant recipients cannot accept any referral fee, kickback, or other thing of value in return for referring an individual to a particular health care provider or that the grant recipient will use any of the funds provided under this

program to pay any fees or costs resulting from any litigation, arbitration, mediation, or other proceeding to resolve a legal dispute.

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.

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 (e.g., the Healthy Communities Access Program administered by HRSA and the breast and cervical cancer screening programs administered by the Centers for Disease Control and Prevention). Additionally, if grant recipients are already receiving Federal funds for activities similar to those described under this program, at the time of the grant application, the applicant must describe how amounts received under this grant will be utilized to provide new services, or to serve new classes of individuals who would not otherwise be served.

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 1 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 180 days after the completion of the demonstration grant program.

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.

X. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in *italic*, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

IN GENERAL

SEC. 301.

(a) * * *

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PART D—PRIMARY HEALTH CARE

Subpart I—Health Centers

SEC. 330. [254b] HEALTH CENTERS.

(a) DEFINITION OF HEALTH CENTER.—

(1) IN GENERAL.—* * *

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Subpart V—Healthy Communities Access Program

SEC. 340. GRANTS TO STRENGTHEN THE EFFECTIVENESS, EFFICIENCY, AND COORDINATION OF SERVICES FOR THE UNINSURED AND UNDERINSURED.

(a) IN GENERAL.—* * *

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(k) * * *

(l) * * *

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.—*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 triads 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, kickback, 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) on the date on which the entity submits an application under subsection (e), 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 180 days 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) *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 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)).

(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 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).

(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.

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