

**Supporting Statement**  
**Health Resources and Services Administration/Bureau of Health Professions**  
**Evaluation of the Patient Navigator Outreach and Chronic Disease Prevention**  
**Demonstration Program**

**A. JUSTIFICATION**

**1. Circumstances of Information Collection**

This is a request for Office of Management and Budget (OMB) approval to conduct the Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program evaluation (OMB No. 0915-NEW). This program is authorized under the Patient Navigator Outreach and Chronic Disease Prevention Act of 2005, P.L. 109-18, Section 340 A of the Public Health Service Act (42 U.S.C.256a.).

The Public Health Service Act (Act 109-18, H.R. 1812) was amended in 2005 to include Patient Navigation Services, authorizing the Secretary of the Department of Health and Human Services to conduct a demonstration program to promote model “patient navigator” programs to improve the health care outcomes for individuals with cancer or other chronic diseases, with a specific emphasis on health disparity populations. The Patient Navigator Outreach and Chronic Disease Prevention (PN) Demonstration Program is authorized under the Patient Navigator Outreach and Chronic Disease Prevention Act of 2005, P.L 109-18, Section 340A of the Public Health Service Act.

Six grants have been awarded to eligible entities for the development and operation of demonstration programs to provide patient navigator services to improve health care outcomes. Preference was given to grant applicants who target those populations in greatest need utilizing patient navigators to overcome barriers related to access and accessibility of quality health care ultimately reducing health care disparities and improving health care outcomes as required by law. The PN program requires defined measures and outcomes but does not require compliance with a specific structure or model for the applicant program or community organization (See Attachment A – Data Dictionary for defined measures and outcomes). Furthermore, there is little programmatic guidance on PN competencies and the supervisory and administrative processes for these demonstration projects. The diversity of communities and variety of settings in which similar programs have been managed successfully at the local level suggests that a “one size fits all” standardized approach for this program is not advisable. A hallmark of the program is the guiding principle of a significant degree of local control and design over the development and implementation of the grant. This includes locally defined, but Federally approved, policies on program recruitment, design in services, credentialing, and training or certification and PN program structure.

Eligible entities for receiving patient navigator grants include:

- Public or nonprofit private health centers
- Community Health Centers
- A 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
- A nonprofit entity that enters into a partnership or coordinates referrals with such health care facilities to provide patient navigator services

The IOM report, “Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care,” recommends the use of community-based health workers to help patients, specifically those from minority neighborhoods, navigate the health care system. In addition, the 2000-2001 President’s Cancer Panel report, “Voices of a Broken System: Real People, Real Problems,” supports funding for community-based programs, including patient navigator programs, that help people obtain cancer information, screening, treatment, and supportive services. The focus on quality improvement is not only for in-patient hospital care, but also for primary care settings to decrease morbidity and mortality. Improving the quality of chronic disease management can improve a community’s health and decrease emergency room visits and hospital admissions.

The Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program should demonstrate how local initiatives can potentially reduce the burden of cancer and other chronic diseases such as obesity, diabetes, asthma and others by reducing the barriers related to accessing high quality health care services. This evaluation consists of two parts: 1) an evaluation of the patient navigators themselves; and 2) an evaluation of health outcomes of the patients who will be navigated.

The authorizing legislation for the PN program requires that the Secretary conduct an evaluation of the program and submit to the Congress a report on such results. The evaluation of PN program is required to include an analysis of baseline and benchmark measures and aggregate information about the patients served and program activities (See Attachment A Table 9 for baseline measures). The report to Congress is also stipulated to include recommendations on whether patient navigator programs could be used to improve patient outcomes in other public health areas.

## **2. Purpose and Use of Information**

The PN program is a quality improvement initiative focused on chronic disease management. Patient navigators will facilitate safe, timely, effective, efficient, patient-centered, and equitable care in order to best provide support and guidance to cancer and chronic disease patients throughout the disease care continuum. The patient navigator grants should provide added value or new community services without duplicating programs or efforts that would qualify for funding under current law. Geographic isolation, cultural and linguistic barriers, limited transportation services, lack of health insurance and information about health options, and socioeconomic status are a few of the significant barriers faced by some communities that a patient navigator will help in addressing.

Grantees have recruited, assigned, and trained patient navigators who have a direct knowledge of the communities they serve. Patient navigators will facilitate the care of individuals by performing each of the six duties as outlined in the legislation. Those duties include:

1. Act as contacts, including by assisting 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, abnormal finding, or diagnosis of, cancer or other chronic diseases.
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.
3. Notify individuals of clinical trial and, on request, facilitate enrollment of eligible individuals in these trials.
4. Anticipate, identify, and help 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 diseases.
5. Coordinate 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.
6. Conduct ongoing outreach to health disparity populations, including the uninsured, rural population, and other medically underserved populations in addition to assisting other individual who are at risk for or who have cancer or other chronic diseases to seek preventative care.

The term “patient navigator” as used in this program represents a concept. The grantee determines which term best applies to their target community. Many patient navigator programs use trained community health workers who may be full-time employees or volunteers. Community health workers are also known as community health advisors, lay health advocates, and promotores de salud. In addition to community health workers, some health care navigator programs utilize trained social workers, nurses and/or nurse practitioners. Navigation spans the period from community outreach, preventive services, health literacy, education of chronic diseases and the health care system, an abnormal finding via a detection procedure, through necessary diagnostic tests, to completion of the treatment and other health care services through the life of the patient. Once a relationship has formed between an individual and a patient navigator, the program extends to helping the individual and family through the health care system.

For the purposes of this program, a patient navigator is a person with direct knowledge of the local community who functions as a “guide” and offers assistance to community members in “navigating” the health care system and accessing related social and financial services to improve chronic disease detection and treatment. A primary function of the navigator is to establish and help maintain communication between patients, their families, physicians, and the health care system while offering additional assistance.

Examples of Patient Navigator activities may include:

- Identifying and scheduling appointments with culturally competent caregivers;
- Arranging for needed language translation or interpretation services;
- Assisting in coordination of transportation to and child/elder care during scheduled diagnosis and treatment appointments;
- Helping patients and their families access support systems;
- Helping patients understand treatment options, diagnoses, and preventive behaviors;
- Providing emotional support and related information; and
- Facilitating access to available financial support and assisting with related paperwork.

Grantees collect much of the standard healthcare administrative and demographic information to be utilized in the Patient Navigator program as standard business practice. This evaluation will focus on the legislative requirements to report on patient outcomes impacted by navigation services and on the demographic characteristics and activities of the patient navigators themselves. These data will be collected through the following data elements: Patient Tracking Log (Attachment B), Patient Navigator Socio-Demographic Characteristics (Attachment A – Table 3), Alternative Appointment Data (Attachment A – Table 5 and 6), and Health Care Coverage (Attachment A – Table 1).

Congress specified the measures that should be collected in this evaluation. The Committee recommended that the evaluation 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 patient referred and follow-up outcomes, 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 Committee recommended that the Secretary include the plan for such training and the outcomes.

### **3. Use of Improved Information Technology**

Improved information technology is utilized where appropriate. The grant program maintains an online “virtual office” at [www.healthdisparities.net](http://www.healthdisparities.net) to share information and data about the various patient navigator sites between the sites and HRSA. Collection of all data measures will occur electronically, on a quarterly basis (Attachment C).

### **4. Efforts to Identify Duplication**

The information collected through the Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program performance evaluation tools is not available from any other source. The required information can only be supplied by the grantees.

## **5. Involvement of Small Entities**

Due to the demonstration designation and small scale of this grant program, the data collection activities do not significantly impact small entities. However, most information requested in these documents is information that grantees already maintain for clinical and management purposes. This minimizes the burden on the respondents.

## **6. Consequences If Information Collected Less Frequently**

Performance data will be collected on a quarterly basis. Because the project period is limited, data will be collected five times from the grantees. Collecting data on a quarterly basis, starting in the fall of 2009, is frequent enough to provide information regarding the program performance while reducing the burdens of compiling, collating, and editing the data for the grantees. Furthermore, stringent data collection mechanisms are necessary to satisfy the requirement of the authorizing legislation to produce a Congressional report with specific data outcome measures.

## **7. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)**

This information collection fully complies with 5 CFR 1320.5(d)(2).

## **8. Consultation Outside the Agency**

The notice required in 5 CFR 1320.8(d) was published in Volume 73, No. 229, pages 72064-72065 of the *Federal Register* on November 26, 2008. There were no comments from the public.

The following three Patient Navigator Outreach and Chronic Disease Prevention Demonstration Project grantee project directors were consulted on the clarity and overall burden of the data collection tools. The respondents thought the data collection measures were clear and the requested information was reasonable and available within their respective organizations.

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## 9. Remuneration of Respondents

Participants in the PN Demonstration Project evaluation will not be remunerated.

## 10. Assurance of Confidentiality

Participating individuals and institutions will be informed that the information collected by the patient navigator will be kept secure and will be protected. This information will be collected from patients or their designated caregiver, patient navigators, and PN program administrators. HRSA will not collect personally identifiable information; patients' health status and demographic information will be collected for this evaluation. However, maintaining privacy of all information is a priority and data collection and disclosure processes will abide by Health Insurance Portability and Accountability Act (HIPPA) Privacy Rule provisions and procedures.

## 11. Questions of Sensitive Nature

Information regarding health care services and conditions will be collected. No data regarding substance abuse or illegal activities will be collected.

## 12. Estimates of Annualized Hour Burden

Form	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours
Navigated Patient <sup>1</sup> Data Intake Form	6000	1	6000	0.5	3,000
<b><i>SubTotal-- Patient Burden</i></b>	<b><i>6000</i></b>	<b><i>1</i></b>	<b><i>6000</i></b>	<b><i>0.5</i></b>	<b><i>3,000</i></b>
Patient Navigator Demographic Information	30	1	30	0.25	7.5
Patient Navigator Encounter/Tracking	30	750	22,500	0.25	5,625

Log <sup>2</sup>					
<b><i>SubTotal -- Patient Navigator Burden</i></b>	<b><i>30</i></b>	<b><i>751</i></b>	<b><i>22,530</i></b>	<b><i>0.5</i></b>	<b><i>5,633</i></b>
Grantee PN Administrative Records <sup>3</sup>	6	1	6	.5	3
Patient Medical Record and Clinic Data <sup>4</sup>	6	1,000	6,000	2	12,000
Clinic Rates (Baseline Measures)	6	1	6	4	24
Quarterly Report	6	4	24	1	24
<b><i>SubTotal -- Grantee Burden</i></b>	<b><i>6</i></b>	<b><i>1,005</i></b>	<b><i>6,036</i></b>	<b><i>3.5</i></b>	<b><i>12,060</i></b>
<b>TOTAL AVERAGE ANNUAL BURDEN</b>	<b>6,048</b>	<b>1,757</b>	<b>34,566</b>	<b>4.5</b>	<b>20,693</b>

These estimates are based on the total number of patients expected to be navigated over the project period based on the grantees applications.

### **13. Estimates of Annualized Cost Burden to Respondents**

There should be no cost to the respondents for this activity.

### **14. Estimates of Annualized Cost to the Government**

An estimated 2 FTEs at the GS 12 level are needed to review and process applications, provide technical assistance to grantees, and serve as project officers for this grant program at an estimated cost of \$146,200 annually. In addition, HRSA maintains a contract with NOVA Research, Inc. at an annual cost of \$249,480 to provide technical assistance and develop performance measures for the grant program.

### **15. Changes in Burden**

As this is a new grant program, there are no changes in burden.

### **16. Time Schedule, Publication and Analysis Plans**

According to statute, The Patient Navigator Outreach and Chronic Disease Prevention Act of 2005 (Attachment D) mandates that these data be collected, analyzed, and reported

to Congress in the form of a report no later than March 30, 2011. The analyses for the Congressional report will include simple statistics and comparison of means for specific health outcomes.

**17. Exemption for Display of Expiration Data**

No exemption is requested and the expiration date will be displayed.

**18. Certifications**

This information collection fully complies with the guidelines in 5 CFR 1320.9. The certifications are included in the package.

**ATTACHMENTS**

Data Dictionary  
Patient Tracking Log  
Quarterly Report  
Patient Navigator Act of 2005  
Data Element Summary  
Logic Model  
Evaluation Matrix