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), which added Section 340A to the Public Health Service Act (42 U.S.C.256a.). Section 340A of the Public Health Service Act was amended by the Patient Protection and Affordable Care Act of 2010 (P.L.111-148, Sec 3510).

The Public Health Service Act 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 outreach to health disparity populations.

Ten 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. As specified in the authorizing legislation, preference was given to grant applicants utilizing patient navigators to overcome significant barriers in order to improve health care outcomes in their communities. This evaluation, required by the law, is designed to determine if patient navigation services can facilitate access to appropriate care and lead to short-term improvement in intermediate health outcomes (including risk factors, clinical status, and patient-reported health status) in patients belonging to health disparities populations. The Patient Navigator (PN) program requires collection of defined measures and outcomes for the evaluation but does not require compliance with a specific structure or model for implementation by the applicant program or community organization (See Attachment – 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. Applicants to this grant program were required to define their own PN proficiencies tailored to the main focus or intervention of the navigator at the time of application, as required by law. 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, credentialing, 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. It is thought that improving the quality of chronic disease management can improve a community's health and decrease emergency room visits and hospital admissions.

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. 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.

If successful and adopted nationally, navigator programs have the potential to reduce the burden and severity of chronic disease in disparities populations. However, since development of navigator programs (particularly those targeting diagnosed disease), is in the early stages, much remains to be learned about how best to implement them. The PN program evaluation will explore whether navigator initiatives that address barriers to health care services improve intermediate health outcomes related to disease prevention and early intervention in chronic disease, as well as timely and appropriate treatment for diagnosed disease. In addition, the evaluation will seek information on practices that optimize program outcomes.

There are two main data collections described in this Supporting Statement. The first involves collection of **qualitative** information from staff associated with PNDP projects, including administrators and managers from grantee organizations, health care/social service providers, navigators, and staff from community organizations. These data will be utilized for grantee oversight, to help ensure the success of current and future programs, and to allow for the interpretation of quantitative information.

The second data collection involves **quantitative** data related to the demographics and care of all patients entering HRSA's Patient Navigation Demonstration Program, as well as from patient navigators providing care under the program. These data will be used to describe the populations

served by the program, the impact of the program, and factors related to program success. The procedures associated with these two collections are delineated in Section B2.

2. Purpose and Use of Information

The PN program is a quality improvement initiative focused on improving access to interventions that prevent and treat chronic diseases and cancer. Evaluation data will be used at a local and a HRSA program level to examine how navigators' efforts to improve health care access and continuity of care are related to clinical improvements in a population that has historically been difficult to reach, screen, and treat.

While it may ultimately be proven that navigator programs are key to reducing the burden and severity of disease in disparities populations (e.g., reducing the number of newly identified advanced cancer cases or diabetes mortality rates), the goals of this evaluation are more modest. As a first step toward investigating the impact of navigator programs on health disparities, this evaluation will focus on:

1) **Describing characteristics of navigator programs**, including navigator characteristics, training, patient recruitment procedures, activities undertaken by navigators, and characteristics of patients served;
2) **Describing the characteristics of services targeted by navigators**, and the proportion that were actually accessed by patients;
3) **Investigating whether services accessed by navigated patients were linked to clinic performance measures** (whether a patient received appropriate care) **and short-term changes in intermediate health outcomes** (as measured by patient-reported health status, clinical status, and risk factors); and
4) **Identifying factors that optimize positive effects** of the program.

This evaluation approach was pilot tested under the prior demonstration project conducted under the initial Patient Navigator Outreach and Chronic Disease Prevention Act of 2005 (P.L. 109-18) (OMB number 200903-0915-003). The current evaluation project, funded through the Patient Protection and Affordable Care Act of 2010 amendment (P.L.111-148, Sec 3510), is similar and builds on this experience.

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 are intended to provide added value or new community services without duplicating programs or efforts. The significant barriers faced by some communities that a patient navigator may help to address include: geographic isolation, cultural and linguistic barriers, limited transportation services, lack of health insurance, lack of health literacy, and low socioeconomic status.

Grantees will recruit, assign, and train patient navigators who have a direct knowledge of the communities they serve. Patient navigators are to facilitate the care of individuals by performing each of the six duties outlined in the legislation. Those duties are:

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 or early detection service are found to have a symptom, 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. 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.
6. Conduct ongoing outreach to health disparity populations, including the uninsured, rural population, 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.

The term "patient navigator" as used in this program represents a general concept applied by grantees according to the needs of their target community. Many patient navigator programs use trained community health workers who are full-time employees. 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 community outreach, promotion of and access to preventive services, health literacy, and education about chronic diseases and the health care system. It can include, for example, assisting a patient through an abnormal finding via a detection procedure, to necessary diagnostic tests, to completion of the treatment and other health care services throughout the patient's care management. Once a relationship has formed between an individual and a patient navigator, the program extends to helping the individual and family navigate 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 patient to various "targets" providing services related to health care as well as social and financial needs. A primary function of the navigator is to establish and help maintain communication between patients, their families, health care providers, and the health care system while assisting in meeting critical social service needs that would otherwise derail health care priorities.

Examples of Patient Navigator activities 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

in culturally relevant ways;
- Providing emotional support and related information; and
- Facilitating access to available financial support and assisting with related paperwork.

All data collected about navigator activities and targets will be made available to grantees in an ongoing manner in order to facilitate local quality improvement and administrative tasks. For example, navigators will be able to look up what navigation targets have not been resolved by a patient visit, and will be able to follow up with the patient. Data will also be reported to HRSA on a quarterly basis in order to provide oversight of program progress.

Information about program administration, navigator activities, and patient characteristics will inform discussions between grantees, evaluators, and HRSA regarding identification of best practices and improvement opportunities. Results of such discussions, combined with analyses of quantitative and qualitative data, will be presented in a Final Evaluation Report. Results will be presented publicly through conferences, as possible. No identifying information will ever be presented or transmitted by HRSA or by the evaluation contractor.

3. Evaluation Overview

This evaluation will focus on the legislative requirements and guidance offered in the accompanying Committee Report (Report 109-104) to report on patient outcomes impacted by navigation services and on the demographic characteristics and activities of the patient navigators themselves. Some of the health care administrative and demographic information collected for the Patient Navigator program is collected as standard business practice; other information is specific to legislative requirements.

There are two parts to the evaluation: a process component and an outcomes component. The process evaluation will describe the characteristics of the program as implemented. Data elements involved in the process component include the following:

- Patient demographics;
- Navigator activities;
- Navigation targets;
- Initial scores on clinical measures and health-related quality of life (VR-12);
- Program administrative data; and
- Qualitative data collected through interviews, discussions, and conversations.

The outcome evaluation will focus on health systems access (i.e., the percent of navigation targets actually accessed), intermediate health outcomes, and clinic-level performance measures involving the following data elements:

- Change in patient-reported health status/health related quality-of-life by patients accessing care (an intermediate health outcome);
- Change in condition-specific clinical information involving risk factors and clinical status in patients accessing care (an intermediate health outcome);
- Change in performance measures at the clinic level;
- Comparison of change scores to longitudinal norms and benchmarks as available; and
- Reports of program impact by navigators and stakeholders collected through qualitative methods.

Data elements from the outcome evaluation are described in detail below.

Information from the process evaluation will inform quantitative analyses investigating predictors of program success as defined by maximum navigation targets achieved, short term improvement in intermediate health outcomes, and clinic performance. Process results and outcomes will then be combined to describe optimal navigator processes and procedures, as well as limits to navigator success (e.g., how a dearth of specialists might be the limiting factor in improving care in a particular geographic area).

Patient Demographics. In the Committee Report accompanying the authorizing legislation, it was recommended that the following data be included in the final report to Congress: patient's insurance status, income, education level, gender, age, race and ethnicity, type and stage of diagnosis. These are data entered at patient intake, intended to document that services provided under the navigator grant program are reaching the populations intended. Multiple studies have found that racial and ethnic minorities, along with groups living near or below the poverty level, receive a lower quality and intensity of health care and diagnostic services across a wide range of procedures and diseases.

Health Status/Health-Related Quality of Life: VR-12 Health Survey (VR-12). The VR-12 is a patient-reported survey instrument that measures patients' health-related quality of life. It was derived from a longer instrument developed during the Medical Outcomes Study and is comprised of two components – the Physical Health Summary Measure (PCS or physical component score) and the Mental Health Summary Measure (MCS or mental component score) (Kazis, Selim, Rogers, Ren, Lee & Miller, 2006). The validity of the VR-12 has been established in a number of studies, documenting a significant relationship between VR-12 results and quality of life (for example, in men with prostate cancer (Krupski et al., 2005)) and clinical outcome (for example, survival in a sample of cervical cancer survivors (Ashing-Giwa, Lim & Tang, 2010)). It has been used as a measure of patient-reported outcome to evaluate quality of care in diverse populations by the Department of Veterans Affairs and by the Centers for Medicare and Medicaid Services (Rogers, Kazis, Miller, Skinner, Clark, Spiro, & Fincke, 2004). It is currently used in the Healthcare Effectiveness Data and Information Set (HEDIS) by the National Committee on Quality Assurance (NCQA) as part of the Medicare Health Outcomes Survey (see http://www.hosonline.org/Content/ProgramOverview.aspx). Current population and disease-specific norms are available (Selim, Iqbal, Rogers, Qiam, Fincke, Rothendler & Kazis, 2009), including norms that track VR-12 scores for populations with specific diseases over time (Kazis,

2011). VR-12 scores will be used to describe the patient population, identify case-mix across sites, stratify cases, and measure outcomes of navigation. The survey is administered at intake and at the end of the navigator program.

Navigator Actions (Navigator Encounters). In the Committee Report accompanying the authorizing legislation, Congress specified that the evaluation collect and include information on barriers identified and addressed by navigator actions. Navigators will report on characteristics of navigator actions related to the care of a particular patient. Documented actions include all communications with patients and their social network as well as related administrative and care coordination tasks. For each action, navigators will track barriers to health care that are identified and/or addressed by the navigator.

Services Targeted by Navigation (Navigation Targets). In the Committee Report accompanying the authorizing legislation, Congress specified that the evaluation collect and include information on compliance rates for appointments and follow-up exams, the number of patients referred to services, time interval between diagnosis or referral and resolution date, and the final outcome or result. In accordance with this recommendation, navigators will facilitate and track patient access to "navigation targets," a range of services including health care, social services, and health education. Navigators will document identified targets as well as their resolution, i.e., whether the patient actually accessed care from the target, whether the patient refused, or whether barriers to care were insurmountable due to lack of available services.

Navigator Demographics. In the Committee Report accompanying the authorizing legislation, it was recommended that the evaluation collect information on navigators, including type of navigator (lay or professional), and the point at which the navigator was brought into the prevention/treatment process. These descriptive data are entered when a navigator is hired. The information is necessary to document that navigators have direct knowledge of the communities they serve. The level and type of the navigator's educational background may also prove to be an important predicator of program success.

Patient Clinical Information. In the Committee Report accompanying the authorizing legislation, Congress specified that the evaluation collect and include information on follow-up outcomes. Data will be entered only for the indices that are relevant for the conditions navigated. Clinical information is program-specific, related to the type of disease and stage of disease targeted by the patient navigator project. Some measures are risk factors (like smoking) that, if improved, are likely to directly and significantly improve health outcomes over time. Others are clinical status measures, such as HbA1c. Clinical experts agree that improvement in these disease-specific clinical measures lead to improvement in long-term care management goals. The current project will evaluate short-term changes in these clinical measures for patients in navigation for an appropriate period of time.

The measures were selected based on the following criteria:

- Described as part of a clinical, evidence-based standard of care in guidelines for disease management;
- Linked to benchmarks and best practices specific to the management of a condition that is the focus of the navigator program;
- Collected in the process of usual clinical practice at the site; and
- Known to be sensitive to clinically relevant change.

Specifically, short-terms changes in the following clinical information will be assessed for patients with the following chronic conditions:

Condition/Diagnosed Disease	Clinical Information
Asthma, at risk/pre-asthma	Smoker
Asthma, diagnosed	Peak Flow, ER/Hospitalization, Albuterol Prescription Date, Smoker
CHF, diagnosed	ER/Hospitalization, Diuretic Prescription, Smoker
CVD, at risk/family history	Smoker
CVD, diagnosed	Blood Pressure, ER/Hospitalization, Lipids, Smoker
Depression, positive screen	Smoker
Depression, diagnosed	Smoker
Diabetes, at risk/family history	Smoker; Fasting Blood Glucose or HbA1c
Diabetes, pre-diabetes	Smoker; Fasting Blood Glucose or HbA1c
Gestational diabetes	Smoker; Fasting Blood Glucose or HbA1c
Diabetes, diagnosed	HbA1c, Dilated Eye Check, Diabetic Foot Check, Diabetes Self-management Plan, Blood Pressure, ER/Hospitalization, Lipids, BMI, Smoker
Diabetes, hypertension, dyslipidemia	HbA1c, Dilated Eye Check, Diabetic Foot Check, Diabetes Self-management Plan, Blood Pressure, Antihypertensive Prescription Date, ER/Hospitalization, Lipids, Statin Prescription Date, BMI, Smoker
Hypertension, diagnosed	Blood Pressure, Antihypertensive Prescription Date, ER/Hospitalization, Lipids, Smoker
Hypertension, positive screen	Smoker
Obesity (Adult)	BMI, Smoker

These data are entered at patient intake and again at completion of navigation. Clinical measures and other health information will never be reported in association with personal identifying information (PII).

Clinic-wide Performance Measures. These measures will be available as baseline and follow up rates for relevant clinical measures, and will include such measures as screening rates, abnormal cancer screening finding rates, broken appointment rates, and other measures specifically targeted by individual grantee navigation programs. The data are reportable in the final two years of the grant program for those sites that (1) have programs specifically targeting clinic-wide rates, (2) have information technology systems capable of producing data reports,

and (3) already report the information through the HRSA Uniform Data System. Sampling of paper medical records is not required, and sites submitting data to the HRSA UDS will NOT be required to submit the data a second time.

Examples of measures of particular interest include:

- Diabetic Foot Check Rate: Proportion of diabetics who have had a foot check in the last year. This is applicable only for sites navigating diabetes.
- Eye Check Rate: Proportion of diabetics with dilated eye check performed in the last year. This is applicable only for sites navigating diabetes.
- Lipid Check Rate: Proportion of persons with diabetes or dyslipidemia with lipid check in the last six months. This is applicable only for sites navigating diabetes and dyslipidemia.
- Percent of asthmatics with an ER or hospital visit in the last six months. This is applicable only for sites navigating asthma.
- Percent of CHF patients with an ER or hospital visit in the last six months. This is applicable only for sites navigating CHF.
- Percent of CVD patients with an ER or hospital visit in the last six months. This is applicable only for sites navigating CVD.

Program Administration Information. In the Committee Report accompanying the authorizing legislation, the Committee recommended that the evaluation examine the plans for training and outreach, and track group screening activities and outcomes. Sites are asked to report once a quarter on Navigator Trainings and Meetings, Outreach Activities, Staffing, Lessons Learned, Notable Cases (noteworthy lessons learned or challenges faced), and Media Coverage. All navigator trainings and meetings, and outreach activities performed by navigators will be tracked, along with a description. In addition, the evaluation will track changes in staffing, resources, or procedures in order to understand what challenges were encountered and what improvements were made in response to the challenges. Ideally, Notable Cases will exemplify how the impact of the program is related to the most common or difficult barriers encountered by patients. For example, program staff may have created a new link to a community organization to obtain needed services, or may have negotiated new clinic procedures that are more patient-friendly. Navigators are also asked to report examples of patient cases that exemplify key aspects of their work. Information from this section will yield qualitative information to augment quantitative findings, as well as identify important innovations.

Qualitative Data for Ongoing Performance Improvement. In order to complement the quantitative data collection effort, the evaluation contractor will collect qualitative data by means of discussions and meetings to enhance and inform understanding of project performance. The contractor will facilitate and guide meetings with health care providers to ascertain their assessment of the patient navigation process, and will facilitate and guide meetings with community service partners to ascertain their assessment of the patient navigation project. Qualitative data will be obtained via:

- Group discussion with health care providers;
- Meetings with health care administrators and/or health care support staff;
- Meetings with social service providers;
- Meetings with community partners; and

- Debriefing with Project Directors about areas of strengths and areas for improvement.

4. Use of Improved Information Technology

Based on previous experience with navigation projects, improved information technology will be utilized via implementation of an online site. The site will be used to facilitate grantee communication, to collect data from the grantee sites, and to report information to HRSA and local sites.

The use of information technology has been optimized based on HRSA's previous experience collecting patient navigator data across multiple sites. Previous experience indicated that grantee sites varied significantly in their ability to develop and maintain local databases (including modifications in Electronic Health Records) to collect grant information. Many sites do not have an EHR system at all. For some sites, this process was quite burdensome and unmanageable without significant contractor assistance. Furthermore, site differences in data interfaces and coding, extended periods between required data uploads, and related delays in error reports created challenges in maintaining data quality. Finally, many sites lacked an IT infrastructure that could provide ongoing information for local quality improvement. In order to minimize these challenges, a central website has been designed to facilitate grantee communication, data entry, and quality improvement reports at both local sites and HRSA.

To facilitate grantee communication, the contractor will maintain a "Resources" section of the online site. The section contains information relevant to patient navigation in general and the grant in particular. All grantees, HRSA, and the contractor have access to this section.

To facilitate data collection, information will be entered by grantees via an online database. The data entry screens are designed to reduce grantee burden and improve data quality, with range limits and logic checks. Error and missing value reports will be available online, on demand. Grantees will be trained to code and enter data in a manner that is consistent across sites. Because online access is often unavailable during visits in the community or at homes, initial collection may be implemented using paper, with later data entry into the online database.

Data will be compiled and reported according to HRSA specifications and programmed by the evaluation contractor. Reports will be provided to HRSA on a quarterly basis. Reports will also be provided to grantee sites via online queries and printable reports, as requested by grantees during training visits.

5. Efforts to Identify Duplication

The information collected from grantees through the Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program performance evaluation tools is not available from any other source. Clinic-Wide Performance Measures at grantee sites who are also Federally Qualified Health Centers (FQHC) are already reportable to HRSA, Bureau of Primary Health Care (BPHC), as part of the Uniform Data Set for FQHCs. The PN program will collaborate with BPHC to acquire the relevant data from existing sources in order to avoid duplication of effort.

All other data elements are unique and cannot be obtained by HRSA except through reporting by the grantees.

6. 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.

7. Consequences If Information Collected Less Frequently

Performance data will be collected on an ongoing basis in accordance with site-specific procedures, and will be reported to HRSA on a quarterly basis. Data will be checked and error reports sent to grantees by the contractor on a monthly basis. Frequent error reports are preferred by grantees, since it is easier to retrieve information close to the date of initial entry, as opposed to months or years later. Information reported less frequently will undermine the efforts to maintain data quality. The data will be compiled, collated, and edited on a quarterly basis, starting in the fall of 2011. The time period is frequent enough to provide adequate information regarding program performance while reducing the burden on 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.

8. Consistency with the Guidelines in 5 CFR 1320.5(d)(2)

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

9. Consultation Outside the Agency

The notice required in 5 CFR 1320.8(d) was published in Volume Vol. 76, No. 37, pages 10373-10374 of the *Federal Register* on February 24, 2011. One comment was received from the public requesting the draft data collection plans and forms.

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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10. Remuneration of Respondents

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

11. 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. Any unique identifiers assigned by sites will not be transmitted to HRSA at any time. 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.

12. 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.

13. Estimates of Annualized Hour Burden

Form	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours
Navigated Patient Data Intake Form[1]	4,827	1	4,827	0.5	2,413.5
VR-12 Health Status Form	4,827	2	9,654	.12	1,158.5
SubTotal-Patient Burden	***4,827***				***3,572***
Patient Navigator Survey	46	1	46	0.2	9.2
Patient Navigator Encounter/Target Services Log[2]	46	629.6	28,961.6	0.25	7,204.4
Patient Navigator Focus Group	46	1	46	1	46
SubTotal-Patient Navigator Burden	***46***				***7,295.6***
Patient Medical Record and Clinic Data[3]	10	482.7	4,827	.17	820.6
Annual Clinic-Wide Clinical Performance Measures Report	5	1	5	8	40
Patient Navigator Cultural Competency Checklist	10	4.6	46	1.17	53.8
Patient Navigator/Health System Administrator Focus Group	50	1	50	1	50
Grantee Health Care Provider Focus Group	30	1	30	1	30
Social Service Provider Focus Group	50	1	50	1	50
Quarterly Report	10	4	40	1	40
SubTotal - Grantee Burden	***165***				***1084.4***
Totals	**5,038**		**48,582.6**		**11,952**
TOTAL AVERAGE ANNUAL BURDEN					**11,952**

[1]Estimated number of navigated patients per year based on grantee applications was rounded to 4,827. See table below for projected numbers navigated by Grantee.

[2] We expect that 46 patient navigators will be employed to work with 4,827 patients annually. On average, 6 contacts will be made per patient, equal to 629.6 responses per navigator.

[3] Includes medical record abstraction and clinic database download on an average of 482.7 individual patients per site. Average data collection is estimated at .17 hours per patient.

Anticipated Number of Patients per Site:

	over 3 yrs.
Clinica Sierra Vista	2280
CMAP	1000
New River	2700
Project Concern	450
Queens Medical Center	500
South County	600
Texas Tech	200
University of Utah	1350
Vista	3000
William F. Ryan	2400
Total	**14,480**

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

14. Estimates of Annualized Cost Burden to Respondents

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

15. Estimates of Annualized Cost to the Government

An estimated .5 FTE at the GS 12 level is needed to serve as the Contracting Officer's Technical Representative (COTR) for the evaluation contract and offer technical assistance to grantee's regarding the evaluation at an estimated cost of $37,400 annually. In addition, HRSA maintains a contract with NOVA Research, Inc. at an annual cost of $418,220 for the evaluation aspects of the contract, which include developing data elements, developing a database, and providing technical assistance, data quality management, and data analysis from the grantee sites.

16. Changes in Burden

As this is a new request to collect information there are no changes in burden.

17. Time Schedule, Publication and Analysis Plans

The Patient Navigator Outreach and Chronic Disease Prevention Act of 2005, as amended by the Affordable Care Act, mandates that data be collected, analyzed, and reported to Congress in the form of a report no later than six months after the completion of the demonstration grant program. Table 1 outlines milestones of the proposed project schedule.

Table 1. Milestones for the PNDP

Milestone	Comment	Date
OMB Approval	Anticipated	August 1, 2011
Data Collection Starts	Immediately following OMB clearance to collect data	August 1, 2011
Data Collection Ends	6 weeks before EOG (End of Grant period)	June 14, 2013
EOG (End of Grant period)		August 31, 2013
First Draft Due to COTR	2 months following EOG	November 29, 2013
Second Draft Due to COTR	1 month after initial draft submission	December 30, 2013
Final Draft Due to COTR	1 month after 2nd draft submission	January 31, 2014

The analyses for the Report to Congress will include:

(1) Simple descriptive statistics;
(2) Documentation of the proportion of patients that actually accessed services at targets identified by navigators;
(3) Changes in health-related quality-of-life, as measured by the VR-12, in patients who accessed care at targets identified by navigators;
(4) Short term changes in other intermediate health outcomes specific to the primary navigated condition for those patients who accessed appropriate care;
(5) Changes in clinic performance rates; and
(6) Identifying factors that are best predictors of positive outcome.

(1) Descriptive Statistics will include patient characteristics such as navigation status, demographics, health care coverage/pharmacy assistance, navigated condition, barriers, and co-occurring disorders; encounter characteristics such as duties performed, persons involved, and mode of encounter; and staffing and administrative data, which will include navigator characteristics, navigator trainings and meetings, outreach activities, and staffing. Examples of tables displaying descriptive statistics are shown in Tables 2-5.

Table 2. Demographic Characteristics of Patients Navigated Under PNDP

Characteristic	Percent of Sample	Number in Analysis
Gender (% Female)		
Education Less than High School Grad High School Grad, no more Some College College Degree Post-College Education		
Ethnicity (Hispanic or non-Hispanic)		

Table 3. Demographic Characteristics of Patients Navigated Under PNDP

Characteristic	Mean	Standard Deviation	Number in Analysis
Age			
Days Since Diagnosis (Diagnosed Patients Only)			

We also will collect information on performance of the six navigator duties included in the authorizing legislation. These include:

- Coordinating Health Care Services and Referrals
- Assisting with Overcoming Barriers to Care
- Coordinating Health Care Coverage
- Conducting Ongoing Outreach and Assisting with Preventive Care
- Facilitating Involvement of Community Organizations
- Notification of Clinical Trials

A seventh category identified by navigators, *proactive navigation*, was added to the list, related to following up with patients in anticipation of the next steps in care.

Table 4. Mean Number of Navigator Encounters Per Patient Involving Duties

Duty	Mean	Standard Deviation
Number of Navigator Encounters Per Patient		
Coordination of Care		
Community Organization Link		
Clinical Trial Notification		
Identify and Address Barriers		
Coordinate Health Care Coverage		
Assisting with Preventive Care		
Proactive Navigation		

N=##,### Navigator Encounters and #,### patients.

(2) The proportion of patients that actually access services at targets identified by the navigator. Navigators work with members of disparities populations to address the multitude of barriers to preventive care and treatment for chronic disorders. By improving access to care, navigator programs are expected to improve health care outcomes. For programs navigating patients with an abnormal cancer screening finding, decreasing the time between initial finding and diagnostic resolution is a key goal. Examining whether patients actually access care in a timely manner is an interim outcome to the overall goal of improving intermediate health outcomes.

Table 5 is an example how such information may be presented.

Table 5. Proportion of Patients Accessing Care at Navigation Targets

Navigation Target	Percent of Patients Accessing Care/ Services	Patients With Identified Target	Days Between Referral and Visit	
			Mean	SD
Diagnostic Test After Positive Cancer Screen				
Specialty Care				
Social Services (Internal)				
Social Services (External)				

Visit rates after referral and time between referral and diagnostic resolution are available at some sites and will serve as pre-navigation comparisons for these findings.

(3) Changes in health-related quality-of-life as measured by the VR-12 will be assessed for patients who accessed appropriate care, as shown in Table 6. Data will be collected at enrollment and when the patient is closed out of navigation. It is expected that improvements in quality-of-life will result from appropriate medical visits and navigators' culturally sensitive explanations of provider recommendations.

Appropriate care may be defined differently according to navigated condition. Patients navigated for diabetes should require several primary care visits before an "appropriate care" criterion is reached. Criteria for "appropriate care" will be determined in consultation with grantee experts for each of the navigated conditions.

The period of time between initial and final data collection for the VR-12 and clinical measures will vary by patient according to two factors: (1) the severity of barriers blocking access to care, and (2) the condition for which the patient is navigated. The more severe and persistent the barriers, the longer it will take a patient to access appropriate care, and the longer the period of navigation. In addition, the period of navigation is longer for conditions with more complex completion criteria. Diagnosed diabetes may require multiple visits to multiple providers, while navigation for an abnormal cancer finding can be resolved by a patient completing a single diagnostic test.

As shown in Table 6, patients accessing appropriate care should show improvement in Mental and Physical Composite Scores (MCS and PCS respectively). A matched *t*-test will be used to investigate whether change scores are statistically different over time. Post-navigation scores will also be compared to national norms. Researchers are working to translate PCS and MCS scores into risk groups and associated medical costs. Therefore, within a few years, improvements in VR-12 scores may be linked to reductions in projected medical costs for high-risk groups such as persons with diabetes, congestive heart failure, and asthma (Kazis, 2011).

Table 6. Change in VR-12 Mental Composite Score (MCS) After Navigation for Patients Who Accessed Appropriate Care

Navigated Condition	Scale	n	Pre-Navigation Mean SD	Post-Navigation Mean SD	Change	Population Norm
Diabetics Accessing Appropriate Care	MCS					

(4) Changes in clinical outcomes specific to the primary navigated condition for those patients who accessed appropriate care. Outcomes include for example, HbA1c for diabetes, blood pressure for hypertension, BMI for obesity, etc.; and clinic performance measures as appropriate: screening rates, (e.g., Pap test rate, screening mammograms administered, diabetic foot check rate) and proportion of patients receiving testing after abnormal finding.

As in Analysis 3, patients included in the analyses will be those meeting criteria for "appropriate care" as determined in consultation with grantee experts. Also, as previously mentioned, the period of time between initial and final data collection for clinical measures will vary by patient according to differences in barriers encountered as well as the condition navigated.

For changes in proportions, McNemar's test will be applied. The test will determine whether changes in the percentage of patients meeting a specific benchmark are statistically significant. Table 7 is shown as an example.

Table 7. Proportion of Navigated Hypertensives Meeting Clinical Benchmarks* Before and After Navigation to Appropriate Care

	Met Post-Navigation	Not Met Post-Navigation
Met Pre-Navigation		
Not Met Pre-Navigation		

Chi-square = #.##, $p<.05$

*Measures and benchmarks have been identified by HRSA as key performance measures and are collected on a clinic-wide level by HRSA from its Federally Qualified Health Centers through the Uniform Data Set administered by the Bureau of Primary Health Care.

It is expected that for patients accessing appropriate care, the proportion of patients meeting benchmarks will significantly increase over time.

For changes in continuous clinical variables, matched *t*-tests will be applied. The test will determine whether changes in clinical measures are statistically significant. Table 8 displays how such findings might be displayed.

Table 8. Change in HbA1c Levels After Navigation Among Patients Who Accessed Appropriate Care

	n	Pre-Navigation Mean SD	Post-Navigation Mean SD	Change
Patients with at Least 3 Primary Care Visits				

t=#.##, $p < .05$

(5) Changes in clinic performance rates. These rates include missed appointment rates, cancer screening rates, follow up rates after abnormal cancer screening tests, diabetic foot check rates, and other outcomes that are indicators of clinic efficiency and quality of care. Rates before and after implementation of the navigator program will be compared in those sites where the data are available. Statistically significant change will be tested for the difference between two proportions in two independent samples.

(6) Predictors of navigation success will be identified for each group of patients with a given navigated condition (e.g., diabetes, cancer, hypertension, asthma, cardiovascular disease). The expectation is that predictors of success or failure are different for patients diagnosed with different diseases (i.e., diabetes, cardiovascular disease or cancer). Furthermore, predictors of navigation success for patients with diagnosed illness are likely to be quite different from those for patients navigated for risk who have not yet been diagnosed. Bivariate and multivariate analyses will be conducted in order to identify these predictors.

Bivariate analyses will compare proportions meeting specific outcomes (e.g., HbA1c level below 7, visit to most of navigation targets, high reported health status) according to different program and patient predictors using simple chi-square for dichotomous variables; an example of a table is shown in Table 9.

Table 9. Health Education Predicts Meeting Benchmark

	Number Meeting Benchmark After Navigation n (% of row)	Number Not Meeting Benchmark After Navigation n (% of row)
Number with at least four navigation encounters involving education		

Chi-square= #.###, $p < .05$

After predictors have been identified, we will use multivariate analysis techniques such as hierarchical linear regression to determine the relative importance of various predictors of program success. Table 10 is an example of how findings could be displayed at the last step of the analysis. It displays the factors thought to affect navigation outcome, based on qualitative findings from the previous Demonstration Program (OMB number 200903-0915-003). The dependent variable will be the number of unresolved targets remaining three months after identification of the target. The first variable entered into the regression will be the overall number of targets identified per patient. The remaining factors will be entered in a stepwise fashion so as to identify the strongest predictors as well as the degree to which the predictors are independent of one another. Not all factors are expected to be statistically significant, independent predictors.

Table 10. Predictors of Poor Outcome – Unresolved Navigation Targets within Three Months of Date of Identification

	Beta	**SE (Beta)**	**B**	***t-test***	***p***
Constant					
Number of Targets Identified					
English is Pt's Primary Language					
Days Since Diagnosis					
# of Patient Education Activities					
# of Health Care Provider Communications					
# of Patient Barriers Identified					
Level Navigator Education (Lay vs. Prof)					
Type of Site (Health care vs. Community)					
Documentation in Shared EHR vs. Paper Chart					
Established Patient vs. New to Health Care					

R-squared of final equation = .##, F=##.##, p< .05

18. Exemption for Display of Expiration Data

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

19. Certifications

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

References

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ATTACHMENTS

Supporting Statement Section B
Federal Register Notice
Data Elements Codebook
Forms:
- Patient Intake Form
- VR-12 Health Survey
- Co-Occurring Disorders Form
- Patient Target Form
- Patient Encounter Form
- Patient Closeout Form
- Navigator Characteristics Form
- Clinical Measures/Lab Test Form
- Clinic-wide Measures Form
- Quarterly Report Form:
  - Staffing
  - Navigator Trainings and Meetings
  - Outreach Activities
  - Lessons Learned
  - Notable Cases
  - Media Coverage
  - Technical Assistance

Focus Group/Structured Discussion Guide
Patient Navigator Outreach and Chronic Disease Prevention Act of 2005, as amended by the Patient Protection and Affordable Care Act of 2010