

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

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

This is a request for Office of Management and Budget (OMB) approval to conduct an additional data collection for the Evaluation of the Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program (PNDP). PNDP and its evaluation 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). OMB approval has previously been obtained for the evaluation under OMB No. 0915-0346, Exp. date 1/31/2015. The current request is for the addition of a Client Opinion Survey to the evaluation.

Legislative authority for PNDP comes from the Public Health Service Act, amended in 2005 to include Patient Navigation Services. The Act authorized 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. One grantee site was taken over by a large hospital that chose not to continue with the program, leaving nine grantee participants.

Patient navigators 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 preventive care.

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 PNDP 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. OMB approval was obtained on January 20, 2012, for a set of standard data elements (OMB Control # 0915-0346, Exp. date 1/31/2015).

However, grant funding for the program was excluded from the 2013 Federal budget, necessitating a greatly shortened period of evaluation. Given the length of time required to establish the program, the two-year period of the truncated demonstration program may not be long enough to detect statistically significant improvements in intermediate outcomes. Thus, gaining information from patients, who are also the clients of the program, is critical. Client experience of the program, including whether the navigator was helpful to the client in meeting specific goals related to six duties specified in legislation, will assist in quality improvement efforts by HRSA and the overall assessment of the program by Congress.

2. Purpose and Use of Information Collection

PNDP is a quality improvement initiative focused on improving access to interventions that prevent and treat chronic diseases and cancer. Client opinion data will be used at a local and a HRSA program level to examine whether navigator efforts were helpful to clients in domains related to the duties of the navigator. Grantees will be able to use the information for program improvement.

Data will be collected using a Client Opinion Form at time of completion of navigation. In order to make sure that the questions are appropriate to the program in which the client participated, there are two slightly different versions available; one for patients navigated for cancer only, and one for patients navigated for all other chronic diseases, with or without cancer. Only one form will be completed per client. Client opinion data entered by grantees into the online database will be linked to other evaluation data by a Study ID. No personal identifying information will ever be entered into the online database.

The evaluation contractor will aggregate and analyze client opinion data, and findings will be reported in conjunction with other evaluation results. In addition to simple descriptive statistics, analyses will be conducted to identify what client or program factors are related to positive experience. Some findings will be included in a Report to Congress, and results will be presented

publicly through conferences, or journal publications as possible. No personal identifying information will ever be presented or transmitted by HRSA or by the evaluation contractor.

3. Use of Improved Information Technology and Burden Reduction

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.

Results will be entered in the PNDP electronic database according to approved procedures (OMB Control #0915-0346, Exp. date 1/31/2015) developed according to HRSA's previous experience. Results may initially be collected on the paper form in Appendix A, and then entered into the PNDP electronic database. Alternatively, data may be entered directly into a form in the database, if the navigator has access to a computer during the client visit. Grantees consider the PNDP database easy to work with and user-friendly.

4. Efforts to Identify Duplication and Use of Similar Information

The client opinion information to be collected from all of the grantee clients who have completed the Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program is not available from any other source. The data are unique and cannot be obtained by HRSA except through reporting by the clients of the grantees.

5. Impact on Small Businesses or Other Small Entities

Due to the demonstration designation and small scale of this grant program, the data collection activities do not significantly impact small entities.

6. Consequences of Collecting the Information Less Frequently

Opinion data will be collected when a client has completed a course of navigation and will be reported to HRSA one-time only, at the end-of-grant. Persons surveyed will be English and Spanish-speaking adults who received patient navigation services between September 2010 and August 2012. These respondents will be drawn from client pools that have had experience with the local PNDP project. If this information is not collected, there is no other mechanism by which to include the voice of the client served by the program. There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

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

8. Comments in Response to the Federal Register Notice/Outside Consultation

Section 8A

The notice required in 5 CFR 1320.8(d) was published in Volume Vol. 77, No. 57, pages **17078-17079** of the *Federal Register* on Friday, March 23, 2012.

Section 8B

The following PNDP grantee project directors and navigators 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.

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9. Explanation of any Payment/Gift to Respondents

Participants in the PNDP evaluation will not be remunerated.

10. Assurance of Confidentiality Provided to Respondents

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 clients by PNDP staff. HRSA will not collect personally identifiable information. Any unique identifiers assigned by sites will not be transmitted to HRSA at any time. 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. Justification for Sensitive Questions

Information regarding receipt of patient navigation services will be collected. No data regarding substance abuse or illegal activities will be collected.

12. Estimates of Annualized Hour and Cost Burden

Staff at nine sites will ask 100 consecutive clients seen in the navigator program after a target date (July 1) to provide information about their experience. We expect that the response rate will be high, about 90 percent, since collection will be integrated with the navigation process. Thus, the total number of persons responding will be about 810. We anticipate that the form will take about seven minutes to complete, and that the total burden hours will be 95 hours, as shown in Table 12A below.

12A. Estimated Annualized Burden Hours

Estimated Annual Reporting Burden					
Form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Navigated Patient1 Data Intake Form	4,827	1	4,827	0.5	2,413.50
VR-12 Health Status Form	4,827	2	9,654	.12	1,158.50
Client Opinion Form	810	1	810	.117	94.77
<i>Sub Total-Patient Burden</i>	4,827	3,666.77
Patient Navigator Survey	46	1.0	46	.20	9.20
Patient Navigator Encounter/Target Services Log	46	629.6	28,961.6	.25	7,240.40
Patient Navigator Focus Group	46	1	46	1	46.00
<i>Sub Total-Patient Navigator Burden</i>	46	7,295.60
Patient Medical Record and Clinic Data	10	482.7	4,827.00	.17	820.59
Annual Clinic-Wide Clinical Performance Measures Report	5	1.0	5.00	8.00	40.00

Patient Navigator Cultural Competency Checklist	10	4.6	46.00	1.17	53.82
Patient Navigator/Health System Administrator Focus Group	50	1.0	50.00	1.00	50.00
Grantee Health Care Provider Focus Group	30	1.0	30.00	1.00	30.00
Social Service Provider Group	50	1.0	50.00	1.00	50.00
Quarterly Report	10	4.0	40.00	1.00	40.00
<i>Sub Total-Grantee Burden</i>	165	1,084.41
<i>Totals</i>	5,038	49392.6	12,046.78

The instrument has been derived from the Consumer Assessment of Healthcare Providers and Systems (CAHPS), and the hour burden estimates were derived from tested results of CAHPS survey administration. A CAHPS survey can be completed in 15 minutes or less. This instrument, modified from CAHPS survey items, contains one-third fewer items than a CAHPS survey does. It incorporates design features that make it easy for respondents to complete the questionnaire.

There should be no direct cost to the respondents for this activity. Respondents are patients from communities with low income with a range of occupations and income, so respondent cost burden cannot be calculated.

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeeper/Capital Costs

There are no capital costs associated with this collection.

14. Annualized Cost to Federal 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.

The anticipated cost to the Federal Government for the Client Opinion Form (COF) is approximately \$18,000 annually for one year. These costs are comprised of: contractor payments for survey development, data cleaning, and analysis. These expenses are necessary to collect the information.

15. Explanation for Program Changes or Adjustments

This document describes the addition of a Client Opinion Survey to the collection previously approved by OMB. The initial submission for data collection for the Evaluation of the PNDP focused heavily on the assessment of intermediate health outcomes, and it did not include a client opinion component. However, grant funding for the program was excluded from the 2013

Federal budget, necessitating a greatly shortened period of evaluation. While some clients will participate in the program for long enough for intermediate health outcomes to be affected, many clients will have a more limited experience. Obtaining information about client experience of the program, including whether the navigator was helpful to the client in meeting specific goals related to six duties specified in legislation, will assist in quality improvement efforts by HRSA and the overall assessment of the program by Congress.

16. Plans for Tabulation and Publication and Project Time Schedule

Data will be cleaned, then transferred into a standard statistical package (e.g., SPSS, STATA) along with other evaluation data. Simple statistics will be reported to describe overall satisfaction with the program, including the degree to which navigators were perceived to accomplish the six duties described in legislation (see Table 1). Analyses will also explore the relationship between reports of negative experience and client factors (e.g., condition navigated, mental health status, or the number of chronic medical conditions) or program factors (e.g., high intensity of intervention, face-to-face versus telephone contact, successful navigation to medical targets). Findings will be reported in a table similar to Table 2 and will allow HRSA to identify areas for improvement. In addition to these quantitative analyses, open-ended responses will be examined and coded for common themes.

Table 1. Client Experience with PNDP

	Percent Reporting Somewhat or Very Helpful	Number in Analysis
Did the Patient Navigator help you get appointments for health care, tests, or treatments?		
Did the Patient Navigator help you find assistance to pay for health care?		
Did the Patient Navigator help you learn what you need to do to take care of an illness or health condition?		
	Percent Reporting Usually or Always	Number in Analysis
Did the Patient Navigator give you the information or help you needed?		
Did the Patient Navigator explain things in a way that was easy to understand?		

Table 2. Characteristics Associated with Low Ratings

Characteristics	Percent Reporting Overall Experience Rating < 50	Number in Analysis
Navigated Condition Abnormal Cancer Screen Diagnosed Cancer Diagnosed Diabetes Diagnosed Cardiovascular Disease		
Comorbidities Two or More No More than One		
Mental Health Summary Score Less than 40 Greater than or equal to 40		
Face to Face Contact More than 25% of encounters 25% of encounters or less		
Navigator Background Professional Lay		
Time in Navigation More than 6 months 6 months or less		

Data will be collected as soon as approval is obtained from OMB, until the end of the data collection period, estimated in early August, 2012. Analyses will be conducted in August. Findings will be included in a Report to Congress, due within six months after the end of the grant program.

Table 3. Milestones for the PNDP Client Opinion Form

Milestone	Comment	Date
Start Data Collection		As soon as possible after OMB approval
Data Collection Ends		August 15, 2012
First Draft Evaluation Report		September 1, 2012
Final Evaluation Report Due	Multiple revisions expected as document proceeds through clearance	September 29, 2012
Congressional Report Due	Due six months after end of grant program in late August, 2012	February, 2013

17. Reason(s) Display of OMB Expiration Date is Inappropriate

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

18. Exceptions to Certifications for Paperwork Reduction Act Submissions

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

ATTACHMENTS

Federal Register Notice

Form: Client Opinion Form

Patient Navigator Outreach and Chronic Disease Prevention Act of 2005, as amended by the Patient Protection and Affordable Care Act of 2010