Supporting Statement

Bureau of Primary Health Care Patient Survey

A. Justification

1. Circumstances Making Collection of Information Necessary

This is a request for Office of Management and Budget (OMB) approval to conduct the Primary Health Care Patient Surveys (survey; OMB No. 0915-NEW). This is a new information collection request. The Bureau of Primary Health Care (BPHC) within the Health Resources and Services Administration (HRSA) for the U.S. Department of Health and Human Service's (DHHS) is conducting this survey. This submission describes the procedures and instrument planned for the Primary Health Care Patient Survey (survey).

HRSA's Bureau of Primary Health Care administers the Health Center Program, as authorized by Section 330 of the Public Health Service (PHS) Act, 42 U.S.C. 254b, as amended (**Attachment 1**). Health centers improve the health of the Nation's underserved communities and vulnerable populations by assuring access to comprehensive, culturally competent, quality primary health care services. The types of health centers authorized under Section 330 of the PHS Act as amended are: Community Health Center (CHC) (section 330(e)), Migrant Health Center (MHC) (section 330(g)), Health Care for the Homeless (HCH) (section 330(h)), and Public Housing Primary Care (PH) (section 330(i)).

Health center grants provide operational support to a variety of community-based and patient-directed public and private nonprofit organizations, which may receive grant funding to support one or more of the four health center program types. Community Health Center program grantees receive funding to serve a variety of underserved populations and areas, Migrant Health Center program grantees receive funding to serve migrant and seasonal agricultural workers and their families, Healthcare for the Homeless program grantees receive funding to serve homeless individuals and families, and Public Housing Primary Care program grantees receive funding to serve residents of public housing.

The survey will include a sample of patients from all four types of section 330-funded health center programs. Specifically, the survey will collect in-depth information about health center patients such as their health status, the reasons they seek care at health centers, their diagnoses, the services they utilize at health centers and elsewhere, the quality of those services, and their satisfaction with the care they receive. This information collection request is for approval to conduct the survey, which will consist of a personal interview of a stratified random sample of patients of the health center program.

The survey builds upon the successes of the Health Care for the Homeless User/Visit Survey conducted in 2003 (OMB No. 0915-0274), the 1995 Community Health Center

User/Visit Survey (OMB No. 0915-0185), and the 2002 Community Health Center and National Health Service Corps Site User/Visit Survey (OMB No. 0915-0186). Data collection for the survey will be conducted in 2009 and 2010. However, the current survey will include interviews of patients who were not targeted in the previous survey such as migrant or seasonal farmworkers or their family members and patients who are residents of public housing. The Research Triangle International Institutional Review Board approved this survey; see the IRB Memo as **Attachment 11**.

Many of the questions on the previous patient surveys were derived from the National Health Interview Survey (NHIS) conducted by the National Center for Health Statistics (NCHS), allowing for comparisons between the NHIS surveys and the health center patient surveys. The current survey instrument was developed using a similar questionnaire methodology drawing questions primarily from the NHIS, but also from the Medical Expenditure Panel Survey and the National Health and Nutrition Examination Survey. Thus, comparisons will be possible between BPHC's survey results and current national survey data, as well as with previous patient survey data. Cognitive interviewing was completed to identify problems with survey question wording and instructions, as well as evaluate the timing and the flow of the questions. The cognitive interviewing results dictated questionnaire improvements that were incorporated into the final survey instrument (**Attachment 2**) submitted with this request.

The data elements included in the survey instrument aim to gather information related to patients': (1) care-seeking behaviors, (2) socio-demographic characteristics, (3) reasons for seeking care, (4) health status, (5) use of services, (6) satisfaction with care, (7) unmet health care needs, and (8) perceived quality of care. In order to meet the research goals detailed, the following 18 modules will be administered to patients: Introduction, conditions, access to care, routine care, follow-up conditions, cancer screening, health center services, substance use, prescription medication, dental, mental health, prenatal care/family planning (females aged 15-49), occupational health (all respondents aged 16+), HIV testing (all respondents aged 18+), living arrangements, health insurance, income and assets, and demographics. Please see **Attachment 3** for a table that outlines these modules and their data elements.

The survey includes in-person interviews of patients of section 330-funded health centers. Specifically, the survey will encompass 4,526 interviews at no more than 600 health center sites (sites) within a sample of 115 health center grantees. Details regarding grantee and site sampling procedures are included in Section B. Materials for recruitment, training site staff, and data collection are included in the **Attachment 4**. Specifically, introductory letters and/or materials for the grantees, sites, and patients are included in **Attachment 4** while informed consent forms and other procedural forms are included in **Attachment 5**.

A BPHC Health Center grantee often has several sites. Once the grantee is recruited, sampled health center sites will be contacted for participation in the survey. Patients seen at the health center in the past 12 months will be eligible for selection. All interviews will be conducted in-person by a field interviewer via Computer Assisted Personal Interview

(CAPI) in either English or Spanish at participating health center sites. (Some rescheduled interviews may take place outside the health center. Details are included in Section B3d.) The interviews will take approximately 1.1 hours (66 minutes). To complete 4,526 interviews, there will be one field interviewer per sampled grantee. Therefore, an estimated 115 local interviewers and approximately 12 traveling field interviewers will be needed, who will supplement at sites needing additional assistance and act as a buffer against interviewer attrition. For grantees that have a substantial Hispanic population, a certified bilingual interviewer will be used.

Interviewers will employ one of the following informed consent procedures depending on respondent type.

- Self-consent for adult respondents aged 18 and older
- Parental/guardian consent for child respondents aged 12 and younger (proxy interviews) — interviewers will present the subject with a copy of the Parent/Guardian Participation in Proxy Interview for Accompanied Children Consent Form (with Flesch-Kincaid Reading Level at 8.0) and read it aloud. Afterward, the subject will be invited to ask any questions about the study. Respondents who agree to participate will be asked to sign the consent form; if respondents cannot sign their names they will be asked to make a mark for their names.
- Parental/guardian consent and adolescent assent for respondents aged 13 to 17 who are accompanied by a parent/guardian

All data collection materials that are shown or read to respondents will be available in both English and Spanish (the later of which will only be used by certified bilingual interviewers).

2. Purposes and Uses of the Information Collection

The survey is unique in its effort to capture person-level data from patients of all types of Health Center Program grantees. BPHC does not routinely collect this type of information from health center sites and these data are not available from the Uniform Data System or any other source. With the current survey, BPHC aims to:

- Gather data about the patients of the CHC, MHC, HCH, and PH programs and the services they obtain;
- Enable comparisons of care received by health center patients with care received by the general population, as measured by NHIS and other national surveys; and
- Gather information which will assist policymakers and BPHC staff to:
    - Assess how well HRSA-supported health care sites are currently able to meet health care needs;
    - Identify areas for improvement and guide planning decisions; and
    - Complement data that are not routinely collected from other BPHC data sources.

Specifically, the BPHC priorities for analysis will be:

1. Comparison of CHC program patients with national data from the NHIS;

2. Comparisons within CHC program patients;
3. Comparisons of PH program patients with CHC program patients;
4. Comparisons of MHC program patients with HCH program patients;
5. Comparison of HCH program 2009 survey patients with HCH program 2003 survey patients; and
6. Comparison of CHC program 2009 survey patients with CHC program 2002 survey patients.

3. Use of Improved Information Technology and Burden Reduction

The survey interview will be administered in-person with trained field staff using a computer-assisted personal interview (CAPI) questionnaire. The use of CAPI will enable the interview to be completed in less time and with more accuracy than conventional paper interviewing techniques. If necessary, respondents will be able to complete a portion of the interview and return to complete the interview at a later time, rather than requiring the interview to be completed in a single session. In addition, random portions of each interview will be recorded by the laptop using computer-assisted recorded interview (CARI) technology for subsequent review by the project staff.

4. Efforts to Identify Duplication and Use of Similar Information

The information to be collected through the Primary Health Care Patient Surveys is unique and cannot be obtained elsewhere.

5. Impact on Small Businesses or Other Small Entities

This project will not have a significant impact on small businesses or small entities.

6. Consequences of Collecting the Information Less Frequently

The survey will be conducted once. Each grantee, site, and patient will only participate in this survey once. Multiple sites within each sampled grantee may be selected to participate and the data collection period at each site may vary depending on the number of patients to be surveyed at that site.

7. Consistency With 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 by 5 CFR 1320.8(d) was published in the *Federal Register* on December 10, 2008 (Vol. 73, No. 238) on pages 75120-75121. No comments were received. The development of the survey included consultations with persons and organizations both internal and external to HRSA and HHS. These individuals provided critical review and input on the design of the survey.

A Technical Advisory Panel (TAP) was assembled and a list of the participants on the project's TAP is provided (**Attachment 6**). Membership represented a broad spectrum of grantee staff members, representatives from coalitions/associations, nationally recognized

research experts, and the Federal government. Panel members served as expert reviewers on the instrument design. A meeting took place in February of 2008 where the TAP reviewed the draft questionnaire. The reviewers received input and recommendations were incorporated into the survey and instrument design.

9. Remuneration to Respondents

Respondents will be provided with remuneration valued at $25 for taking part in a 66-minute English or Spanish interview. Consistent with the procedures used in the 2003 Health Care for the Homeless User/Visit Survey (OMB number 0915-0274), project staff will consult with site staff to determine their preferred form of remuneration, which may include one of the following alternatives to cash remuneration: Visa gift cards, food vouchers, telephone cards, personal hygiene bags, and movie tickets. The non-cash remuneration options mitigate the potential for the incentive to facilitate substance abuse, which is particularly a concern for organizations that provide services to homeless individuals. All patients participating at a site will receive the same form of remuneration. Interviewers will be required to complete a receipt for all remuneration and have the respondent sign the receipt.

10. Assurance of Confidentiality

Participating individuals and institutions will be informed that the information provided in the survey will be kept secure and will be protected. Data collected will be in total conformity with HRSA's standards for protecting personally identifiable information on individuals. Consistent with the Privacy Act of 1974, HRSA will not provide participant names or information about participants to persons who are not part of the survey team.

The plan for maintaining privacy is outlined in a Data Security Plan (**Attachment 7**). Some highlights from the Data Security Plan include (1) procedures for safeguarding survey materials in the field, (2) procedures for shipping and storing, and 3) the training on data privacy and security protocols to be provided to survey staff.

To avoid someone obtaining the information provided during the interview, the interview will be conducted in a private location where answers cannot be overheard. In addition, an identification (ID) number will be created which will be used instead of the respondent's name. The patients will also be selected for the study using onsite recruitment procedures that will protect the patients' identity before they consent to participate in the study. The patient selection procedures are also designed to address HIPAA privacy concerns, as the health centers will not be asked to provide patient names. The interviewer will not be allowed to approach any of the site's patients nor obtain any information about the patients unless the selected patient voluntarily initiates contact with the interviewer. The consent form accompanying the questionnaire will serve to inform respondents that their participation is voluntary and will reiterate the protection of survey information.

All of the information collected will be kept private. Project staff will keep in their possession the forms for recording respondent consent, receipt of remuneration, and the actions which took place with each case including the current case status (via a contact summary report form). The data collection protocol was designed to minimize the amount of identifying information (i.e., information which could identify the respondent

as a participant in the study) that is stored on paper forms. Only the consent form and the contact summary report form will include the respondent's personal information. The consent form will include the respondent's signature while the contact summary report form will include the respondent's case id and only if an appointment is set the respondent's first name, contact number, appointment location, and parent or guardian's name (if applicable).

11. Questions of a Sensitive Nature

The survey instrument contains several items, which may be viewed as "sensitive."

The following is the additional justification for those areas that have been identified as potentially sensitive:

1. Questions on substance use and mental health status, and perceived need for and use of mental health and substance abuse services may be perceived as sensitive by some respondents. However, such information is important for understanding of the degree of unmet need for mental health and substance abuse services.
2. Questions on HIV testing status and HIV infection status may be perceived as sensitive by some respondents. However, such information is important for understanding the HIV testing and/or treatment experiences of health center patients.
3. There are questions inquiring about the respondent's family income and receipt of public assistance. The question is designed to obtain the most accurate response to annual income. However, respondents can elect to respond using an income range if they feel more comfortable.

As noted in the informed consent procedures detailed previously, prior to conducting the interview all respondents are informed about the voluntary nature of their participation and the private treatment of their survey responses.

12. Estimates of Annualized Burden Hours and Costs

Burden estimates for data collection activities and estimated costs to respondents are presented in Table 1**.**

Table 1. Maximum estimated costs to respondents for the survey

Survey							
Type of Respondent; Activity Involved	**Number of Respondents**	**Responses per Respondent**	**Total Number of Responses**	**Burden per Respondent**	**Total Burden Hours**	**Rate per hour ($)**	**Total Cost ($)**
Grantee/Site Recruitment and Site Training	115	3	345	3.75	1294	10	12940
Patient Recruitment	5658	1	5658	.167	945	10	9450
Patient Survey	4526	1	4526	1.10	4979	10	49790
Total – Survey	5,773		10,529		7218		$72180

13. Estimates Other Total Annual Cost Burden to Respondents and Record Keepers

There are no capital, startup, or operating costs to respondents for participation in the project. No equipment, printing, or postage charges will be incurred to respondents.

14. Estimated Cost to the Federal Government

The estimated cost to the Federal Government includes contract costs and the costs for the Project Officer monitoring the activity. The costs are categorized by contract costs total costs in Table 2.

Included in the contract estimates are all staff time, reproduction, postage and telephone costs associated with the management, data collection, analysis, and reporting.

Table 2. Individual and total costs to HRSA

Costs	Amount (in $)
HRSA Salaries and expenses	45,600
Contract costs	3,798,121
Total	3,843,721

15. Changes in Burden

This is a new data collection activity.

16. Time Schedule, Publication and Analysis Plan

The operational schedule for the survey is shown in Table 3. This will not be a public use data file. The results of the survey will be used in internal and external presentations regarding the Health Center Program, and for analyses, including analyses that may be published in peer-reviewed journals. In addition, conducting the patient survey is one of the items on BPHC's Program Assessment Rating Tool (PART) Improvement Plan.

Table 3. Operational schedule for survey

Activity	Projected Completion (# weeks post OMB Approval)
Recruit Grantees and Sites	Week 19
Interviewer Training	Week 20
Data Collection	Week 37
Final Report and Products Delivery	Week 46

17. Exemption for Display of Expiration Date

The expiration date for OMB approval of the information collection will be displayed on data collection instruments and materials. No special exception to this request is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.