OFFICE OF MANAGEMENT AND BUDGET
SUPPORTING STATEMENT
BRIGHT FUTURES FOR WOMEN'S HEALTH AND WELLNESS
INTERMEDIATE ASSESSMENT

A. JUSTIFICATION

1. CIRCUMSTANCES OF INFORMATION COLLECTION

This statement is a request for Office of Management and Budget (OMB) approval for the intermediate assessment of the *Bright Futures for Women's Health and Wellness* (*BFWHW*) initiative's physical activity and healthy eating materials for women. Specifically, clearance is requested for three assessment forms to be completed by the users of the *BFWHW* materials – namely young women, adult women, and their health care providers – at six health care centers. The data collection effort is designed to gather information to determine how the *BFWHW* materials are used in health care organizations during wellness and health maintenance/check-up visits, and whether their use affects women's early intentions to change their behaviors relating to physical activity and healthy eating.

The Department of Health and Human Services (HHS) Health Resources and Services Administration's (HRSA) Office of Women's Health (OWH) developed *BFWHW* to expand the scope of women's preventive health activities particularly related to physical activity and healthy eating. A pilot test of draft materials for adult women at three sites (OMB # 0915-0273) ended June 30, 2004. Recommendations from this effort centered on: simplifying language used in the materials; providing more information on goal setting for both women and their health care providers; and simplifying the materials by clarifying the instructions and shortening the text.

These changes were incorporated into the final versions of the *BFWHW* materials. HRSA released the young women's materials in 2004; these materials are being revised to incorporate the *2005 Dietary Guidelines for Americans*, and are planned for release in 2007. The adult women's materials, released by HRSA in 2006, include the most recent dietary guidelines.

An intermediate assessment of the final versions of the *BFWHW* physical activity and healthy eating guides is now needed in order to evaluate the use of the *BFWHW* materials. This one-time data collection effort will accomplish three goals: (1) assess how the *BFWHW* materials can stimulate conversation on physical activity and healthy eating during a health care visit, (2) inform future *BFWHW* programming, and (3) add to the peer-reviewed literature regarding women's health and wellness initiatives. This requested intermediate assessment of the *BFWHW* physical activity and healthy eating materials is also consistent with the needs of HRSA to meet its OMB Program Assessment Rating Tool requirements.

History and Legislative Requirements
Over the past decade, there has been a growing recognition of the need to prevent serious illness and premature mortality among women of all ages through physical activity and healthy eating behaviors. Considerable improvement is still needed, however, to meet the *Healthy People 2010*

targets for women. The challenge for health care professionals is to find ways to reach an increasingly diverse population of women with materials and messages that can help them adopt healthier behaviors. One approach to prevention and to reducing health disparities is to provide women and their health care providers with strategies for maintaining and improving health.

In fiscal year (FY) 2001, HRSA OWH sponsored a new initiative, *BFWHW*, to plan, develop, implement, and evaluate a variety of culturally competent consumer, provider, and community-based products to increase awareness and use of preventive health services for all women across their lifespan. The *BFWHW* initiative was modeled after and built upon the approach used in the *Bright Futures for Infants, Children, and Adolescents* health education tools previously developed by HRSA. Like that initiative, *BFWHW* was formulated through a collaborative process, which brought together multiple disciplines and health care experts to address health promotion and disease prevention from a holistic perspective based on evidence-based preventive care guidelines produced by the Federal government, including the U.S. Preventive Services Task Force and the *Dietary Guidelines for Americans*. *BFWHW* is intended to be an inclusive approach to women's health, involving women, their health care providers, and their communities in the promotion and acceptance of preventive health services as a means of preventing serious illness and mortality among women of all ages. This goal is achieved by providing clear and practical information to women and their health care providers on preventive services appropriate for each stage of a woman's life and offering strategies for maintaining and improving health.

The BFWHW Materials to Be Evaluated

The *BFWHW* materials being evaluated (using the assessment forms submitted for clearance) are designed to help young and adult women self-assess their dietary and physical activity behaviors and to facilitate conversations with their health care providers aimed at setting goals for healthy physical activity and healthy eating. The materials to be evaluated are:

- *My Bright Future: Physical Activity and Healthy Eating Guide and Tip Sheets for Adult Women; and*
- *My Bright Future: Physical Activity and Healthy Eating Guide and Wallet Card for Young Women.*

The materials are designed to help young and adult women:

- Assess their current physical activity and eating behaviors;
- Talk with their health care provider about physical activity and healthy eating behaviors and ask questions;
- Understand their body mass index (BMI) or BMI percentile, as calculated by their health care provider after measuring their height and weight;
- Set goals with their health care provider around areas that need improvement; and
- Learn information on physical activity and healthy eating behaviors that will help get them started on the path toward reaching their goals.

The materials for adult women are found in Tab A and for young women in Tab B.

The adult women materials were developed for women aged 21 and older, while the materials for young women focus on women ages 11–20. These age ranges reflect the use of the body mass

index (BMI)-for-age percentile, as opposed to actual BMI, for individuals up to age 20. [1] The selected age ranges also allow for the dissemination of age-appropriate physical activity and healthy eating recommendations in each set of materials. For the purpose of this evaluation, the materials for adult women will be assessed by women aged 21 and older. The materials for young women will be evaluated in school-based health centers with young women ages 13 to 17; women ages 18–20 will not be included in the evaluation. Using respondents in these age ranges simplifies distribution of *BFWHW* materials as well as the evaluation process. It will mean that only one type of *BFWHW* materials (for either young or adult women) will be distributed at any given site (e.g., in health clinics that see adult women, only the tool for those 21 years and older will be tested). It will also mean that only one consenting process will be used (if those 18-20 years of age were included in the study conducted in the school based health clinic the consent/assent process would have to be changed to allow for those who are not minors and are therefore able to consent to participate).

The materials for adult women and young women are structured similarly with the following four sections:

- The "Getting Started" section includes four questions related to physical activity and seven questions related to healthy eating behaviors for adult woman; for young women, there are three questions related to physical activity and nine related to healthy eating behaviors. In each case, the woman completes the questions on her own in the waiting room prior to her health care visit and then shares her answers with her health care provider during the visit.

- The "My Health Care Visit" section is completed by the health care provider during the health care visit. Specifically, this section includes spaces for the health care provider to calculate the adult woman's BMI based on height and weight measurements or the young woman's BMI percentile based on height, weight, and age. For adult women, there is a place to record blood pressure and cholesterol measurements. For young women, there is a section to record growth comments. After measurements are recorded, the provider then reviews the answers that the woman gave to the questions in the "Getting Started" section. This helps the provider to determine whether his/her patient's behaviors are on target or need improvement, and to identify areas in which she can make changes. There is space for the provider to record up to three recommendations.

- The "Setting My Goals" section provides a sample goal, e.g., lose 10 pounds in three months, and steps to take toward that goal. On the following page, there is space provided for the provider and the woman to set up to two goals during the health care visit.

- The "What I Should Know" section (which is called "Reaching My Goals" for young women) provides women with additional information about physical activity and healthy eating behaviors and ways in which to reach the goals that she sets. The provider may make references to specific segments in this section when making recommendations about how to improve physical activity and healthy eating behaviors, but this section is designed as a reference that the women can use after the health care visit.

Adult women will also be given tip sheets to help them get started on their goals. There are four tip

[1] http://www.cdc.gov/nccdphp/dnpa/bmi/childrens_BMI/about_childrens_BMI.htm

sheets on topics related to physical activity, including starting physical activity, starting a walking program, getting daily physical activity, and physical activity for patients with disabilities. Six tip sheets address topics related to healthy eating behaviors, including grocery shopping, understanding the food label, getting iron, getting calcium, eating out, and reaching a healthy weight.

Young women will be given a wallet card that includes brief versions of some of the tips. The wallet card is meant to be a quick reference "on the go," which young women can keep with them in their purses, wallets, lockers, backpacks, or another convenient place. Both the tip sheets and wallet card also will be assessed during this assessment. All *BFWHW* consumer materials have been reviewed and received clearance by the HHS Dietary Guidance Review Committee.

To facilitate the use of the *BFWHW* materials, each health care site will be provided a BFWHW *Administrator's Handbook: Training and Implementation of* BFWHW *Physical Activity and Healthy Eating Guides*. This 11- page document can be used by the administrator to introduce the *BFWHW* materials to the staff. PowerPoint training modules to introduce the *BFWHW* materials to health care center staff and help with training are also available online at www.hrsa.gov/womenshealth.

To encourage the providers to counsel their female patients about physical activity and healthy eating behaviors, copies of the two-page Counseling Support Tool for providers will be made available to all health care providers. This tool is designed to give providers some ideas for having a conversation with young and adult women about physical activity and healthy eating behaviors.

Previous Studies

In FY 2003, HRSA OWH awarded a contract to Health Systems Research, Inc. (HSR) to pilot test a draft version of the *BFWHW* materials for adult women. The goal was to evaluate the materials for their ease of use, appropriateness, usefulness, acceptance, and appeal. Feedback from women, health care providers, and health care administrators regarding the materials for adult women was obtained through OMB-approved survey forms and through three telephone interviews. Recommendations from this effort included shortening and simplifying the materials— revisions that were made before the materials were submitted for HHS clearance by the HHS Dietary Guidance Review Committee.

In FY 2006, HRSA OWH awarded another contract to HSR to perform this intermediate outcomes assessment for which this OMB clearance is being requested. This data collection is designed to answer questions regarding use of the materials in health care settings; inform future *BFWHW* programming; and add to the peer-reviewed literature regarding women's health and wellness initiatives.

2. PURPOSE AND USE OF INFORMATION

A total of six health care organizations will be purposively selected for this assessment. The contractor's staff and the HRSA OWH staff, in collaboration with the staff of HRSA's Bureau of Primary Health Care and HHS' Federal Occupational Health, have identified potential sites that serve HRSA's target populations, including women who are underserved, uninsured/ underinsured, and medically vulnerable. Sites must have the capability and willingness to be an active partner in assessment activities with policies, procedures, and experience in conducting research. In addition,

since the *BFWHW* materials will be tested in English only, sites also must have a primarily English-speaking patient population. The *BFWHW* materials for women will be tested in two Federally Qualified Health Centers/Community Health Centers, one faith-based organization that offers health care services, and one Federal workplace health center. The *BFWHW* materials for young women will be evaluated in two school-based health care centers. Preliminary discussions have been held with potential sites.

At each of the six sites selected for the assessment, data will be collected using one-time anonymous assessment forms. The data collected will include measures such as:

- Distribution and use of the materials in the health care centers during wellness and health maintenance/check-up visits;
- Patient and provider awareness of physical activity and healthy eating behaviors;
- Patients' and providers' attitudes about the importance of physical activity and healthy eating behaviors;
- Perceived self-efficacy of women to take steps to make changes in these behaviors; and
- Increase in knowledge and intent to change physical activity and healthy eating behaviors.

The Assessment

The sequence of steps reflected in the scripts that the health care staff will use in distributing and collecting the *BFWHW* materials and assessment forms can be found in Tab F. For adult women patients, activities associated with the use of the *BFWHW* materials and the assessment include:

- receiving the materials and reading an introductory letter upon arrival at the health care center;
- reading the materials while in the waiting room and developing questions for the health care provider;
- discussing the materials with their health care provider during the visit;
- listening to the support staff ask them to participate in the assessment during the check-out procedure;
- consenting or refusing to consent to fill out the assessment form;
- signing (or refusing to sign) the consent form:
- placing the signed consent form in an envelope, sealing it, and returning it to the support staff;
- reading and filling out the assessment form before leaving the health care center;
- placing the assessment form in an envelope, sealing it, and writing XXX's across the seal; and
- returning the sealed envelope with the assessment form to the support staff.

For young women patients, for whom the parent or guardian has supplied the school based health center with informed consent for their daughter or ward to participate in the use of the *BFWHW* materials and the assessment, the sequence of steps is identical to that followed for adult women, discussed above.

For support staff engaging with adult women, the activities include:

- reviewing the scripts and asking any questions to the contractor's staff at the initial staff meeting or via telephone and email as the need arises;
- following the scripts in setting up appointments for wellness and health maintenance visits;

- using the script to distribute the *BFWHW* materials when patients check in for their appointments;
- logging each set of *BFWHW* materials distributed;
- using the script to recruit the patients to fill out the assessment form and handing out a consent document during the check-out procedure;
- administering the consent, and collecting a signed consent document during the check-out procedure;
- if the adult woman gives her consent to participate, having her sign the consent form and placing it in an envelope to be mailed weekly to the contractor;
- logging the number of patients approached to participate, the number who refuse, and the number who consent to participate;
- distributing the assessment form;
- receiving the assessment form in a sealed envelope from patients and logging each sealed envelope received; and
- packaging and sending sealed envelopes to the contractor on a weekly basis.

For support and clinic staff engaging with young women, the activities include:

- reviewing the scripts and asking any questions to the contractor's staff at the initial staff meeting or via telephone and email as the need arises;
- sending out an informed consent form to parents or guardians as part of the regular paperwork parents receive to consent to his or her child or ward before receiving services at the school-based health center;
- including returned consent form in young woman's file;
- indicating on the young woman's file (using the health center's usual system for doing so) that the young woman has parental consent to participate in the *BFWHW* assessment;
- following the scripts in setting up appointments for wellness and health maintenance visits;
- using the script to distribute the *BFWHW* materials when patients check in;
- logging each set of *BFWHW* materials distributed;
- using the script to recruit the patients to fill out the assessment form,
- administering the assent, and collecting a signed assent document during the check-out procedure;
- if the young woman gives her assent to participate, having her sign the assent form and placing it in an envelope to be mailed weekly to the contractor;
- logging the number of patients approached to participate, the number who refuse, the number who assent/consent to participate;
- distributing the assessment form;
- receiving the assessment form in a sealed envelope from patients and logging each sealed envelope received; and
- packaging and sending sealed envelopes to the contractor on a weekly basis.

For health care providers, activities include:

- reviewing the materials in preparation for their use at a staff meeting or training session arranged by the administrator with the contractor's staff;
- discussing and completing the materials with patients during health care visits;
- signing (or refusing to sign) the consent document;
- placing the signed consent document in an envelope, sealing it, and returning it to the

support staff;
- completing a one-time assessment form at the end of the data collection period;
- placing the assessment form in an envelope and sealing it; and
- returning the sealed envelope with the assessment form to the designated support staff.

For the health care administrator, the steps include:
- signing a letter of commitment agreeing to participate in this assessment;
- identifying the support staff/receptionists to handle the assessment materials;
- identifying the health care providers who will be participating in the assessment and distributing the materials to the health care providers;
- setting a date for the assessment to begin;
- monitoring the implementation of the assessment to address any issues that arise with the contractor's staff;
- handing out packets containing consent forms, assessment forms, and envelopes to participating providers; and
- participating in a 30-minute telephone interview with the contractor's staff at the conclusion of the assessment to assess implementation and overall impressions.

Women at the participating sites will be asked to complete a one-time assessment of the *BFWHW* materials after their visit with the health care provider, but before they leave the health care center. The assessment forms (Tab C for adult women and Tab D for young women) have been written at a seventh grade and sixth grade reading level, respectively. The forms take approximately 25 minutes to complete, and include the following components:

About You and Your Health. In this section, respondents provide basic information about their age, race and/or ethnicity, education, general health, and health insurance status.

Before You Saw Your Health Care Provider Today. Respondents are asked to provide information regarding any intentions to change their behaviors regarding physical activity and healthy eating prior to their health care visit and the reason for their visit.

During Your Visit with Your Health Care Provider. In this section, respondents are asked about their prior knowledge of the *BFWHW* guides, with whom they discussed physical activity and healthy eating during their visit, what topics were discussed, and to what extent each topic was helpful to them. They are also asked about their thoughts on their ability to meet the physical activity and healthy eating goals they set with their health care provider.

After Your Visit with Your Health Care Provider. In this section, respondents' knowledge, attitudes, and early intentions to change their behavior with regard to physical activity and healthy eating are assessed through a series of short statements with which the respondents can report their level of agreement or disagreement, and short multiple-choice questions.

Health Care Provider Assessment

Health care providers at participating sites will be asked to fill out a one-time assessment at the end of the data collection period. The assessment (Tab E) takes approximately 20 minutes to complete and includes the following components:

Provider Information. In this section, providers are asked to answer questions related to their practice area, gender, years of experience, and average age of their female patients.

Information About Your Patients and Clinical Practice Regarding Physical Activity and Healthy Eating. In this section, providers are asked about (1) the amount of time they spent—prior to the implementation of *BFWHW*—discussing physical activity and healthy eating, (2) when they discussed these topics and with which patients, and (3) what topics they discussed.

Preparation for the BFWHW *Implementation.* In this section, providers are asked about their preparation for using the *BFWHW* materials, topics on which they need more practice or guidance, and suggestions regarding more effective training for providers using the *BFWHW* materials.

Using the BFWHW *Tools with Your Patients.* This section asks providers about their use of the *BFWHW* tool, including which specific portions were used, how providers selected patients with whom to use the tool (if they did not use it with all patients coming in for a well visit), and the amount of time spent on physical activity and healthy eating.

Reactions to Using BFWHW. Through a series of statements with which providers can record their level of agreement and disagreement, this section elicits feedback regarding the *BFWHW* materials on providers' discussion and goal setting regarding physical activity and healthy eating with their patients. Providers are also asked about (1) the extent to which using the *BFWHW* materials has changed their views on discussing physical activity and healthy eating with their patients and (2) their perceived influence on patients' behaviors. Finally, this section asks what might have made the materials easier to use with patients, as well as limitations on the use of the materials.

The data collection period is estimated to last four months at each site. There has been no previous collection of this information, nor is there any current data collection activity.

Federal Uses of Information

Information obtained through this assessment will be used by HRSA OWH to examine how *BFWHW* can be implemented in various health care settings and associated intermediate outcomes. Additionally, this data collection effort will assess how the *BFWHW* materials can be used to stimulate a conversation on physical activity and healthy eating during a health care visit; inform future *BFWHW* programming; and add to the peer-reviewed literature regarding women's health and wellness initiatives. The results of this assessment will highlight attributes and processes to ensure the most efficient and effective operation of the initiative's materials in the future.

3. USE OF IMPROVED INFORMATION TECHNOLOGY

This information collection effort does not lend itself to the use of information technology for the purpose of reducing respondent burden. One-time, anonymous, paper-based assessment forms will be administered to all respondent groups for data collection. The contractor's staff will work with selected sites, both during an in-person visit prior to the start of data collection, and through conference calls and emails during data collection, to ensure that the assessment forms are administered in the most efficient and least intrusive manner possible for each site. The contractor's staff will work with the sites to insert assessment form administration into their regular visit

sequence.

4. EFFORTS TO IDENTIFY DUPLICATION

The information collected for this assessment is unique to the *BFWHW* program and is not available elsewhere. This data collection effort has not taken place previously. This information will be collected during an annual wellness visit.

5. INVOLVEMENT OF SMALL ENTITIES

Not applicable.

6. CONSEQUENCES IF INFORMATION COLLECTED LESS FREQUENTLY

This is a one-time data collection effort. Each person will be asked only once to respond to this request.

Given the current lack of adequate data to understand the implementation, delivery, and effects of the *BFWHW* materials, the viability and utility of the *BFWHW* initiative may be adversely affected if the information is not collected. This information collection effort will contribute to an understanding of how the *BFWHW* materials can be used in health care settings during a wellness or health maintenance/check-up visit and inform future *BFWHW* programming.

7. CONSISTENCY WITH THE GUIDELINES IN 5 CFR 1320.5(D)(2)

This assessment will be conducted in a manner consistent with the guidelines in 5 CFR 1320.5(D)(2), with one exception: respondents will be asked to respond to the request for a collection of information in fewer than 30 days after receipt of it. They will be asked to respond to the request immediately after seeing a health care provider.

Women given the *BFWHW* materials will be asked to fill out an anonymous assessment form at the end of their health care visit. The assessment form takes approximately 25 minutes to complete. The women will be asked to return their assessment form before leaving the health care center. This approach is being taken to maximize the response rate to the assessment form; based on research, it is anticipated that if patients were asked to return or mail back the assessment forms, a very low response rate could be expected.

Health care providers will be asked to fill out an anonymous assessment form at the end of the *BFWHW* assessment period at their health care center. Providers at participating sites will be given the assessment form by the site's support staff. The health care providers will be asked to complete and return the forms to the support staff at the health care center within two weeks of receipt. The assessment form is approximately six pages in length and completion requires approximately 20 minutes. It is entirely subjective and does not require the provider to review clinical notes or medical records. Prior experience indicates that 2 weeks will give all health care providers sufficient time to complete the assessment form and will enable them to recall events and impressions.

8. CONSULTATION OUTSIDE THE AGENCY

The notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on March 7, 2006, on pages 11,435–11,436. No comments were received with regard to this notice.

Because of revisions made in the estimate of burden hours, a second 60-day *Federal Register* notice was published on February 6, 2007, on page 5446. No comments were received with regard to this notice.

The *BFWHW* initiative has been developed in consultation with individuals from academia, clinical practice, and community organizations, as well as consumer representatives. A subset of these individuals provided guidance in the development of the assessment forms and in the selection of data collection sites.

The *BFWHW* materials in this assessment have been reviewed by the HHS Dietary Guidance Review Committee and have received approval. The assessment protocol is being submitted to the Institutional Review Board of the National Center for Health Statistics, Centers for Disease Control and Prevention, HHS.

9. REMUNERATION OF RESPONDENTS

Patients and health care providers at the participating sites will not receive any remuneration from the contractor. Because the health care centers will be actively involved in the assessment activities, using the *BFWHW* materials and collecting assessment data, participating sites, if eligible, will receive a nominal remuneration ($1,000) to partially reimburse the center for the direct expenses of administration and support staff effort in the dissemination and collection of respondent assessment forms, and the photocopying of the logs before they are sent to the contractor.

10. ASSURANCE OF CONFIDENTIALITY

Confidentiality

Both the patient and provider assessment forms associated with the use of the *BFWHW* materials are anonymous. Sites will be identified through a site identification number that will be part of the numbering sequence on each assessment form; this number will be the first number in the number on the survey (i.e., assessment form number 1234 would be from site 1 and would be the 234th survey collected). Some demographic information will be collected on each assessment form but the information is insufficient to identify an individual. The type of demographic information requested on the assessment forms include the age, education, race, ethnicity, and health insurance status of the women and the gender and years in practice of the providers.

Young woman, adult woman, and health care provider assessment forms will be collected in sealed envelopes, batched, and returned to the contractor on a weekly basis, to further protect anonymity of the responses.

Patients and providers will be handed, along with the assessment form, an envelope in which to place the completed form. They will be asked to place the completed form in the envelope, to seal the envelope, and then to place a series of X's across the seal to ensure that the responses are not reviewed or altered. Patients will hand the sealed envelope to the site-designated support staff (most commonly the receptionist). Providers will place their assessment form in the sealed envelope and hand it to the support staff designated to collect the forms. The support staff will send the assessments to the contractor.

The support staff will be trained by the contractor's staff in the data collection procedures in an initial face-to-face meeting and by telephone as needed. The contractor's staff will provide all sites and support staff with telephone numbers to use to contact evaluators whenever necessary.

Informed Consent/Assent: Young Women

This evaluation will only be conducted at sites with procedures already in place for handling the consent/assent process for young women. Therefore, the informed consent procedures for young women patients will follow those already in place at the selected school-based health centers. A typical approach is as follows:

- The parent/guardian informed consent form will be part of the packet of information and consent forms that are completed at the beginning of the school year in order for the student to receive services at the school-based health center. The parent/guardian consent form for this evaluation is found at Tab G.
- When the parent/guardian signs and returns this consent form, the form will be placed in the young woman's medical record and the file (and electronic record system if possible) will be marked with a colored dot, indicating that the young woman is eligible to be a participant in the evaluation.
- Young women patients, for whom the parent or guardian has supplied the school based health center with informed consent for their daughter or ward, will be recruited to be part of the evaluation at the station where they check out at the end of a visit at the school-based health center. If a young woman agrees to participate, she will be given an assent form and will be asked to sign it (see Tab G). The signed assent form will be given back to the clinic support staff person, who will place it in an envelope to be sent to the contractor. The young woman will be given an unsigned copy of the assent form to keep, as well as the assessment form to fill out before she leaves, and an envelope in which to place the completed assessment form. The completed assessment form will be placed in the envelope by the young woman, who will seal it, place a series of Xs across the seal, and return the envelope to the clinic support staff. The clinic support staff will mail a batch of envelopes containing assessment forms and signed assent forms to the contractor on a weekly basis.

Informed Consent: Adult Women

As previously mentioned, adult woman patients aged 21 and over who read and write English and who use the health care setting during the data collection period for a wellness or health maintenance visit will be recruited to complete the assessment forms after their visit with the health care provider. The women will be given an informed consent form during the check-out procedure. The form describes the assessment and explains that participation in the assessment does not have any risks or gains. If a woman agrees to participate, she will be asked to sign the consent form and place it in an envelope. The informed consent form for adult women is at Tab H. The woman will then be given an unsigned copy of the assent form to keep, as well as the assessment form to fill out before she leaves, and an envelope in which to place the completed assessment form. The completed assessment form will be placed in the envelope by the woman, who will seal it, place a series of Xs across the seal, and return the envelope to the clinic support staff. The clinic support staff will mail a batch of envelopes containing assessment forms and signed consent forms to the contractor on a weekly basis.

Informed Consent: Health Care Providers

At the end of the data collection period, health care providers will be recruited to participate in the assessment of the *BFWHW* materials. Health care providers will be given a packet containing two copies of the informed consent form (one for the provider to sign and return, and the other for him/her to keep), the assessment form, and envelopes for each. The informed consent form for providers can be found in Tab I. This form describes the assessment and the lack of risk or gains associated with fill out the assessment form. If the health care provider agrees to fill out the assessment form, he or she will be asked to sign the consent form, place it in the envelope provided, and return it to the health center support staff.

The health care provider will then be asked to return the assessment form to the designated support staff within two weeks of receipt. The clinic support staff will mail the batch of envelopes containing signed consent forms and completed health care provider assessment forms to the contractor.

11. QUESTIONS OF A SENSITIVE NATURE

The assessment forms contain no questions that are truly sensitive in nature. The forms do contain questions, however, about circumstances that may be considered sensitive including questions about education, race/ethnicity, and health insurance status. In the analysis, these demographic variables are essential to control for potential factors that may affect the need for and access to services. Data collection training will stress the importance of these questions as well as ways, if asked, to explain that the questions are important to the assessment. Patients also will be assured that they do not need to respond to any questions that they do not want to answer.

12. ESTIMATES OF ANNUALIZED HOUR BURDEN

Estimates of response hour burden to respondents are cited in the table below. The total annualized cost to the respondents is $39,890.90. This cost estimate was calculated based on the total respondent hour burdens noted below and estimated wage rates received from the Bureau of Labor Statistics.[2] An average of the mean hourly wages for a family medicine or general practitioner ($67.49), an obstetrician or gynecologist ($82.60), and a nurse (including nurse practitioners) ($27.35) was calculated to estimate the average wage for the various health care providers participating in the assessment ($59.15). The rate for clinic administrator ($37.09) was used for administrators. The rate for medical secretary ($13.65) was used for site support staff participating in the assessment. The minimum wage rate ($5.15) was used as the hourly wage estimate for the patients.

Calculations of burden hours are presented in the table by respondent group and include ***all associated activities.*** Activities include all steps associated with the clinical use of the *BFWHW* physical activity and healthy eating materials as well as activities associated with the assessment. For patients, activities associated with the use of the *BFWHW* materials and the assessment include: receiving the materials and reading the attached introductory letter; reading and completing the materials while waiting to see a health care provider; discussing the materials with their provider during their visit; listening to the support staff ask them to participate in the assessment during their check-out procedure; consenting or refusing to consent to fill out the assessment form; reading and filling out the assessment form after their appointment; and placing the assessment form in an

[2] U.S. Department of Labor, Bureau of Labor Statistics. *2005 National Occupational Employment and Wage Estimates*. Available at: http://stats.bls.gov/oes/. Accessed August 23, 2006.

envelope, sealing it, and returning it to the support staff. The overall burden estimate for patients is 49 minutes, which includes the 25 minutes estimated for completing the assessment form. This estimate includes average time that patients will spend on each of the activities listed above, based on previous similar studies and discussions with potential sites. This overall estimate is slightly less than the estimate proposed in the 60-day *Federal Register* notice, which was published on February 6, 2007, on page 5446. After publication of the 60-day notice, it was determined that the time burden for patients was overestimated and was subsequently reduced. The 30-day *Federal Register* notice (May 10, 2007, pg. 26640) reflects this change.

For administrators, activities include obtaining consent for participation in the assessment, check-ins with contractor staff over the course of the data collection and taking part in the assessment interview. The overall burden estimate for administrators is 4 hours and 13 minutes, which includes the 30 minutes spent discussing their experiences implementing *BFWHW* with contractor staff. This estimate includes the average amount of time that site administrators will spend conducting the activities listed above during the course of the study, based on previous similar studies and discussions with potential sites. This estimate is slightly less than the estimate proposed in the 60-day *Federal Register* notice, which was published on February 6, 2007, on page 5446. After publication of the 60-day notice, discussions with potential sites led to the determination that the time burden for administrators was overestimated and was subsequently reduced. The 30-day *Federal Register* notice (May 10, 2007, pg. 26640) reflects this change.

For support staff, activities include reviewing the materials in preparation for the staff's taking part in the implementation; distributing the materials when patients check in and logging each set of materials handed out; recruiting patients to fill out the assessment form and handing out a consent document during the check-out procedure; receiving the assessment form in a sealed envelope from patients and logging each form received; and batching and sending completed assessment forms to HSR on a weekly basis. The overall burden estimate for support staff is 63 hours and 40 minutes. This estimate includes the average amount of time that support staff will spend conducting the activities listed above during the course of the study, based on previous similar studies and discussions with potential sites. The estimate is slightly less than the estimate proposed in the 60-day *Federal Register* notice, which was published on February 6, 2007, on page 5446. After publication of the 60-day notice, it was determined that the time burden for support staff was overestimated and was subsequently reduced. The 30-day *Federal Register* notice (May 10, 2007, pg. 26640) reflects this change.

For health care providers, activities include: reviewing the materials in preparation for their use; discussing and completing the materials with patients during health care visits; and completing a one-time assessment form at the end of the data collection period. The overall burden for providers is just under 6 hours (5 hours and 58 minutes) which includes the 20 minute burden estimate for providers to complete the assessment form. The burden estimate is slightly less than the estimate proposed in this project's 60-day *Federal Register* notice. After the publication of the 60-day notice, discussions with potential sites led to the decrease in amount of time spent during the patient-provider interaction , in order to not substantially alter the clinic flow. The 30-day *Federal Register* notice (May 10, 2007, pg. 26640) reflects this change.

The data collection period at each site is estimated to last four months. The estimated response burden is as follows:

	Estimated Data Collection Burden Hours					
Data Collection Activity	**Number of Respondents**	**Hours per Response**	**Responses per Respondent**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Cost**
Patients	3,000	.81	1	2,430	$ 5.15	$12,514.50
Administrators	6	4.22	1	25	$37.09	$ 927.25
Support Staff	6	63.67	1	382	$13.65	$ 5,241.30
Providers	60	5.98	1	359	$59.15	$21,234.85
Total	**3,072**			**3,196**		**$39,890.90**

13. ESTIMATES OF ANNUALIZED COST BURDEN TO RESPONDENTS

There are no capital, startup, operation, or maintenance costs associated with this data collection for respondents.

14. ESTIMATES OF ANNUALIZED COST TO THE GOVERNMENT

HRSA administered an open competition to select a contractor to conduct the intermediate assessment of the *BFWHW* initiative Physical Activity and Healthy Eating Tool. HSR was awarded a 2-year cost plus fixed fee contract for $273,481; this amounts to an annualized cost to the government of $136,740.50.

15. CHANGES IN BURDEN

This is a new project.

16. TIME SCHEDULE, PUBLICATION, AND ANALYSIS PLANS

Time Schedule

Data collection will begin after OMB clearance and institutional review board approval are obtained. Submission of a final report to HRSA OWH is scheduled for Spring 2008.

Publication

The results of this data collection will be tabulated and summarized in a final report that will be submitted to HRSA OWH. This report will be an internal document. Additionally, a manuscript for a journal article will be written. This article will reflect the findings of this multi-site assessment and will discuss the level of acceptability and perceived usefulness of the *BFWHW* physical activity and healthy eating materials in the participating settings. This manuscript will be practice-oriented, targeted at persons in organizations interested in providing preventive health services. It is also anticipated that findings from this assessment will be presented at professional meetings.

Analysis Plan

The information derived from the data collection effort of this assessment will be entered into a database and analyzed using SAS, a statistical computing software program. Frequencies on all variables will be produced, and all items will be evaluated for non-response and out-of-range

values. The data analysis results will be presented in a final report, which will answer the assessment questions using the data from the assessment forms. Specifically, the report will contain findings that:

- Assess knowledge, attitudes, self-efficacy, and intentions related to physical activity and healthy eating behaviors;
- Describe the characteristics of respondents at each of the health care sites;
- Depict how the *BFWHW* physical activity and health eating materials were used in the interaction between the women and their health care providers;
- Detail provider acceptance of the *BFWHW* physical activity and health eating materials and their effect on practice;
- Assess satisfaction of all respondents with the use of the *BFWHW* physical activity and healthy eating materials.

Descriptive analyses will be conducted. The goal of the descriptive analyses will be to present self-reported information from respondents. Differences among the distinct sites and among subgroups will be explored using chi-square tests for categorical variables and analyses of variance for continuous variables. Descriptive analyses that control for demographic and site differences will be used to explore the associative relationships between (1) how the *BFWHW* physical activity and healthy eating materials were used; and (2) the level of self-efficacy, mediated by attitudes of the women. Data collected from health care providers will be used descriptively to discuss acceptability in a busy health care environment.

17. EXEMPTION OF DISPLAY OF EXPIRATION DATE

We do not seek approval to eliminate the expiration date from the form.

18. CERTIFICATIONS

There are no exceptions.