

Supporting Statement

HRSA Office of Women's Health Bright Futures for Women's Health and Wellness Survey

A. Justification

1. Circumstances of Information Collection

The Health Resources and Services Administration (HRSA), Office of Women's Health (OWH) is requesting OMB approval for the evaluation of the Bright Futures for Women's Health and Wellness (BFWHW) Initiative's Emotional Wellness Guides for women. This is a new information collection request. Approval is requested for two written survey instruments and one focus group guidance for two years. The Consumer Survey will be completed by adult and young women who receive the emotional wellness guides at four evaluation sites. The Distributor Survey will be completed by medical and social service professionals who distribute the emotional wellness guides to consumers. Focus groups will be conducted with small groups of adult and young women consumers at each of four evaluation sites. This three year evaluation will examine the impact and use of these guides in health care and social service organizations, focusing on the following areas:

- 1) The acceptability of the emotional wellness guides by the target audiences;
- 2) The strategies for ensuring the use of the emotional wellness guides; and
- 3) The outcomes associated with the use of these emotional wellness guides in selected health and social service sites (i.e., Healthy Start projects, Federally Qualified Community Health Centers, and Ryan White Part D sites).

The evaluation also will examine how the BFWHW Emotional Wellness Guides have been used, by whom, and under what circumstances to assess whether the emotional wellness guides are being used in a way that maximizes effectiveness. The evaluation will provide feedback to identify barriers related to their distribution and use, and support replication of best practices at other locations.

Background

Women's health research often emphasizes the use of health promotion and prevention as strategies to support emotional well-being, prevent or minimize the effects of many serious mental health conditions across populations.

The Department of Health and Human Services (DHHS) is dedicated to creating a "culture of wellness" and has devoted significant resources across a variety of programs to promote health and wellness. In FY 2001, HRSA's Office of Women's Health launched the Bright Futures for Women's Health and Wellness (BFWHW) Initiative. The goal of the BFWHW Initiative is to plan, develop, implement and evaluate a variety of evidence-based and culturally competent materials for consumers, primary care providers, and communities. Materials are intended to increase awareness and use of preventive health services among women, particularly underserved and minority women across the lifespan, as a means of preventing serious illness

and mortality among women of all ages. 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. The goal of this evaluation is to address questions regarding use of the BFWHW Emotional Wellness Guides in different settings; inform future BFWHW programming; and add to the peer-reviewed literature regarding women's health and wellness initiatives. This evaluation will not address the BFWHW Initiatives intent to increase awareness and use of preventive services among women.

The BFWHW Initiative first launched a series of Physical Activity and Healthy Eating guides for adult women (released in 2006) and for young women (released in 2007). The second series of guides focuses on Emotional Wellness (to be evaluated through this effort). These guides were developed through the work of a 10-member panel of emotional health experts (medical doctors, psychiatrists, and researchers) from across the country. The Woman's Guide to Emotional Wellness and the Young Woman's Guide to Emotional Wellness were designed to help meet the immediate needs of consumers for information about emotional health. These guides provide practical information to women on emotional wellness and offer strategies for maintaining and improving emotional health. The tips and information in these booklets are drawn from recent research around what helps women thrive in their day-to-day lives.

This evaluation is designed to address questions regarding use of the BFWHW Emotional Wellness Guides in different settings; inform future BFWHW programming; and add to the peer-reviewed literature regarding women's health and wellness initiatives.

The BFWHW Emotional Wellness Guides to be evaluated are:

- *Bright Futures: A Young Woman's Guide to Emotional Wellness; and*
- *Bright Futures: A Woman's Guide to Emotional Wellness.*

The BFWHW Emotional Wellness Guides are designed to help young and adult women:

- Improve their emotional wellness, well-being, satisfaction, and overall quality of life by using the tips offered in the guide.
- Feel their best by using coping skills (such as flexibility, feeling strong, and optimism), personal traits (positive self-esteem), and resources (spiritual practices and support from family and friends), which can boost a woman's emotional wellness.

The guide for adult women is found in *Appendix A* and the guide for young women in *Appendix B*. The adult women's guide was developed for women aged 18 and older, and the guide for young women was developed for female youth ages 13-17.

2. Purpose and Use of Information

Data for this study will be collected through a combination of methods:

- Surveys of the young and adult women who seek care at one of the four evaluation sites (i.e., consumer survey).

- Surveys of the individuals who distribute the BFWHW Emotional Wellness Guides, which may include physicians, nurses, social workers, and community outreach workers who provide services at one of the four evaluation sites (i.e., distributor survey).
- On-site focus groups with young adult and adult women who receive services at the four evaluation sites. Six to eight adult women in one focus group at each site and six to eight young women in another focus group at each site will be asked to participate in a 1.5 hour focus group.

This information collection request seeks approval for the consumer survey, the distributor survey and the consumer focus group guidance (see *Appendix H*). The surveys will be administered one time only. The evaluation team will conduct one site visit to each of the four evaluation sites, during which focus groups will be conducted with young and adult women consumers. There will be a maximum of two focus groups per site (1 with adult women and 1 with young women). Depending on the age demographic of women served at the evaluation site, some sites may just have one focus group with either young women or adult women (not both). At sites that serve enough adult women, six to eight adult women will be asked to participate in a 1.5 hour focus group. At sites that serve enough young women, six to eight young women will be asked to participate in a separate 1.5 hour focus group. Women who participate in a focus group will not be eligible to complete the written survey.

Administering surveys to and conducting focus groups with young and adult women consumers across these four program sites is necessary to capture the process and outcomes information needed to evaluate the BFWHW Emotional Wellness Guides. The primary objective of the consumer survey is to capture a uniform set of information in a standardized manner across all respondents that assess the extent to which the consumers found the guides easy to read and understand, useful/actionable, and relevant to their lives. The consumer survey will enhance OWH's programmatic and data collection efforts by capturing important information about the woman that is otherwise not being captured in a standardized and quantifiable manner across program sites (e.g., consumers' overall level of concern about emotional wellness and comfort with talking to providers about this topic).

Surveying the professionals who distribute the BFWHW Emotional Wellness Guides is necessary to information across all respondents that assesses: (a) the types of emotional concerns reported by the women consumers they serve; (b) the frequency of distribution; (c) their comfort level talking with consumers about issues of emotional health; and (d) their experience distributing the guides and its impact on their routine practice. The distributor survey will enhance OWH's programmatic and data collection efforts by capturing important process information (i.e., providers' experience with the guide, their willingness to recommend the guide to other professionals, and their intention to distribute the guides beyond the evaluation period).

The primary objective of the consumer focus groups is to gather more richly nuanced data from women in the BFWHW target population than can be collected through a written survey. Through these in-person conversations, the evaluation team can gather feedback and comments about the guides, their usefulness, comprehensibility, cultural and age appropriateness, and relevance to their lives. In the context of discussing the guides, other issues will be raised such as the participants' own emotional health, their experience talking with professionals about

emotional health and wellness, and need for or desire for help in improving their emotional health and wellness.

Data Collection Process

This section describes the process by which consumers, providers, and site program staff will participate in the distribution of the BFWHW Emotional Wellness Guides and the evaluation. The data collection period is estimated to last up to six months at each site. There has been no previous collection of this information nor is there any current data collection of this information.

The evaluation team and the HRSA OWH staff have used a sample of convenience to select four HRSA funded sites to serve as evaluation sites: two Maternal and Child Health Bureau grantees, one Ryan White Part D grantee, and one Federally Qualified Health Center/Community Health Center. These sites serve HRSA's target populations, including women who are underserved, uninsured/ underinsured, and medically vulnerable. A sample of convenience was used due to funding constraints that limited the evaluation to four sites. Additionally, HRSA chose to use a convenience sample to attempt to use sites that provided more interest in conducting an evaluation of these tools. Preliminary discussions that were held with all of the potential sites for this evaluation confirmed that they have the capability and willingness to be active partners in the evaluation. Thus, the four selected sites are highly motivated to participate in (and to encourage consumers to participate in) the evaluation, which may result in a higher response rate.

To facilitate the use of the BFWHW Emotional Wellness Guides, each evaluation site will be provided with copies of the BFWHW consumer guides as well as the BFWHW Health Care Providers Guide to Promoting Women's Emotional Wellness. These four sites also will be provided with technical assistance to help them develop guidance for distributing the guides and the surveys in line with the way services are delivered at their site. The process for distributing the BFWHW Emotional Wellness Guides and surveys will vary at each site depending on how and in what settings they interact with consumers. For example, one site sees female consumers in individual appointments at the consumers' homes. In this case, the same individual service provider/professional would likely distribute the guides and the informed consent forms and surveys in the context of these in-home individual appointments. Another site holds prenatal support groups for pregnant women; the professionals leading the support group would likely distribute the guides in the group context and the site program staff who assist with the check-out process would distribute the informed consent forms and surveys.

The evaluation team will provide technical assistance with data collection to the participating sites throughout the course of the evaluation. First, the team will schedule a group conference call with the selected sites to provide an overview of the evaluation, including a review of the data collection instruments submitted to OMB, survey distribution guidance and plans for on-site visits. During on-site visits, the evaluation team will conduct training with site program staff about data collection guidance. After the site visits and the sites begin survey distribution, there will be up to three webinars conducted with the site program staff to answer questions, discuss

challenges, and adjust methodology. In addition, sites can contact the evaluation team via telephone and/or email as needed to receive technical assistance.

- At each of the four sites selected for the evaluation, data will be collected using the aforementioned consumer and distributor surveys and focus groups. Each site will be asked to keep a basic record of the number of women asked to complete the survey and a record of response rates. The evaluation sites will not be asked to collect additional output or outcome data for this study.

We anticipate that for the adult women consumers, the activities associated with the use of the BFWHW Emotional Wellness Guides and participation in the evaluation will include:

- Receiving the women's guide to emotional wellness guide in the context of a medical or other social service appointment or during a support group;
- Reviewing the guide and discussing it with the professional or paraprofessional who gave it to them (e.g. physician, nurse, case manager, social workers, or outreach worker) during the visit;
- Being asked by the distributor or other site program staff ask to participate in the evaluation;
- Receiving the informed consent form and consenting (by signing the form) or refusing to consent to complete the consumer survey;
- Completing the written survey; and
- Sealing the completed survey in the envelope and returning it to the site program support staff (or they may take it with them to mail directly to the evaluation team).

For young women, the process outlined above will be identical except that site program staff will obtain the informed consent of both the young woman and her parent or guardian.

Some female consumers will be asked to participate in a focus group to be conducted on-site by the evaluation team. However, these female focus group participants will not be eligible to participate in the distributed written survey. The sites will recruit participants for the focus group who they deem as most likely to actively participate in a focus group based on past participation in other focus groups or support groups that the site has convened. Since not all sites will serve both young and adult women, focus groups will be organized accordingly. The activities associated with their participation in these focus groups will include:

- Being invited by site program staff to participate in a focus group and asked to complete an informed consent form (to be signed by parent or guardian as well for women under 18); and
- Participating in a 1.5 hour group session to review the BFWHW Emotional Wellness Guides and discuss the Emotional Wellness Guides with members of the evaluation team and other women in their age group.

For professionals who will distribute the BFWHW Emotional Wellness Guides to consumers, activities include:

- Working with program administrators as appropriate to develop the guidance for how, to whom and under what circumstances the guides and surveys will be distributed;
- Participating in preliminary training sessions (to be conducted by phone/webinar before the formal evaluation begins) with the evaluation team to review and discuss the guides, the evaluation and related materials;
- Distributing the guides and discussing them with consumers following the distribution guidance and instructions;
- Participating in on-site training with evaluation staff during the one-time site visits to discuss the sites preliminary experiences distributing the guides, the process of distribution, and to review and finalize survey distribution procedures; and
- Completing the one-time web-based distributor survey form near the conclusion of the data collection period.

For the site program administrators, activities include:

- Signing a letter of commitment agreeing to participate in the evaluation;
- Working with the evaluation team to develop guidance for how, to whom and under what circumstances the guides and surveys will be distributed;
- Participating in staff meetings or training sessions with the evaluation team to review and discuss the distribution of the guides;
- Identifying the professionals who will distribute the guides to consumers and providing the guides to them;
- Working with evaluation team to schedule the site visit and focus groups that will mark the beginning of the formal period, after which survey distribution will begin;
- Identifying the site program staff who will distribute the surveys;
- Working with the evaluation team to schedule and conduct in-person training sessions with the staff who distribute the guides and the staff who will distribute the surveys;
- Distributing to site program staff the packets containing the consent forms, surveys, and envelopes;
- Discuss with the evaluation team the sites' preliminary experiences distributing the guides, the process of distribution, and the emotional health issues faced by the target population served; and
- Continuing to monitor the implementation of the evaluation after the site visit and working with evaluation team to address any questions, problems or concerns.

For site program staff who will distribute *surveys* to adult women, the activities include:

- Participating in staff meetings or training sessions with the evaluation team to review and discuss the evaluation and related materials;
- Following the guidance developed by the site staff and evaluation team that outlines how, to whom, and under what circumstances they should distribute the survey;

- Following a script from the evaluation team that outlines how to recruit the women to complete the survey and distribute the informed consent document;
- Administering and collecting the informed consent form;
- Distributing the consumer surveys;
- Receiving the survey in a sealed envelope from consumer and distributing incentive to respondent;
- Packaging and sending the signed consent forms and completed surveys to the evaluation team on a weekly basis.
- Keeping a record of the number of adult women approached to participate in the evaluation, the number who refuse, the number who consent to participate; the number who completed the survey;

For site program staff who will distribute *surveys* to young women, the activities include:

- Participating in any necessary staff meetings or training sessions with the evaluation team to review and discuss the evaluation and related materials;
- Following the guidance developed by the site program staff and evaluation team that outlines how, to whom, and under what circumstances they should distribute the survey;
- Following a script from the evaluation team that outlines how to recruit the young women to complete the survey and distribute the informed consent document;
- Administering and collecting the informed consent form signed by both the young woman and their parent/guardian. The consent form may be administered to parent/guardian at the same time as the survey if the parent/guardian is present in person at that time. Alternatively, sites may send 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. Site would indicate in the young woman's file (using the health center's standard procedures) that the young woman has parental consent to participate in the BFWHW evaluation;
- Distributing the consumer surveys;
- Receiving the survey in a sealed envelope from consumer and distributing incentive to respondent;
- Packaging and sending signed consent forms and completed surveys to the evaluation team on a weekly basis.
- Keeping a record of the number of young women approached to participate in the evaluation, the number who refuse, the number who consent to participate; the number who completed the survey;

Consumer Survey

Women at the participating sites will be asked to complete a one-time survey of the BFWHW Emotional Wellness Guide during or after a service visit. The consumer survey (see *Appendix E*)

has been written at a sixth grade reading level. The same survey will be distributed to adult and young women. The survey takes approximately 15 minutes to complete and asks questions in the following areas:

About the Consumer: Respondents are asked to provide basic information about their age, race, education background, marital status, and to answer questions about their current emotional health.

About the Health Care/Social Service Provider: Respondents are asked about their reason for a visit, the number of visits in the last year, and overall satisfaction with the services received. Women are asked about how often they discuss their emotional health with their provider and how comfortable they are about talking to health care providers about emotional health.

About the Guides: If the woman has received a copy of the emotional wellness guide, she will be asked whether she read the guide, how easy the guide was to read and understand, whether the advice from the guide might improve her life, and how relevant the examples in the guide were to her. The women will be asked if they would recommend the guide to friends or family, whether they are more likely to discuss emotional health with their providers, and whether they would be interested in more information to improve emotional health.

Distributor Survey

Health care and social service providers at participating sites will be asked to complete a one-time survey near the conclusion of the data collection period. The web-based survey (*Appendix G*) takes approximately 15 minutes to complete and includes the following components:

About the Provider: Providers are asked questions related to their gender, age, race, role in organization, primary professional qualification, and years of experience.

About the Women Served: Providers are asked about the services provided, number of women seen monthly as well as estimates of their age and race. Providers are asked about the frequency and the types of emotional issues raised by the women they see and how comfortable the providers are about talking about emotional well-being with the women they see.

About the Guides: Providers are asked about their use of the BFWHW Emotional Wellness Guides, including the number of guides distributed, how providers selected women with whom to use the guide (if they did not use it with all women coming in for an appointment), and the amount of time spent discussing emotional wellness during a visit. Finally, providers are asked to rate the usefulness of the information in these emotional wellness guides for women, the ease in which the provider can talk about the guides, and the relevance of the examples in the guides for the women served by that provider. Providers are also asked about the extent to which using the BFWHW Emotional Wellness Guides has increased the number of emotional wellness discussions with women and referrals for further emotional health services.

Focus Groups

Six to eight adult women in one focus group at each site and six to eight young women in another focus group at each site will be asked to participate in a 1.5 hour focus group. The sites

will recruit participants for the focus group who they believe will actively participate in this focus group based on their past participation in other focus groups or support groups. At most, two focus groups will take place at each site allowing for women to be divided according to age group (age 13-17 for the focus group including young women and another focus group for women age 18 and older). Since not all sites will serve both young and adult women, focus groups will be organized accordingly. Discussion in the focus group will focus on the content in the BFWHW Emotional Wellness Guides (*Appendix H*). After being given an opportunity to read and review the BFWHW Guide (Woman's Guide for those over 18 and Young Woman's Guide for those 13-17), participants will be asked to discuss their general reactions to the guides. In particular, they will be asked if the information presented is understandable, useful, and relevant to their lives.

Federal Uses of Information

Information obtained through this evaluation will be used by HRSA OWH to examine how BFWHW can be most successfully implemented in various settings. Additionally, this data collection effort will assess how the BFWHW Emotional Wellness Guides can be used to stimulate a conversation on emotional wellness during a health care visit; inform future BFWHW programming. The results of this evaluation will highlight attributes and processes to ensure more efficient and effective distribution of the initiative's emotional wellness guides in the future. *Appendix D* provides an overview of the evaluation questions guiding the evaluation and indicators that will be measured.

3. Use of Improved Information Technology

Based on feedback from preliminary discussions with each of the selected sites, the use of electronic, web-based information collection instruments for women consumers may pose a respondent burden. The sites reported that some of their consumers may not have access to the internet, which is a requirement in order to complete a web-based survey. Moreover, some consumers may not be familiar with computers and/or web-based surveys. Therefore, using electronic surveys with these women may pose a burden and potentially reduce the response rate. Thus, paper based surveys will be utilized. One-time, anonymous, paper-based surveys will be administered to the adult and young women respondent groups and in-person focus groups will be conducted.

Based on feedback from preliminary discussions with each of the selected sites, the use of electronic, web-based information collection instruments for distributors would not pose a respondent burden. Therefore, the distributor survey will be a fully electronic web-based survey to facilitate timely submission and ease of responding. A paper-based written survey will also be available for distributors to complete on-site and returned in a sealed envelope via mail.

The evaluation team will coordinate with the sites to ensure that survey administration is integrated into their regular visit sequence. The evaluation team will provide technical assistance to the participating sites throughout the course of the evaluation and help them adjust the data collection guidance as needed, which will help ensure that the surveys are administered in the least intrusive manner possible for each site.

4. Efforts to Identify Duplication

There are no other OWH data collection activities that focus on the BFWHW Emotional Wellness Guides; the information collected for this evaluation is unique to the BFWHW program and is not available elsewhere. This data collection effort has not taken place previously.

5. Involvement of Small Entities

The surveys do not involve small businesses and, therefore, the surveys pose no burden on such entities.

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.

This information collection effort will contribute to an understanding of how the BFWHW Emotional Wellness Guides can be used in health care and social service settings during a wellness or health maintenance/check-up visit and inform future BFWHW programming. Currently, there is little data available on the extent to which the guides are useful and acceptable by target audiences. These data collection instruments are also the only mechanism by which the OWH can determine the commonalities and differences across participating sites in terms of their experience with the distribution of emotional wellness guides and the outcomes found.

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

The notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on May 13, 2009, Volume 74, Number 91 (page(s) 22556-7). The 30 day notice was published in the *Federal Register* on July 17, 2009 (page 34759). No comments were received for either 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 served on an Evaluation Expert Committee that helped develop the framework for this evaluation, and provided guidance in the development of the surveys and in the selection of data collection sites.

In addition to posting the *Federal Register* Notice, the evaluation team consulted with respondents (i.e., female consumers) from whom the information will be requested. The evaluation team conducted cognitive interviewing with 4 women at a HRSA grantee site that provides services to women that are similar to the four selected evaluation sites, but which will not otherwise participate in the evaluation. Each woman was asked to assess the following:

- Readability and understandability of the questions;
- Clarity and comprehensiveness of the questions; and
- Ease and time needed to answer questions.

Upon completion of the cognitive interviewing, OWH made revisions to the consumer survey instrument for clarity and comprehension. The final version of the consumer survey is in *Appendix E*.

OWH also shared a draft of the consumer and distributor survey with the four evaluation sites and the Expert Committee members to solicit their feedback. The evaluation team made revisions to the both surveys for clarity and comprehension. The final version of the distributor survey is in *Appendix G*.

8. Consultation Outside the Agency

The notice required in 5 CFR 1320.8(d) was published in the Federal Register on May 13, 2009 volume 74 page 22566, and the 30 day notice published on July 17, 2009, volume 74 page 34759. No comments were received.

9. Payments/Gifts to Respondents

A woman or young woman who agrees to complete a survey or participate in a focus group will be offered a gift card of a nominal amount (\$10). The gift card will be issued by a major credit card company (e.g. MasterCard or Visa), so the participant has the flexibility to use the money towards their specific need (e.g. gas or grocery). The four sites participating in the BFWHW Evaluation were offered an incentive to help offset the administrative burden. In this case, burden includes activities such as (but not limited to) consent procedures for participants; distribution, collection and mailing of surveys; and coordinating the focus groups and consumers who will participate in the evaluation. Sites participating will receive a one-time incentive of \$250. An incentive was offered in order to increase the likelihood of participation in current and future evaluation activities funded by the federal government.

10. Assurance of Confidentiality

Confidentiality

Both the consumer and distributor surveys associated with the use of the BFWHW Emotional Wellness Guide are anonymous. No identifying information will be collected.

Informed Consent: Young Women

Young women aged 13-17 who receive services from an evaluation site during the data collection period will be recruited to complete the survey during or after a service visit. This evaluation will be conducted at sites with procedures already in place for handling the consent process for young women. Therefore, the informed consent procedures for young women will follow those already in place at the selected evaluation sites. The parent/guardian will be given the informed consent statement and form to sign (*Appendix F*). Different approaches may be used by different sites, as follows:

- The parent/guardian who accompanies their child/ward to a service appointment will be asked to sign the written consent form during the context of the in-person service appointment, at the same time the young woman is asked to consider participating in the evaluation.

- The parent/guardian informed consent form will be part of the packet of information and consent forms that are sent by the health care or social service provider to the parent when their child/ward begins receiving services. When the parent/guardian signs and returns this consent form, the form will be placed in the young woman's service record and her file (in an electronic record system if possible) will be marked to indicate that the young woman is eligible participate in the evaluation.

Young women, for whom the parent or guardian has supplied the evaluation site with informed consent for their daughter or ward, will be recruited to be part of the evaluation. If a young woman agrees to participate, she will be given her own copy of the informed consent statement and form and will be asked to sign the last page. The statement describes the evaluation in a question and answer format. The signed form will be returned to the site program staff who will place it in an envelope to be sent to the evaluation team. The young woman and/or her parent or guardian may keep the informed consent statement to refer to as needed. Then the young woman will be given the consumer survey to complete with a pre-addressed, pre-stamped envelope in which to place the completed survey. The young woman will be asked to place the completed survey in the envelope, seal it and return it to the site program staff from whom she received it. The site program staff will mail a batch of envelopes containing surveys and signed consent forms to the evaluator on a weekly basis. If the young woman elects to complete the survey off site, she can return the completed survey in the mail herself (with the provided pre-stamped envelope).

Informed Consent: Adult Women

Adult women aged 18 and over who receive services from an evaluation site during the data collection period will be recruited to complete the survey during or after a service visit. The women will be asked if they would consider participating in the evaluation and given an informed consent statement to read containing a form to sign (*Appendix F*). The form describes the evaluation in a question and answer format. If a woman agrees to participate, she will sign the form and return it to the site program staff person, who will place it in an envelope to be sent to the evaluation team. The woman may keep the informed consent statement to refer to as needed. The woman will then be given the consumer survey to complete with a pre-addressed, pre-stamped envelope in which to place the completed survey. The woman will be asked to place the completed survey in the envelope, seal it and return it to the site program staff from whom she received it. The site program staff will mail a batch of envelopes containing surveys and signed consent forms to the evaluator on a weekly basis. If the young woman elects to complete the survey off site, she can return the completed survey in the mail herself (with the provided pre-stamped envelope).

11. Questions of a Sensitive Nature

There are no questions of a sensitive nature in this survey, and the site program staff who will distribute the surveys will assure survey respondents that they do not have to respond to any question that makes them uncomfortable or that they do not want to answer.

12. Estimates of Annualized Hour Burden

Estimates of burden hours are presented in Exhibit A below. The total annualized cost to the respondents is \$1,810.76. 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.¹ 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 survey (\$59.15). The minimum wage rate (\$5.15) was used as the hourly wage estimate for the women and young women completing the survey or participating in a focus group.

The activities listed below include all the steps associated with the use of the BFWHW Emotional Wellness Guides as well as activities associated with the evaluation.

For female consumers, activities associated with the use of the BFWHW Emotional Wellness Guides and the evaluation include: receiving and reading the emotional wellness guides; discussing the guides with a service provider during a social services or health care visit; listening to the site program staff ask them to participate in the evaluation; consenting or refusing to consent to fill out the survey; reading and completing the survey during or after their appointment, and placing the survey in an envelope, sealing it, and returning it to the support staff (or mailing back the survey if not completed during the site visit).

For distributors, activities include: reviewing the emotional wellness guides in preparation for their use; distributing the emotional wellness guides; discussing the emotional wellness guides with the women they serve during routine visits; and completing the one-time web-based survey.

For program administrators, activities include: consenting to participate in the evaluation, assisting the evaluation team in designing distribution guidance and instruction for the emotional wellness guides and the survey instruments, helping to arrange site visits and schedule focus groups, taking part in discussions with the evaluation team, and checking in with the evaluation team over the course of the data collection as needed.

For other site program staff, activities include: reviewing the emotional wellness guides and surveys in preparation for the staff taking part in the evaluation; recruiting women to participate in the evaluation and distributing informed consent forms and surveys; recording the number of surveys handed out; receiving the survey in a sealed envelope from women and logging each form received; and batching and sending completed surveys to the evaluation team on a weekly basis.

Results from Cognitive Interviewing:

Consumer Survey

¹ 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.

Four women at a HRSA grantee site (not to be used in the evaluation) completed cognitive interviewing for the consumer survey and noted that the burden placed on them involved: (a) completing the survey, which involved recalling the number of clinic appointments and discussions about emotional health with the provider in the last twelve months. Based on this feedback, we revised the consumer survey as follows:

- To minimize the burden placed on respondents to complete the survey, questions and answer options have been made clearer.
 - For example, terms like “site,” “discussed,” and “relevant” were not understood by some of the consumers involved in pretesting, so we revised these terms with more understandable terms.
 - The skip pattern caused confusion for a respondent who participated in pre-testing, so we clarified this language.

The women who participated in the cognitive interviewing noted that the average time to complete the consumer survey was 15 minutes.

Distributor Survey

The four evaluation sites and the Expert Committee noted that the burden for completing the distributor survey involved completing the survey, which involved determining the number of individuals seen each month as well as estimating the percentage of women seen by age and race. Based on this feedback as well as the feedback from 5 potential distributors at one of the four evaluation sites, we revised the distributor survey as follows:

- Questions have been made clearer to minimize the burden placed on respondents to complete the survey questions.
 - Terms like “project” were not understood by some of those involved in pretesting, so we revised these terms with more understandable terms like “evaluation.”

The five individuals who participated in the pre-testing noted that the average time to complete the distributor survey was 15 minutes.

The data collection period at each site is estimated to last 12 months. Exhibit A (below) estimates the annual collection burden on participants in this effort.

Exhibit A: Estimates of Annual Collection Burden

Form Name	Number of Respondents	Responses per Respondent	Total Responses	Hours per Response	Total Burden Hours	Hourly Wage Rate	Total Cost
Survey of Consumers	563	1	563	0.25	140.75	\$5.15	\$724.86
Surveys of the Distributors of the Consumer Guides	40	1	40	0.25	10	\$59.15	\$591.50
Consumer Focus Groups	4 sites x 16 focus group participants per site = 64	1	64	1.5	96	\$5.15	\$494.40
Total	667	3	667	2.00	246.75		\$1810.76

13. Estimates of Annualized Cost Burden to Respondents

This data collection activity will not result in any additional capital, start-up, maintenance or purchase costs to respondents or record keepers.

14. Estimates of Annualized Cost to the Government

HRSA administered an open competition to select a contractor to conduct the evaluation of the BFWHW Emotional Wellness Guides. The Lewin Group was awarded a 3-year Time and Materials contract totaling \$298,483 (base year plus 2 option years) as specified under Contract Number GS23F984OH, Task Order Number HSH240H7808. The base year funding totaled \$73,048, option year 1 equals \$129,174 and option year 2 equals \$96,261. Therefore, the total annualized cost to the government is \$99,494.33.

15. Changes in Burden

This is a new information collection request.

16. Time Schedule, Publication and Analysis Plan

Time Schedule

Data collection will begin after OMB approval is obtained. Submission of a final report to HRSA OWH is scheduled for the fall of 2011. The evaluation timetable is outlined in Exhibit B below.

Exhibit B: Projected Evaluation Timeline

Task	Estimated Time Frame
Submit OMB Package	May/June 2009
Conduct on-site focus groups with young and adult women	2-4 months after OMB approval
Administer survey to young women, adult women, and distributors	2-10 months following OMB approval
Data Input and Analysis	8-18 months post-OMB approval
Submit Draft Report to OWH	22 months post-OMB approval
Submit Final Report to OWH	23 months post-OMB approval

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 peer-reviewed journal will be written. This manuscript will include a basic summary of the evaluation methodology, discussion of the key findings from the surveys, focus groups, and key information interviews from the four evaluation sites, and recommendations for further planning and evaluation of emotional wellness initiatives in support of healthy lifestyles. This manuscript will also discuss the level of acceptability and perceived usefulness of the BFWHW Emotional Wellness Guides in the participating evaluation sites. This manuscript will be practice-oriented and will be targeted at persons in organizations interested in providing preventive health services.

Analysis Plan

Information derived from the data collection efforts of this evaluation are qualitative and descriptive data that will be coded and entered in one of the following databases: Excel, Access or SAS (a statistical computing software program) using fields that correspond to the survey format. Data will be tabulated and then an analysis of the data will be conducted in Excel, Access or SAS. When appropriate, data will be aggregated across the sites.

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 evaluation questions using the data from the surveys. Specifically, the report will contain findings that highlight:

- Characteristics of respondents at each of evaluation sites;
- Utilization of the BFWHW Emotional Wellness Guides in the interaction between the women and their service providers;

- Readability, usefulness, relevance, and cultural appropriateness of the BFWHW Emotional Wellness Guides from the provider and consumer perspectives;
- Acceptance of the BFWHW Emotional Wellness Guides by providers (and distributing organization) and the effect of the guides on the providers' practice;
- Effectiveness of guides at improving providers' and women's comfort level in talking about emotional issues; and
- Major factors, barriers, and facilitators that impact the distribution of these guides to young women and adult women.

Descriptive analyses will be conducted. The goal of the descriptive analyses will be to present self-reported information from respondents. Differences among the sites and among subgroups will be explored. Descriptive analyses that control for demographic and site differences will be used to explore (1) how the BFWHW Emotional Wellness Guides were used and distributed; and (2) the level of comfort women had to discuss emotional health with their providers. Data collected from service providers will be used descriptively to discuss acceptability of the emotional wellness guides in a different social service and health care environments.

17. Exemption for Display of Expiration Date

We do not seek approval to eliminate the expiration date from this form, so the expiration date will be displayed.

18. Exceptions to Certifications for PRA Submissions

There are no exceptions to the certification statement.