

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Health Resources and Services Administration

Maternal and Child Health Bureau
Division of Healthy Start and Perinatal Services

Guidelines for Women's Preventive Services

Announcement Type: New
Funding Opportunity Number: HRSA-16-057

Catalog of Federal Domestic Assistance (CFDA) No. 93.110

FUNDING OPPORTUNITY ANNOUNCEMENT

Fiscal Year 2016

Letter of Intent Due Date: November 30, 2015

Application Due Date: January 4, 2016

***MODIFIED on November 10, 2015: Due Dates for the
Application (IV-4) and the Letter of Intent (IV.7) Corrected to
Coincide with Cover Page***

*Ensure SAM.gov and Grants.gov registrations and passwords are current immediately!
Deadline extensions are not granted for lack of registration.
Registration in all systems, including SAM.gov and Grants.gov,
may take up to one month to complete.*

Release Date: November 3, 2015
Issuance Date: November 3, 2015

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Authority: Title V, § 501(a)(2) of Social Security Act (42 U.S.C. 701(a)(2)), as amended.

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB) is accepting applications for fiscal year (FY) 2016 Guidelines for Women's Preventive Services. The purpose of this project is to improve adult women's health across the lifespan by engaging a coalition of health professional organizations to recommend updates to the HRSA-supported Women's Preventive Services Guidelines. HRSA would then decide whether or not to support, in whole or in part, the recommended updates to the guidelines.

Under Section 2713 of the Public Health Service Act, as added by the Patient Protection and Affordable Care Act,¹ P.L. 111-148 (42 U.S.C. 300gg-13), non-grandfathered group health plans and non-grandfathered group and individual health insurance coverage must include coverage, without cost sharing, for the preventive services identified in that section, including those provided for in the HRSA-supported Women's Preventive Services Guidelines.²

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|---|---|
| Funding Opportunity Title: | Guidelines for Women's Preventive Services |
| Funding Opportunity Number: | HRSA-16-057 |
| Due Date for Applications: | January 4, 2016 |
| Anticipated Total Annual Available Funding: | Up to \$950,000 |
| Estimated Number and Type of Award(s): | One (1) cooperative agreement |
| Estimated Award Amount: | Up to \$950,000 per year |
| Cost Sharing/Match Required: | No |
| Project Period: | March 1, 2016 through February 28, 2021 (five years) |
| Eligible Applicants: | <p>Any public or private entity, including an Indian tribe or tribal organization (as defined at 25 U.S.C. 450b) is eligible to apply for Federal funding. Faith-based and community-based organizations are also eligible to apply for these awards.</p> <p>[See Section III-1 of this funding opportunity announcement (FOA) for complete eligibility information.]</p> |

Application Guide

All applicants are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide*, available online at <http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf>, except where instructed in this FOA to do otherwise. A short video for applicants explaining the *Application Guide* is available at <http://www.hrsa.gov/grants/apply/applicationguide/>.

¹ See <http://www.hrsa.gov/womensguidelines/>

² See <http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/html/PLAW-111publ148.htm>

Technical Assistance

MCHB will host a technical assistance webcast on **Friday, November 20, 2015, from 10:00am – 12:00 pm EST** to review the FOA and answers applicants' questions. Applicants can access the webcast at: **<https://hrsa.connectsolutions.com/hrsa16-057/>**. Click "Enter as a Guest" and type in name. The conference line is 1-866-714-2132, and participant passcode is 1427617#. If an applicant is unable to attend the live webcast, a recording of the webcast will be available on <http://www.hrsa.gov/womensguidelines/index.html> after November 23, 2015.

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I. Program Funding Opportunity Description

1. Purpose

This announcement solicits applications for *Guidelines for Women's Preventive Services*. The purpose of this project is to improve adult women's health across the lifespan by engaging a coalition of health professional organizations to recommend updates to the HRSA-supported Women's Preventive Services Guidelines. Under Section 2713 of the Public Health Service Act, as added by the Patient Protection and Affordable Care Act,³ P.L. 111-148 (42 U.S.C. 300gg-13)⁴, non-grandfathered group health plans and non-grandfathered group and individual health insurance coverage must include coverage, without cost sharing, for the preventive services identified in that section, including those provided for in the HRSA-supported Women's Preventive Services Guidelines.

The specific aims of the project are to:

- 1) Establish a process for developing and regularly recommending updates to the guidelines for women's preventive services;
- 2) Obtain participation by health professional organizations on developing recommended guidelines for women's preventive services;
- 3) Review and synthesize existing guidelines and new scientific evidence for women's preventive services;
- 4) Develop recommended guidelines for women's preventive services;
- 5) Disseminate HRSA-supported comprehensive guidelines for use in clinical practice.

Support of HRSA Strategic Goals

The following HRSA Strategic Goals are supported by the *Guidelines for Women's Preventive Health Services*⁵:

Goal I: Improve Access to Quality Care and Services

- Strengthen health systems to support the delivery of quality health services.
- Promote innovative and cost efficient approaches to improve health.

Goal II: Strengthen the Health Workforce

- Ensure the health workforce is trained to provide high quality care that is culturally and linguistically appropriate.

Goal III: Build Healthy Communities

³ See <http://www.hrsa.gov/womensguidelines/>.

⁴ See <http://www.gpo.gov/fdsys/pkg/PLAW-111publ148/html/PLAW-111publ148.htm>.

⁵ See <http://www.hrsa.gov/about/strategicplan.html>.

- Lead and collaborate with others to help communities strengthen resources that improve health for the population.
- Strengthen the focus on illness prevention and health promotion across populations and communities.

Goal IV: Improve Health Equity

- Reduce disparities in quality of care across populations and communities.
- Monitor, identify and advance evidence-based and promising practices to achieve health equity.

2. Background

This program is authorized by Title V, § 501(a) (2) of Social Security Act (42 U.S.C. 701(a) (2)), as amended. In 2010, the Department commissioned a study by the Institute of Medicine (IOM), an independent non-profit organization, to review the evidence related to preventive services specifically related to women's health and well-being and to make recommendations for services to be included in a clinical preventive services benefit for women.⁶ IOM conducted a scientific review and provided recommendations on specific health services that meet the unique health needs of women. In July 2011, HRSA adopted the IOM's recommendations on women's preventive services, filling gaps in existing guidelines.

The current HRSA supported Guidelines for Women's Preventive Services consists of eight preventive health services:

- Well-Woman Visits
- Gestational Diabetes Screening
- Human Papillomavirus (HPV) DNA Testing
- Sexually Transmitted Infection (STI) Counseling
- Human Immunodeficiency Virus (HIV) Screening and Counseling
- Contraception and Contraceptive Counseling
- Breastfeeding Support, Supplies, and Counseling
- Interpersonal and Domestic Violence Screening and Counseling

HRSA has titled this package of services "Guidelines for Women's Preventive Services."

The IOM, as part of its report, recommended that HHS periodically update the review of women's preventive services through the establishment of an independent commission. The report further states: *"Five years is a common benchmark for reevaluation of guidelines and is the benchmark used by the National Guidelines Clearinghouse, but the committee notes that the process of scanning for new developments often uncovers issues that may require updates at*

⁶ Institute of Medicine. *Report at a Glance: Recommendations for Preventive Services for Women that should be considered by HHS.*

other times” (page 159). To date, no changes or updates have been made to the Women’s Preventive Services Guidelines. Given that the IOM report was published in 2011, the end of 2016 would meet the recommended five-year benchmark.

The Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA), Maternal and Child Health Bureau (MCHB), aims to improve adult women’s health through *Guidelines for Women’s Preventive Services* using an approach similar to that of *Bright Futures Guidelines for Health Supervision of Infants, Children, and Adolescents*.

II. Award Information

1. Type of Application and Award

Type of applications sought: New

Funding will be provided in the form of a cooperative agreement. A cooperative agreement is an award instrument of financial assistance where substantial involvement is anticipated between HRSA and the recipient during performance of the project.

The awardee must have and exercise both direct fiduciary and administrative responsibility over the project.

Under this cooperative agreement, HRSA Program involvement will include:

- Consultation on maintaining and updating of *Guidelines for Women’s Preventive Services*, including compliance with all applicable federal requirements.
- Participation, as appropriate, in meetings conducted during the period of the cooperative agreement;
- On-going review and final recommendation on all activities and procedures to be established and implemented for accomplishing the scope of work;
- Participation in the development of the initiative’s evaluation and dissemination plan.
- Participation in the development and implementation of the initiative’s plan for obtaining expert participation and public comment under this cooperative agreement.

The cooperative agreement recipient’s responsibilities include, but are not limited to:

- Adhere to HRSA requirements pertaining to acknowledgement and disclaimer on all products produced by HRSA award funds.
- Participate in meetings and conference calls with HRSA/MCHB conducted during the period of grant.

- Collaborate, communicate, and coordinate with HRSA/MCHB and other health professional organizations with expertise in women's health on the development and dissemination of the recommended guidelines.
- Participate in disseminating information on project activities.
- Ensure timely completion of activities approved by HRSA/MCHB that are proposed in response to the application review criteria listed in this FOA.
- Evaluate the impact of the completed activities of the project.

In addition, the cooperative agreement recipient's responsibilities under each specific aim listed below include, but are not limited to:

Aim #1: Establish a process for developing and regularly recommending updates to the guidelines for women's preventive services

- Build upon existing HRSA-sponsored guidelines that were proposed by an IOM committee and adopted by establishing, documenting, and implementing a process for developing and regularly recommending updates to guidelines for women's preventive services; the process should adhere to the standards for developing trustworthy guidelines established by the Institute of Medicine (<http://iom.nationalacademies.org/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx>).
- Define the process by which public input will be sought for: 1) identifying categories of screenings and services to be considered; 2) identifying sources of evidence and conclusions; and 3) recommending guideline development and for HRSA-adopted guidelines dissemination.

Aim #2: Obtain participation from health professional organizations on developing recommended guidelines for women's preventive services

- Convene and coordinate a multidisciplinary Steering Committee to guide the coordination, review, and recommending of updates to the women's preventive services guidelines that is comprised of health professional organizations with expertise in adult women's health across the lifespan (including, but not limited to, national organizations representing family physicians, internal medicine, obstetricians and gynecologists, nurse practitioners, nurse-midwives, and other nurses, as well as researchers from organizations such as women's academic centers). Participation of professional organizations on the Steering Committee should include, at a minimum, those representing primary care, chronic disease management, obstetrics and gynecology, behavioral health, oral health, and gerontology professionals, public health professionals, and patient and consumer organization representatives.

Aim #3: Review and synthesize existing guidelines and new scientific evidence for women's preventive services

- Convene and coordinate review workgroups, as necessary, consisting of a broad range of content experts in adult women's preventive health care across the lifespan. Review workgroup members should represent content and methodological experts and researchers.
- Review and synthesize existing guidelines for women's clinical preventive services, including but not limited to USPSTF recommendations, Bright Futures for adolescents, HHS Women's Preventive Services Guidelines, and practice guidelines recommended by professional organizations that represent providers of adult women's preventive services across the lifespan.
- Review and synthesize new scientific evidence for women's preventive services not addressed in previous guidelines. Whenever possible, the reviewers should use standards for systematic review used by USPSTF.
(<http://www.uspreventiveservicestaskforce.org/Page/Name/procedure-manual>) The reviewers should provide a summary of relevant available evidence (and evidentiary gaps), including a description of the quality, quantity, and consistency of aggregate available evidence.

Aim #4: Develop recommended guidelines for women's preventive services

- Establish a process for developing consensus among partner organizations.
- Develop recommended comprehensive guidelines for women's preventive services based on review and synthesis of existing clinical guidelines and new scientific evidence. The IOM standards for establishing foundations for, and rating strengths of, recommendations, articulation of recommendations, as well as external reviews should be met in developing these guidelines. Additionally, processes should be incorporated to assure public input and transparency, as well as participation by patient and consumer representatives, in the development of these guidelines. The first set of recommended guidelines for women's preventive services are due to HRSA/MCHB no later than December 1, 2016.
- Assure that the recommended guidelines are comprehensive resources for the purpose of dissemination throughout the health care community, including insurers, through multiple channels.
- Provide HRSA/MCHB with a complete copy of the recommended comprehensive guidelines in an electronic zip file by the end of the project period.
- Maintain and, as needed, update the *Guidelines for Women's Preventive Services* and related materials and tools, in response to changing standards and new scientific knowledge; and ensure wide dissemination of those guidelines and materials to health care and public health professionals, families, health professions educators, payers and others.
- Collaborate with HRSA/MCHB in the ongoing review of activities, evaluation design, budget items, and information/publication prior to dissemination.

Aim #5: Disseminate HRSA-supported comprehensive guidelines for use in clinical practice.

- Disseminate the resource to providers and consumers at national meetings, medical and nursing schools, and online via a publicly available website.
- Assist professional organizations and other affected groups in disseminating the resource to their membership.

2. Summary of Funding

This program will provide funding during Federal fiscal years 2016 – 2021. Approximately \$950,000 is expected to be available annually to fund one (1) recipient. Applicants may apply for a ceiling amount of up to \$950,000 per year. The actual amount available will not be determined until enactment of the final FY 2016 Federal budget. This program announcement is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, applications can be processed, and funds can be awarded in a timely manner. The project period is five (5) years. Funding beyond the first year is dependent on the availability of appropriated funds in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

Effective December 26, 2014, all administrative and audit requirements and the cost principles that govern Federal monies associated with this award are subject to the Uniform Guidance [2 CFR 200](#) as codified by HHS at [45 CFR Part 75](#), which supersede the previous administrative and audit requirements and cost principles that govern Federal monies.

III. Eligibility Information

1. Eligible Applicants

As cited in 42 CFR 51a.3 (a), any public or private entity, including an Indian tribe or tribal organization (as defined at 25 U.S.C. 450b) is eligible to apply for Federal funding under this Part. Faith-based and community-based organizations are also eligible to apply for these grants.

2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

3. Other

Applications that exceed the ceiling amount will be considered non-responsive and will not be considered for funding under this announcement.

Any application that fails to satisfy the deadline requirements referenced in *Section IV.3* will be considered non-responsive and will not be considered for funding under this announcement.

NOTE: Multiple applications from an organization are not allowable.

If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates), an application is submitted more than once prior to the application due

date, HRSA will only accept the applicant's **last** validated electronic submission, under the correct funding opportunity number, prior to the Grants.gov application due date as the final and only acceptable application.

IV. Application and Submission Information

1. Address to Request Application Package

HRSA *requires* applicants for this FOA to apply electronically through Grants.gov. Applicants must download the SF-424 application package associated with this FOA following the directions provided at [Grants.gov](https://www.grants.gov).

2. Content and Form of Application Submission

Section 4 of HRSA's [SF-424 Application Guide](#) provides instructions for the budget, budget justification, staffing plan and personnel requirements, assurances, certifications, and abstract. You must submit the information outlined in the Application Guide in addition to the program-specific information below. All applicants are responsible for reading and complying with the instructions included in HRSA's [SF-424 Application Guide](#) except where instructed in the FOA to do otherwise.

See Section 8.5 of the *Application Guide* for the Application Completeness Checklist.

Application Page Limit

The total size of all uploaded files may not exceed the equivalent of **80 pages** when printed by HRSA. The page limit includes the abstract, project and budget narratives, attachments, and letters of commitment and support required in the *Application Guide* and this FOA. Standard OMB-approved forms that are included in the application package are NOT included in the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) will not be counted in the page limit. **We strongly urge applicants to take appropriate measures to ensure the application does not exceed the specified page limit.**

Applications must be complete, within the specified page limit, and validated by Grants.gov under the correct funding opportunity number prior to the deadline to be considered under the announcement.

Program-Specific Instructions

In addition to application requirements and instructions in Section 4 of HRSA's [SF-424 Application Guide](#) (including the budget, budget justification, staffing plan and personnel requirements, assurances, certifications, and abstract), please include the following:

i. Project Abstract

See Section 4.1.ix of HRSA's [SF-424 Application Guide](#).

ii. Project Narrative

This section provides a comprehensive framework and description of all aspects of the proposed project. It should be succinct, self-explanatory and well organized so that reviewers can understand the proposed project.

Use the following section headers for the Narrative:

- **INTRODUCTION** -- *Corresponds to Section V's Review Criterion 1*

This section must briefly describe the purpose of the proposed project. The applicant must demonstrate a clear understanding of the aims and timeline of the *Guidelines for Women's Preventive Services* project. The applicant must include a discussion that exhibits an expert understanding of women's health issues, the HHS Guidelines for Women's Preventive Services, and issues related to the Affordable Care Act's preventive services provisions, and, in particular, those related to women's health. The applicant must also demonstrate understanding of, and expertise in, the development of recommended clinical guidelines for adult women's preventive services.

- **NEEDS ASSESSMENT** -- *Corresponds to Section V's Review Criterion 1*

This section helps application reviewers understand the need for the guidelines and the needs of the guideline's target population/audience. This section must describe and document the current state of preventive health services for women. The applicant should describe the target population's and/or audience's 1) knowledge of recommended preventive services, and 2) delivery or provision of recommended preventive services for women. The applicant should also describe limitations of the current recommendations/guidelines.

Preventive health needs of women must be described and documented in this section. Disparities based on race, ethnicity, sexual orientation, geography, socioeconomic status, disability status, primary language, health literacy, and other relevant dimensions that improve health equity should be considered. The needs assessment findings must inform the project activities. Therefore, the applicant should describe how the needs assessment findings will be applied in the development, implementation and dissemination of the recommended guidelines for women's preventive services. Data must be used and cited whenever possible to support the information provided. Please discuss any relevant barriers found through the needs assessment that the project hopes to overcome and possible solutions.

- **METHODOLOGY** -- *Corresponds to Section V's Review Criterion 2*

This section helps application reviewers understand how the applicant plans to accomplish the goals/aims and activities of the *Guidelines for Women's Preventive Services* project. This section should include innovative and evidence-based approaches, to the extent possible, towards achieving the goals/aims and activities in this funding opportunity announcement. All applicants are expected to describe proposed methods that will be used to meet the initiative's requirements, project activities and expectations outlined in this FOA.

The following aims and activities **must** be addressed in the methodology:

Aim #1: Establish a process for developing and regularly recommending updates to the guidelines for women's preventive services

- Building upon existing HRSA-sponsored guidelines that were proposed by an IOM committee and adopted by HRSA, describe a process for developing recommended updates to the guidelines for adult women's preventive services, including how the process will adhere to the standards for developing trustworthy guidelines established by the Institute of Medicine (<http://iom.nationalacademies.org/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx>), including its recommendations addressing conflict of interest.
- Describe plans for how the scope of the preventive services topics to be reviewed will be defined, for example across the lifespan.
- Explain the process by which public input will be sought and transparency will be assured when: 1) defining the scope of the recommended guidelines; 2) reviewing evidence; and 3) developing and disseminating the HRSA-recommended guidelines.

Aim #2: Obtain participation from health professional organizations on developing recommended guidelines for women's preventive services

- Describe the process for convening and coordinating a multidisciplinary Steering Committee and describe the composition of the Committee. Explain how you will ensure the composition of the Committee meets the requirements referenced on page five of this FOA.

Aim #3: Review and synthesize existing guidelines and new scientific evidence for women's preventive services

- Describe the process for convening and coordinating the Steering committee and subgroups that consist of a broad range of content and methods experts in adult women's health across the lifespan and describe proposed composition and qualifications of the review workgroups. Explain how you will ensure the composition of the review workgroups meets the requirements referenced on page six of this FOA and a process for handling any conflicts of interest among review workgroup members.
- Describe how the review and synthesis of existing guidelines for women's preventive services, including but not limited to USPSTF recommendations, *Bright Futures Guidelines for Health Supervision of Infants, Children, and Adolescents*, HHS Women's Preventive Services Guidelines, and practice guidelines recommended by professional organizations that represent providers of adult women's preventive services across the lifespan, as well as inclusion of new scientific evidence for women's preventive services, will be conducted. Please include the standards for systematic review that will be used and management of conflict of interest, as a professional organization may appear to have vested interests in recommending certain services.

Aim #4: Develop recommended guidelines for women's preventive services

- Explain how recommended updates to the guidelines for women's preventive services will be developed based on review and synthesis of existing clinical guidelines and new scientific evidence, including how the applicant will prevent duplication or contradiction with USPSTF and Advisory Committee on Immunization Practices (ACIP) recommendations. Include a description of the process for developing consensus among partner organizations.
- Describe how the IOM standards for establishing foundations for and rating strengths of, recommendations, articulation of recommendations, as well as external reviews will be met. Additionally, describe processes that will be in place to assure public input and transparency, as well as participation by patient and consumer representatives in the development of these recommended guidelines.
- Provide a timeline for the completion of the first review and development of a set of recommended updates to the guidelines for women's preventives services by December 1, 2016.
- Describe a plan for developing any HRSA-recommended guidelines into comprehensive resources for the purpose of dissemination, including how gaps in existing training and related products on women's preventive services guidelines will be determined and met.

Aim #5: Disseminate HRSA-supported women's preventive services guidelines for use in clinical practice

- Describe a plan for disseminating the resource to providers and consumers. Describe resources, materials, and tools that will be developed, and the channels that will be used for dissemination.

Applicants must also propose a plan for project sustainability after the period of Federal funding ends for continued dissemination. Recipients are expected to sustain key elements of their cooperative agreement projects (e.g., strategies or services and interventions) which have been effective in improving practices and those that have led to improved outcomes for the target population.

■ *WORK PLAN -- Corresponds to Section V's Review Criteria 2 and 4*

In this section, the applicant should describe the activities or steps that will be used to achieve each of the major activities proposed during the entire project period in the Methodology section. The work plan (Attachment 1) should closely correspond to the needs assessment findings and other activities described in the program narrative, including those under the Methodology section. The action steps are those activities that will be undertaken to implement the proposed project and provide basis for evaluating the project.

Using a five-year project period timeline, the applicant should submit a work plan broken out by year that includes: 1) project goals; 2) SMART (specific, measureable, achievable, realistic, and time measureable) objectives for each major activity from the Methodology section; 3) key action steps; 4) timeframe for completion; 5) responsible staff and 6) method of evaluation. Applicants are asked to include appropriate milestones and any products to be developed. Include information on identified partnerships and resources that will be used to complete activities/tasks/action steps, and identify meaningful support and collaboration with key stakeholders in planning, designing and implementing all activities, including development of the application.

Applicants must submit a logic model (Attachment 1) for designing and managing their projects. A logic model is a one-page diagram that presents the conceptual framework for a proposed project and explains the links among program elements. While there are many versions of logic models, for the purposes of this announcement the logic model should summarize the connections between the:

- Goals of the project (e.g., objectives, reasons for proposing the intervention);
- Assumptions (e.g., beliefs about how the program will work and its supporting resources; assumptions should be based on research, best practices, and experience);
- Inputs (e.g., organizational profile, collaborative partners, key staff, budget, other resources);
- Target population (e.g., the individuals to be served);
- Activities (e.g., approach, listing key intervention);
- Outputs (i.e., the direct products or deliverables of program activities); and
- Outcomes (i.e., the results of a program, typically describing a change in people or systems).

Applicants **must** submit a process flow chart (Attachment 6), which outlines the steps that will be utilized for developing recommended updates to the women's preventive services guidelines. A process flow chart is a picture of the separate steps of a process in sequential order. Elements that may be included are: sequence of actions, inputs and outcomes, decision points, people who become involved, time involved at each step and/or process measurements.

- ***RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion 2***
Discuss challenges that are likely to be encountered in designing and implementing the activities described in the Work Plan, and approaches that will be used to resolve such challenges. Applicants **must** address potential challenges with stakeholders, identified resources, and processes that will be utilized to maintain engagement and discuss ways to resolve such challenges.
- ***EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria 3***

EVALUATION:

This section is for the applicant to describe any measurement and data strategy to collect, analyze and track data to measure process and impact/outcomes. The applicant should explain how the data will be used to inform ongoing project development and implementation.

Applicants must describe the plan for the project performance evaluation that will contribute to continuous quality improvement. The performance evaluation should monitor ongoing processes (e.g., the review committee, recommending updates to the guidelines) and the progress towards the goals and objectives of the project. Discuss plans for monitoring and assessment of performance, including how methods will be employed by staff members to ensure that proposed activities are being successfully documented and completed based on the overall Work Plan. Include descriptions of the inputs (e.g., organizational profile, collaborative partners, key staff, budget, and other resources), key processes, and expected outcomes of the funded activities. The evaluation of the initiative must include an evaluation in two areas: 1) the planning, review process, and development of the recommended updates to the guidelines, and 2) the packaging and dissemination on the appropriate use of the product.

▪ ***ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion 5***

Provide information on the applicant organization's current mission and structure, scope of current activities, an organizational chart (Attachment 5), and describe how these all contribute to the ability of the organization to conduct the project requirements and meet project expectations. Discuss expertise of staff as it relates to the scope of this project. Provide information on the organization's resources and capabilities to support provision of culturally and linguistically competent and health literate services. Describe past performance managing federal awards/cooperative agreements.

The applicant must provide information on their ability, capacity, and past experience to enhance health care professionals' knowledge and practice of appropriate preventive health services. Specifically, the applicant must describe experience with health promotion and preventive health services for adult women across the lifespan, particularly with the development and implementation of clinical guidelines for delivering such services, as well as the ability to access and engage significant numbers of health professional organizations with expertise in women's health care at the national, state and local levels. Describe experience in developing and disseminating clinical guidelines, informational materials/resources and providing training to providers.

The applicant must also provide information on their ability, capacity, and past experience to foster partnerships between various health professional organizations with expertise in women's health (i.e., health care professionals, public health professionals, consumers, and patient groups) to promote women's health. The applicant must discuss collaborative efforts with health care organizations and medical/health care professional organizations with expertise in women's health. The applicant must provide letters of agreement (Attachment 4) from a broad spectrum of health professional organizations with expertise in adult women's health across the lifespan who have committed to participate on the Steering Committee to guide the coordination, review, and recommended updating of women's preventive services guidelines.

Describe how all of these factors contribute to the organization's ability and capacity to conduct the project requirements and meet project expectations. Emphasis should be focused on any experience related to convening stakeholders, preventive services for adult

women across the lifespan, creating and disseminating resources and materials, and training women's health care providers.

Additionally, provide information on the organization's experience with developing and maintaining an Internet-based website. Also, provide confirmation that the organization will maintain and exercise both direct fiduciary and administrative responsibility for the project.

| NARRATIVE GUIDANCE | |
|--|---|
| In order to ensure that the Review Criteria are fully addressed, this table provides a crosswalk between the narrative language and where each section falls within the review criteria. | |
| <u>Narrative Section</u> | <u>Review Criteria</u> |
| Introduction | (1) Need |
| Needs Assessment | (1) Need |
| Methodology | (2) Response |
| Work Plan | (2) Response and (4) Impact |
| Resolution of Challenges | (2) Response |
| Evaluation and Technical Support Capacity | (3) Evaluative Measures and (5) Resources/Capabilities |
| Organizational Information | (5) Resources/Capabilities |
| Budget and Budget Narrative | (6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested. |

iii. Budget

See Section 4.1.iv of HRSA's [SF-424 Application Guide](#). Please note: the directions offered in the SF-424 Application Guide differ from those offered by Grants.gov. Please follow the instructions included the Application Guide and the additional budget instructions provided below.

Reminder: The Total Project or Program Costs are the total allowable costs (inclusive of direct **and** indirect costs) incurred by the recipient to carry out a HRSA-supported project or activity. Total project or program costs include costs charged to the award and costs borne by the recipient to satisfy a matching or cost sharing requirement, as applicable.

The Consolidated and Further Continuing Appropriations Act, 2015, Division G, § 203, (P.L. 113-235) states, “None of the funds appropriated in this title shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level II.” Please see Section 4.1.iv Budget – Salary Limitation of HRSA’s [SF-424 Application Guide](#) for additional information. Note that these or other salary limitations will apply in FY 2016, to the extent required by law.

iv. Budget Justification Narrative

See Section 4.1.v. of HRSA’s [SF-424 Application Guide](#).

v. Program-Specific Forms

1) Performance Standards for Special Projects of Regional or National Significance (SPRANS) and Other MCHB Discretionary Projects

HRSA has modified its reporting requirements for SPRANS projects, Community Integrated Service Systems (CISS) projects, and other grant programs administered by MCHB to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). This Act requires the establishment of measurable goals for Federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act, MCHB’s authorizing legislation. Performance measures for other MCHB-funded grant programs have been approved by the Office of Management and Budget and are primarily based on existing or administrative data that projects should easily be able to access or collect. An electronic system for reporting these data elements has been developed and is now available.

2) Performance Measures for the Guidelines for Women’s Preventive Services project

To inform successful applicants of their reporting requirements, the listing of MCHB administrative forms and performance measures for this program can be found at: https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UH0_1.html

NOTE: The performance measures and data collection information is for your PLANNING USE ONLY. These forms are not to be included as part of this application. However, this information will be due to HRSA within 120 days after the Notice of Award.

vi. Attachments

Please provide the following items in the order specified below to complete the content of the application. **Unless otherwise noted, attachments count toward the application page limit.** Indirect cost rate agreements and proof of non-profit status (if applicable) will not count toward the page limit. **Each attachment must be clearly labeled.**

Attachment 1: Work Plan

Attach the Work Plan for the project that includes all information detailed in Section IV. ii. Project Narrative, including logic model

Attachment 2: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of HRSA's [SF-424 Application Guide](#))

Keep each job description to one page in length as much as possible. Include the role, responsibilities, and qualifications of proposed project staff.

Attachment 3: Biographical Sketches of Key Personnel

Include biographical sketches for persons occupying the key positions described in Attachment 2, not to exceed two pages in length. In the event that a biographical sketch is included for an identified individual who is not yet hired, please include a letter of commitment from that person with the biographical sketch.

Attachment 4: Letters of Agreement and/or Description(s) of Proposed/Existing Contracts (project-specific)

Provide any documents that describe working relationships between the applicant organization and the broad spectrum of health professional organizations with expertise in adult women's health across the lifespan who have committed to participate on the Steering Committee to guide the coordination, review, and recommendations for updating of women's preventive services guidelines. Documents that confirm actual or pending contractual agreements should clearly describe the roles of the contractors and any deliverable. Letters of agreement must be dated.

Attachment 5: Project Organizational Chart

Provide a one-page organizational chart of the project including Steering Committee partners.

Attachment 6: Tables, Charts, etc.

Provide a process flow chart which outlines the steps that will be utilized for developing recommendations for updating the women's preventive services guidelines and regular updating.

Attachment 7: For Multi-Year Budgets--Fifth Year Budget (NOT counted in page limit)

See Section 4.1.iv of HRSA's [SF-424 Application Guide](#).

Attachments 8 – 15: Other Relevant Documents

Include here any other documents that are relevant to the application, including letters of support. Letters of support must be dated and specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.).

3. Dun and Bradstreet Universal Numbering System Number and System for Award Management

Applicant organizations must obtain a valid DUNS number and provide that number in their application. Each applicant must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by an agency (unless the applicant is an individual or Federal agency that is exempted from those requirements under 2 CFR 25.110(b) or (c), or has an exception approved by the agency under 2 CFR 25.110(d)).

HRSA may not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time HRSA is ready to make an award, HRSA may determine that the applicant is not qualified to receive an award and use that determination as the basis for making an award to another applicant.

If an applicant/recipient organization has already completed Grants.gov registration for HRSA or another Federal agency, confirm that the registration is still active and that the Authorized Organization Representative (AOR) has been approved.

The Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (<http://fedgov.dnb.com/webform/pages/CCRSearch.jsp>)
- System for Award Management (SAM) (<https://www.sam.gov>)
- Grants.gov (<http://www.grants.gov/>)

For further details, see Section 3.1 of HRSA's [SF-424 Application Guide](#).

Applicants that fail to allow ample time to complete registration with SAM or Grants.gov will not be eligible for a deadline extension or waiver of the electronic submission requirement.

4. Submission Dates and Times

Application Due Date

The due date for applications under this FOA is *January 4, 2016 at 11:59 P.M. Eastern Time*.

See Section 8.2.5 – Summary of e-mails from Grants.gov of HRSA's [SF-424 Application Guide](#) for additional information.

5. Intergovernmental Review

The *Guidelines for Women's Preventive Services* program is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR 100.

See Section 4.1 ii of HRSA's [SF-424 Application Guide](#) for additional information.

6. Funding Restrictions

Applicants responding to this announcement may request funding for a project period of up to five (5) years, at no more than \$950,000 per year. Awards to support projects beyond the first budget year will be contingent upon Congressional appropriation, satisfactory progress in meeting the project's objectives, and a determination that continued funding would be in the best interest of the Federal Government.

The General Provisions in Division G of the Consolidated and Further Continuing Appropriations Act, 2015 (P.L. 113-235) apply to this program. Please see Section 4.1 of

HRSA's [SF-424 Application Guide](#) for additional information. Note that these or other restrictions will apply in FY 2016, as required by law.

All program income generated as a result of awarded funds must be used for approved project-related activities.

7. Other Submission Requirements

Notification of Intent to Apply

An applicant is eligible to apply even if no letter of intent is submitted. The letter should identify the applicant organization and its intent to apply, and briefly describe the proposal to be submitted. Receipt of Letters of Intent will ***not*** be acknowledged.

This letter should be sent via e-mail by November 30, 2015, to:

Director, Division of Independent Review
HRSA Digital Services Operation (DSO)
Please use HRSA opportunity number as e-mail subject (HRSA-16-057)
HRSADSO@hrsa.gov

V. Application Review Information

1. Review Criteria

Procedures for assessing the technical merit of applications have been instituted to provide for an objective review of applications and to assist the applicant in understanding the standards against which each application will be judged. Critical indicators have been developed for each review criterion to assist the applicant in presenting pertinent information related to that criterion and to provide the reviewer with a clinical for evaluation. Review criteria are outlined below with specific detail and scoring points.

These criteria are the basis upon which the reviewers will evaluate the application. The entire proposal will be considered during objective review.

Review Criteria are used to review and rank applications. The *Guidelines for Women's Preventive Services* has six (6) review criteria:

Criterion 1: NEED (5 points) – Corresponds to Section IV's Introduction and Needs Assessment the extent to which the application demonstrates the problem and associated contributing factors to the problem.

- 1) The extent to which the applicant demonstrates a clear understanding of the project goals and timeline, and demonstrates an expert understanding of women's preventive health issues, the HHS Guidelines for Women's Preventive Services, and issues related to the Affordable Care Act's preventive services provisions related to women's health.
- 2) The extent to which the applicant demonstrates expertise in the development of recommendations for updating and disseminating preventive services guidelines for adult women across the lifespan.
- 3) The extent to which the applicant documents the current state of preventive health services to women.
- 4) The extent to which the applicant documents limitations of the current recommendations/guidelines and how this project will address those limitations.
- 5) The extent to which the applicant discusses any relevant barriers found and possible solutions.

Criterion 2: RESPONSE (35 points) – Corresponds to Section IV's Methodology, Work Plan, and Resolution of Challenges

The extent to which the proposed project responds to the "Purpose" included in the program description and the specific aim's addressed in the methodology sections. The strength of the proposed goals and objectives, and their relationship to the identified project. The extent to which the activities (scientific or other) described in the application are capable of addressing the problem and attaining the project objectives.

- 1) The extent to which the applicant describes how the IOM's Standards for Developing Trustworthy Guidelines will be utilized.
- 2) The extent to which the applicant outlines plans for identifying Steering Committee members, including selection criteria, required competencies, and conflicts of interest.
- 3) The extent to which the applicant describes how it will convene and coordinate a multidisciplinary Steering Committee comprised of health professional organizations with expertise in adult women's preventive health services across the lifespan, methodological experts and public health professionals, and patient and consumer organization representatives.
- 4) The extent to which the applicant clearly defines the scope of the initiative.
- 5) The extent to which the applicant assures public input and transparency in the process.
- 6) The extent to which the applicant describes the process for convening and coordinating review work groups with broad range of content and methods experts in adult women's health across the lifespan, including selection criteria, required competencies, and conflicts of interest.
- 7) The extent to which the applicant details how the review and synthesis of existing guidelines and new scientific evidence will be conducted, including standards for systematic review.
- 8) The extent to which the applicant outlines the process for developing consensus when creating the recommended updates to the guidelines for women's preventive services based on the review and synthesis of existing guidelines and scientific research.
- 9) The extent to which the applicant describes how the HRSA-supported guidelines will be packaged into a resource and then disseminated to a broad range of women's health care providers.
- 10) The extent to which the applicant describes the activities that will be used to achieve each of the major aims proposed during the project period.

- 11) The extent to which the applicant presents a five-year work plan that includes project goals, SMART objectives, key action steps, timeframe for completion, responsible staff, and the method of evaluation.
- 12) The extent to which the process flow chart outlines the proposed steps to be utilized in guideline development and updating.
- 13) The extent to which the applicant discusses any challenges that are likely to be encountered in designing and implementing the activities outlined in the Work Plan, outlines how the applicant will address challenges with stakeholders, and discusses the approaches that will be used to resolve each challenge.

Criterion 3: EVALUATIVE MEASURES (5 points) – Corresponds to Section IV’s Evaluation and Technical Support Capacity

The strength and effectiveness of the method proposed to monitor and evaluate the project results. Evidence that the evaluative measures will be able to assess: 1) to what extent the program objectives have been met, and 2) to what extent these can be attributed to the project.

Criterion 4: IMPACT (10 points) – Corresponds to Section IV’s Methodology

The feasibility and effectiveness of plans for dissemination of project results

- 1) The extent to which project results may be national in scope.
- 2) The extent to which the applicant provides a project timeline for the completion of the first review and development of recommended updates to the guidelines for women’s preventive services by December 1, 2016.
- 3) The degree to which the project activities are replicable and the sustainability of the project beyond the period of federal funding.

Criterion 5: RESOURCES/CAPABILITIES (30 points) – Corresponds to Section IV’s Organizational Information

The extent to which project personnel are qualified by training and/or experience to implement and carry out the project. The capabilities of the applicant organization and the quality and availability of facilities and personnel to fulfill the needs and requirements of the proposed project

- 1) The extent to which the applicant provides information on the organization’s current mission, structure, scope of current activities, an organizational chart, and describes how these factors contribute to the organization’s ability to conduct the project activities.
- 2) The extent to which the applicant demonstrates partnership and collaboration with professional organizations that represent health professionals with expertise in adult women’s health across the lifespan, public health professionals, and patient and consumer groups at the national, state, and local levels;
- 3) The extent to which the applicant demonstrates significant experience and expertise in developing and disseminating clinical guidelines, informational materials, and training to health care providers.
- 4) The extent to which the applicant discusses staff expertise as it relates to the scope of the project.
- 5) The extent to which the applicant provides letters of agreement from a broad spectrum of national health professionals organizations with expertise in women’s health to

participate in the Steering Committee to guide the coordination, review and updating of the women's preventive services guidelines.

Criterion 6: SUPPORT REQUESTED (15 points) – Corresponds to Section IV's Budget and Budget Narrative

The reasonableness of the proposed budget for each year of the project period in relation to the objectives, the complexity of the project activities, and the anticipated results.

- 1) The extent to which costs, as outlined in the budget and required resources sections, are reasonable given the scope of work.
- 2) The extent to which key personnel have adequate time devoted to the project to achieve project objectives.

2. Review and Selection Process

Please see Section 5.3 of HRSA's [*SF-424 Application Guide*](#).

This program does not have any funding priorities, preferences or special considerations.

Please Note: The Health Resources and Services Administration may elect not to fund applicants with management or financial instability that directly relates to the organization's ability to implement statutory, regulatory or other requirements ([45 CFR § 75.205](#)). The decision not to make an award or to make an award at a particular funding level, is discretionary and is not subject to appeal to any OPDIV or HHS official or board.

3. Anticipated Announcement and Award Dates

It is anticipated that awards will be announced prior to the start date of March 1, 2016.

VI. Award Administration Information

1. Award Notices

The Notice of Award will be sent prior to the start date of March 1, 2016. See Section 5.4 of HRSA's [*SF-424 Application Guide*](#) for additional information.

2. Administrative and National Policy Requirements

See Section 2 of HRSA's [*SF-424 Application Guide*](#).

3. Reporting

The successful applicant under this FOA must comply with Section 6 of HRSA's [*SF-424 Application Guide*](#) and the following reporting and review activities:

- 1) **Progress Report(s).** The recipient must submit a progress report to HRSA on an **annual** basis. Further information will be provided in the award notice.

2) Performance Reports. HRSA has modified its reporting requirements for SPRANS projects, CISS projects, and other awards administered by MCHB to include national performance measures that were developed in accordance with the requirements of the Government Performance and Results Act (GPRA) of 1993 (Public Law 103-62). This Act requires the establishment of measurable goals for Federal programs that can be reported as part of the budgetary process, thus linking funding decisions with performance. Performance measures for states have also been established under the Block Grant provisions of Title V of the Social Security Act, MCHB's authorizing legislation. Performance measures for other MCHB-funded awards have been approved by the Office of Management and Budget and are primarily based on existing or administrative data that projects should easily be able to access or collect.

a) Performance Measures and Program Data

To prepare successful applicants for their reporting requirements, the listing of MCHB administrative forms and performance measures for this program can be found at: https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UH0_1.html.

b) Performance Reporting

Successful applicants receiving HRSA funds will be required, within 120 days of the Notice of Award (NoA), to register in HRSA's Electronic Handbooks (EHBs) and electronically complete the program-specific data forms that appear for this program at: https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UH0_1.html. This requirement entails the provision of budget breakdowns in the financial forms based on the award amount, the project abstract and other award/cooperative agreement summary data as well as providing objectives for the performance measures.

Performance reporting is conducted for each year of the project period. Recipients will be required, within 120 days of the NoA, to enter HRSA's EHBs and complete the program-specific forms. This requirement includes providing expenditure data, finalizing the abstract and grant/cooperative agreement summary data as well as finalizing indicators/scores for the performance measures.

c) Project Period End Performance Reporting

Successful applicants receiving HRSA funding will be required, within 90 days from the end of the project period, to electronically complete the program-specific data forms that appear for this program at: https://perf-data.hrsa.gov/mchb/DgisApp/FormAssignmentList/UH0_1.html. The requirement includes providing expenditure data for the final year of the project period, the project abstract and grant/cooperative agreement summary data as well as final indicators/scores for the performance measures.

VII. Agency Contacts

Applicants may obtain additional information regarding business, administrative, or fiscal issues related to this FOA by contacting:

Hazel N. Booker
Grants Management Specialist, Maternal Child and Health Systems Branch
HRSA Division of Grants Management Operations, OFAM
Parklawn Building, Room 10W57D
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-4236
Fax: (301) 443-6686
E-mail: nbooker@hrsa.gov

Additional information related to the overall program issues and/or technical assistance regarding this funding announcement may be obtained by contacting:

Kimberly C. Sherman, MPH, MPP
Public Health Analyst, Division of Healthy Start and Perinatal Services
Attn: *Guidelines for Women's Preventive Services*
Maternal and Child Health Bureau, HRSA
Parklawn Building, Room 13-71
5600 Fishers Lane
Rockville, MD 20857
Telephone: (301) 443-8283
Fax: (301) 594-0186
E-mail: wellwomancare@hrsa.gov

Applicants may need assistance when working online to submit their application forms electronically. Applicants should always obtain a case number when calling for support. For assistance with submitting the application in Grants.gov, contact Grants.gov 24 hours a day, seven days a week, excluding Federal holidays at:

Grants.gov Contact Center
Telephone: 1-800-518-4726 (International Callers, please dial 606-545-5035)
E-mail: support@grants.gov
iPortal: <https://grants-portal.psc.gov/Welcome.aspx?pt=Grants>

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's Electronic Handbooks (EHBs). For assistance with submitting information in HRSA's EHBs, contact the HRSA Contact Center, Monday-Friday, 8:00 a.m. to 8:00 p.m. ET:

HRSA Contact Center
Telephone: (877) 464-4772
TTY: (877) 897-9910
Web: <http://www.hrsa.gov/about/contact/ehbhelp.aspx>

VIII. Other Information

Technical Assistance:

MCHB will host a technical assistance webcast on **Friday, November 20, 2015, from 10:00am – 12:00 pm EST** to review the FOA and answers applicants' questions. Applicants can access the webcast at: <https://hrsa.connectsolutions.com/hrsa16-057/>. Click "Enter as a Guest" and type in name. The conference line is 1-866-714-2132, and participant passcode is 1427617#. If an applicant is unable to attend the live webcast, a recording of the webcast will be available on <http://www.hrsa.gov/womensguidelines/index.html> after November 23, 2015.

Resource List

Clinical Preventive Services for Women: Closing the Gaps

<http://iom.nationalacademies.org/Reports/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps.aspx>

HHS Women's Preventive Services Guidelines

<http://www.hrsa.gov/womensguidelines/>

Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents

<https://brightfutures.aap.org/materials-and-tools/guidelines-and-pocket-guide/Pages/default.aspx>

Institute of Medicine Standards for Guidelines

<http://iom.nationalacademies.org/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx>

Agency for Healthcare Research and Quality

<http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/index.html>

U.S. Preventive Services Task Force (USPSTF)

<http://www.uspreventiveservicestaskforce.org/>

IX. Tips for Writing a Strong Application

See Section 4.7 of HRSA's [SF-424 Application Guide](#).