# **U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**



Health Resources & Services Administration

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

# Women's Preventive Services Initiative

Funding Opportunity Number: HRSA-21-045 Funding Opportunity Type(s): Competing Continuation, New Assistance Listings (CFDA) Number: 93.110

# NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2021

# Application Due Date: October 5, 2020

Ensure your SAM.gov and Grants.gov registrations and passwords are current immediately! HRSA will not approve deadline extensions for lack of registration. Registration in all systems, including SAM.gov and Grants.gov, may take up to 1 month to complete.

# Issuance Date: June 29, 2020

Johannie Escarne Acting Senior Advisor, Division of Healthy Start and Perinatal Services Telephone: (301) 443-0543 Email: <u>wellwomancare@hrsa.gov</u>

Authority: 42 U.S.C. § 701(a)(2)

# **EXECUTIVE SUMMARY**

The Health Resources and Services Administration (HRSA) is accepting applications for fiscal year (FY) 2021 for the Women's Preventive Services Initiative (WPSI). The purpose of this program is to improve women's health across the lifespan by engaging a coalition of provider, academic, and patient-focused health professional organizations to do the following: 1) identify, deliberate, and recommend evidence-based updates to the HRSA-supported Women's Preventive Services Guidelines (Guidelines); 2) increase clinicians' adoption and utilization of the Guidelines; and 3) raise awareness and knowledge of the Guidelines.

Under § 2713 of the Public Health Service Act, as added by the Patient Protection and Affordable Care Act, 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.

The FY 2021 President's Budget does not request funding for this program. This notice is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately. You should note that this program may be cancelled prior to award.

Funding Opportunity Title:	Women's Preventive Services Initiative
Funding Opportunity Number:	HRSA-21-045
Due Date for Applications:	October 5, 2020
Anticipated Total Annual Available FY 2021 Funding:	\$950,000
Estimated Number and Type of Award(s):	Up to one cooperative agreement
Estimated Award Amount:	Up to \$950,000 per year subject to the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	March 1, 2021 through February 28, 2026
	(5 years)
Eligible Applicants:	Any domestic public or private entity, including an Indian tribe or tribal organization (as those terms are defined at 25 U.S.C. § 450b) is eligible to apply. See 42 CFR § 51a.3(a). Domestic faith- based and community-based organizations are also eligible to apply.
	See <u>Section III.1</u> of this notice of funding opportunity (NOFO) for complete eligibility information.

# **Application Guide**

You (the applicant organization/agency) are responsible for reading and complying with the instructions included in HRSA's *SF-424 Application Guide*, available online at <a href="http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf">http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf</a>, except where instructed in this NOFO to do otherwise.

# **Technical Assistance**

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Tuesday, August 18, 2020 Time: 3–4 p.m. ET Call-In Number: 1-877-329-5062 Participant Code: 8138038 Weblink: <u>https://hrsa.connectsolutions.com/rnr95mwhwy77/</u>

HRSA will record the webinar and make it available at: <u>https://mchb.hrsa.gov/fundingopportunities/default.aspx</u>.

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# I. Program Funding Opportunity Description

# 1. Purpose

This notice announces the opportunity to apply for funding under the Women's Preventive Services Initiative (WPSI). WPSI's purpose is to improve women's health across the lifespan by engaging a coalition of provider, academic, and patient-focused health professional organizations to do the following:

- 1) Identify and recommend evidence-based updates to the HRSA-supported Women's Preventive Services Guidelines (Guidelines);
- 2) Raise awareness and knowledge of these Guidelines; and
- 3) Increase clinicians' adoption and utilization of these Guidelines.

Under 42 U.S.C. § 300gg-13(a)(4) and 45 CFR § 147.130(a)(1)(ivi), as further implemented, non-grandfathered group health plans and health insurance issuers offering group and individual health insurance coverage must provide coverage without cost sharing (such as a copayment, coinsurance, or a deductible) for preventive care and screenings as provided for in such HRSA-supported comprehensive preventive services guidelines for women.

As of June 2020, the HRSA-supported Women's Preventive Services Guidelines cover 12 topics: well-woman visits, human immunodeficiency virus infection, cervical cancer, contraception, breast cancer, urinary incontinence, interpersonal and domestic violence, gestational diabetes mellitus, sexually transmitted infections, breastfeeding services and supplies, diabetes mellitus after pregnancy, and screening for anxiety.

### **Program Goal**

The goal of this initiative is to improve awareness and increase utilization of recommended preventive health screenings and services, which may lead to improved health outcomes for women across the lifespan.

### **Program Objectives and Impact Measures**

HRSA expects the successful award recipient to develop a program that achieves the objectives in the following categories: Program Implementation and Recommendation Development, Guideline Awareness, and Guideline Adoption.

### • Program Implementation and Recommendation Development

- Annually, starting on March 1, 2021, the award recipient will engage in a process to consider and review new and existing Guidelines developed by a multidisciplinary group of women's health professional organizations.
- By December 1<sup>st</sup> of each year of the period of performance, beginning in 2021, the award recipient will review, synthesize, update, and/or reaffirm the existing recommendations, based on emerging scientific evidence, for women's preventive services and submit recommended updates (e.g., evidence reports and recommendation statements) to HRSA.
- By February 28, 2022, the recipient will convene an expert panel comprised of a multidisciplinary group of women's health professional

organizations aimed at developing recommended Guidelines for women's preventive services that are culturally- and linguistically-competent.

 By February 28, 2022, the recipient will convene or continue to convene an expert panel comprised of a multidisciplinary group of women's health professional organizations aimed at disseminating Guideline resources and tools to both patients and practitioners.

# • Guideline Awareness

By February 28, 2026, the award recipient will:

- produce and update patient and provider tools and resources (e.g., Well-Woman Chart, Billing & Coding Guides, and Patient Brochures).
- disseminate HRSA-supported comprehensive Guidelines for use in clinical practice and by patient populations.
- o increase provider awareness and knowledge about the Guidelines.
- o increase patient access to and utilization of the Guidelines.

# • Guideline Adoption

By February 28, 2026, the award recipient will:

- increase and/or broaden acceptance and sponsorship of the Guidelines by health professional organizations aimed at improving the health outcomes of women.
- assess utilization of the Guidelines in clinical settings, and share the results of those findings with HRSA.
- facilitate training on the Guidelines into workforce development of health care providers, public health professionals, and medical and nursing students/health professional students.

The award recipient will report on progress towards meeting the above objectives in the annual progress report.

# 2. Background

This program is authorized by 42 U.S.C. § 701(a)(2).

Research has shown that regular and consistent preventive care for women is associated with improvement of women's health across the lifespan, and that individuals with lower socioeconomic status frequently delay or forego preventive services if cost is a factor.<sup>1,2</sup> In 2010, the U.S. Department of Health and Human Services (HHS) commissioned a study by the Institute of Medicine (IOM), now known as the National Academy of Medicine, to review the evidence, provide objective advice on preventive services for women's health and well-being, and make recommendations for what should be included in comprehensive Guidelines for women's preventive services.<sup>3</sup> In July 2011, HRSA adopted the IOM's eight recommendations on women's Preventive services, and titled this package of services, "Guidelines for Women's Preventive

<sup>&</sup>lt;sup>1</sup> Institute of Medicine. Clinical Preventive Services for Women: Closing the Gaps. Washington, DC: National Academies Press; 2013.

<sup>&</sup>lt;sup>2</sup> Maciosek MV. Greater Use of Preventive Services in U.S. Health Care Could Save Lives at Little or No Cost. Health Aff (Millwood) 2010;29(9):1656–60.

<sup>&</sup>lt;sup>3</sup> Institute of Medicine. Report at a Glance: Recommendations for Preventive Services for Women that should be considered by HHS.

Services." The IOM also recommended reviewing and updating these recommendations every 5 years.

HRSA established the WPSI in 2016 to identify gaps, review evidence, and provide recommendations for preventive health screenings and services for women. Since the program's inception, WPSI has reaffirmed the initial eight <u>Women's Preventive Services</u> <u>Guidelines</u>, and added <u>new recommendations</u> to the set of women's preventive services. The Guidelines fill a crucial gap in the literature and collection of clinical recommendations that define and support well-woman care. In addition, HRSA uses the Guidelines as the basis for determining which preventive services are made available to women through insurance coverage without cost sharing, thereby making these services more accessible, particularly to lower-income women. WPSI reviews the recommendations biannually, or upon the availability of new evidence. Topics for future consideration may also be submitted on a rolling basis at the <u>Women's Preventive Services Initiative website</u>.

WPSI is a key component of HRSA's maternal health portfolio. During the current period of performance, Fiscal Years 2016–2021, WPSI has laid the groundwork for this effort by convening a broad-based coalition of experts to consider and develop a comprehensive set of recommendations to improve women's health outcomes. Its purpose has been to improve women's health across the lifespan by engaging a coalition of provider, academic, and patient-focused health professional organizations to do the following: (1) identify and recommend evidence-based updates to the HRSA-supported Guidelines; (2) raise awareness and knowledge of these Guidelines; and (3) increase clinicians' adoption and utilization of the Guidelines. Relying on both expert and public input, WPSI follows a guideline development model similar to that used by the U.S. Preventive Services Task Force<sup>4</sup>, which develops recommendations for the general population, and Bright Futures Guidelines<sup>5</sup>, which focuses on well-child care from birth through age 21. WPSI is unique, being the only federal initiative that focuses on developing preventive services Guidelines for health issues specific to, or uniquely affecting women.

To do this work, WPSI has a program structure composed of three separate bodies that come together, as needed:

- **Advisory Panel**: A small group of experts that provide program oversight, management, and strategic planning.
- Multidisciplinary Steering Committee (MSC)
  - Coalition of national provider organizations, public health professionals, consumer organizations, patients, and other stakeholders
  - Methodologists, content experts, and providers with expertise across a woman's lifespan—adolescent, early, middle, and late adulthood, including reproductive health and pregnancy
- Dissemination and Implementation Steering Committee (DISC)

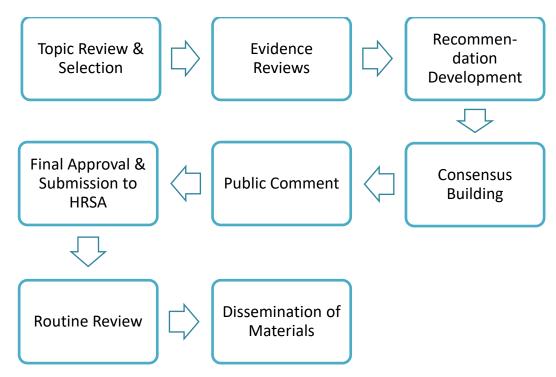
 <sup>&</sup>lt;sup>4</sup> <u>https://www.uspreventiveservicestaskforce.org/Page/Name/specific-populations</u> (accessed on 12/17/2019)
<sup>5</sup> https://brightfutures.aap.org/Pages/default.aspx (accessed on 12/17/2019)

- Develop strategies for the implementation and dissemination of any new or revised WPSI clinical recommendations
- Increase health care provider and consumer knowledge of preventive services through existing, adapted, and new tools and resources

WPSI currently partners with the Pacific Northwest Evidence-Based Practice Center (EPC). EPC has extensive experience in evidence-based analyses on women's health and other topics; including the U.S. Preventive Services Task Force (supported by the Agency for Healthcare Research and Quality), and the Bright Futures project (also supported by HRSA). EPC has been able to use and share its experience, knowledge, and expertise across the projects to assist and advance the development of these frameworks.

The WPSI process for recommendation development and approval involves the following steps:

- 1. Identify Gaps in Prevention
- 2. Literature Search Research librarian conducts reviews of all topics
- 3. The Evidence-based Practice Center (EPC) investigators create evidence maps for each proposed topic
- 4. EPC presents evidence summary to the Multidisciplinary Steering Committee (MSC)
- 5. MSC subcommittee creates draft recommendation
- 6. MSC further discusses recommendation and provides input
- 7. MSC votes on recommendation. A 75 percent agreement is required to adopt the recommendation
- 8. Recommendation is published in Federal Registry Notice for public comment
- 9. HRSA reviews recommendation for approval by the HRSA administrator
- 10. Implementation Steering Committee (ISC) develops plan for dissemination & implementation



For more information about the WPSI methodology to pass recommendations, please click <u>here</u>.

Each recommendation has three components:

- Clinical Recommendation: the component of the recommendation that is reviewed and approved by HRSA for purposes of health insurance coverage without cost-sharing by group health plans and health insurance issuers.
- Implementation Considerations: this section contains information that is not subject to approval by HRSA, nor does it relate to insurance coverage, but provides guidance for clinicians.
- Research Recommendations: this section aims to address gaps in the existing evidence.

The program has also produced patient and provider materials (e.g., Well-Woman Chart, Billing & Coding Guide, Patient Trifold) to support awareness and utilization of the recommendations in standard clinical practice. Finally, the program has fostered collaboration among key stakeholders in the adult women's health, maternal health, and children's health fields through the convening of a multidisciplinary coalition, which meets regularly to conduct scientifically rigorous reviews of the evidence and submit new or updated recommendations to HRSA. Examples of partners who may participate in this project includes the following: Academy of Women's Health, American Academy of Pediatrics, and American Academy of Physician Assistants, National Medical Association, and National Partnership for Women & Families.

For this next WPSI award, HRSA supports continuing many of the existing WPSI processes, while increasing the focus on dissemination and implementation of the new and existing recommendations. Specifically, the new program will enhance awareness and adoption of preventive services and aligned performance measures among providers and patients, increase acceptance of WPSI's Guidelines among health

professional organizations, develop additional recommendations to address other priority gaps in women's care, strengthen collaboration among key stakeholders, develop Preventive Service Test Sites/Well-Woman Care Implementation Pilot Program implementation strategies, and launch provider and student trainings on guideline implementation.

# Support of HRSA Strategic Goals

WPSI supports the following HRSA Strategic Goals.<sup>6</sup>

# **Goal I: Improve Access to Quality Health Services**

- Improve and expand the availability of comprehensive health services.
- Enhance the knowledge and use of evidence-based primary care and preventive services, treatment guidelines, promising practices, and models of care within communities and by health care providers.
- Connect patient populations to primary care and preventive services.

# Goal II: Foster a Health Care Workforce Able to Address Current and Emerging Needs

- Expand the number and types of training and technical assistance opportunities educating students and providers.
- Inform strategic decision-making to educate policy makers, researchers, and the public about health care workforce trends, supply, demand, and policy issues.

# **Goal III: Achieve Health Equity and Enhance Population Health**

- Improve health outcomes by supporting integration and coordination of health services, primary care providers, and the public health sector. Strengthen the focus on illness prevention and health promotion across populations and communities.
- Expand outreach and communication, and develop stakeholder partnerships that lead to sustainable initiatives that eliminate health disparities.

# II. Award Information

# 1. Type of Application and Award

Type(s) of applications sought: Competing Continuation, New

HRSA will provide funding in the form of a cooperative agreement. A cooperative agreement is a financial assistance mechanism where substantial involvement with the recipient during performance of the contemplated project.

# HRSA program involvement will include:

• Providing the assistance of experienced HRSA personnel available as participants in the planning and development of the project;

<sup>&</sup>lt;sup>6</sup> See <u>https://www.hrsa.gov/about/strategic-plan/index.html</u>

- Participating, as appropriate, in conference calls, meetings, and technical assistance sessions that are conducted during the period of the cooperative agreement;
- Providing consultation on maintaining and updating of Guidelines for Women's Preventive Services, including compliance with all applicable federal requirements;
- Providing on-going review and final recommendation on all activities and procedures to be established and implemented for accomplishing the program goals and objectives;
- Participating in the development and implementation of the plan for obtaining expert participation and public comment under this cooperative agreement;
- Coordinating the partnership and communication with federally-funded maternal health programs and other federal entities that may be relevant for the successful completion of tasks and activities identified in the approved scope of work;
- Establishing federal interagency partnerships, collaboration, and cooperation that may be necessary to conduct the project;
- Conducting an ongoing review of the activities, procedures, measures, and tools used to accomplish the goals of the cooperative agreement; and,
- Participating with the award recipient in the dissemination of project findings, best practices, and lessons learned from the project.

# The cooperative agreement recipient's responsibilities will include:

- Collaborating, communicating, and coordinating with HRSA/MCHB and other health professional organizations with expertise in women's health on the development and dissemination of the recommended Guidelines;
- Completing activities proposed in response to the <u>Program Expectations section</u> of this notice of funding opportunity (NOFO);
- Providing the federal project officer with the opportunity to review and discuss any publications, audiovisuals, and other materials produced under the auspices of this cooperative agreement;
- Consulting with the federal project officer at the time of concept development of materials and include review of drafts and final products;
- Participating in face-to-face meetings and conference calls with HRSA conducted during the period of performance, including participation at the annual Maternal Health Learning and Innovation Center Learning Institute and Maternal Health Summit;
- Consulting with the federal project officer in conjunction with scheduling any meetings that pertain to the scope of work and at which the project officer's attendance would be appropriate (as determined by the project officer);
- Collaborating with HRSA on ongoing review of activities, procedures, budget items, and information/publications prior to dissemination;
- Providing leadership in data collection and analysis;
- Completing, in a timely fashion, all administrative data and performance measure reports, as designated by HRSA;
- Participating in the development of training and continuing education components for medical and nursing students/health professional students, and current practitioners, respectively, to ensure early and ongoing awareness, and proper utilization of the Guidelines;

- Developing plans to utilize the Guidelines in clinical settings at the community level; pilot these plans for utilization through a Preventive Service Test Sites/Well-Woman Care Implementation Pilot Program; and replicate/scale best practices at the state/territory level;
- Maintaining, recommending updates, and reaffirming new and existing Guidelines for Women's Preventive Services, including compliance with all applicable federal requirements and the integration of Guidelines in training into workforce development of health care providers and public health professionals and dissemination for use in clinical practice and within public health systems;
- Identifying gaps in women's preventive services; investigating new women's health preventive service topics (as needed); conducting evidence reviews; developing recommendations; and submitting additional recommendations to HRSA for review during Years 3 and 5 of the period of performance;
- Developing and implementing a plan for obtaining expert participation and public comment under the cooperative agreement; and,
- Creating a program evaluation and dissemination plan.

# 2. Summary of Funding

HRSA estimates approximately \$950,000 to be available annually to fund one recipient. The actual amount available will not be determined until enactment of the final FY 2021 federal appropriation. You may apply for a ceiling amount of up to \$950,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The FY 2021 President's Budget does not request funding for this program. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately.

The period of performance is March 1, 2021 through February 28, 2026 (5 years). Funding beyond the first year is subject to the availability of appropriated funds for the Women's Preventive Services Initiative in subsequent fiscal years, satisfactory recipient performance, and a decision that continued funding is in the best interest of the Federal Government.

All HRSA awards are subject to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements at 45 CFR part 75.

# **III. Eligibility Information**

# 1. Eligible Applicants

Any domestic public or private entity, including an Indian tribe or tribal organization (as those terms are defined at 25 U.S.C. 450b) is eligible to apply. See 42 CFR § 51a.3(a). Domestic faith-based and community-based organizations are also eligible to apply.

# 2. Cost Sharing/Matching

Cost sharing/matching is not required for this program.

HRSA-21-045

# 3. Other

HRSA will consider any application that exceeds the ceiling amount non-responsive and will not consider it for funding under this notice.

HRSA will consider any application that fails to satisfy the deadline requirements referenced in <u>Section IV.4</u> non-responsive and will not consider it for funding under this notice.

NOTE: Multiple applications from an organization are not allowable.

HRSA will only accept your **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* you to apply electronically. HRSA encourages you to apply through <u>Grants.gov</u> using the SF-424 workspace application package associated with this NOFO following the directions provided at <u>http://www.grants.gov/applicants/apply-for-grants.html</u>.

The NOFO is also known as "Instructions" on Grants.gov. You must select "Subscribe" and provide your email address for each NOFO you are reviewing or preparing in the workspace application package in order to receive notifications including modifications, clarifications, and/or republications of the NOFO on Grants.gov. You will also receive notifications of documents placed in the RELATED DOCUMENTS tab on Grants.gov that may affect the NOFO and your application. You are ultimately responsible for reviewing the For Applicants page for all information relevant to this NOFO.

# 2. Content and Form of Application Submission

Section 4 of HRSA's <u>SF-424 Application Guide</u> provides instructions for the budget, budget narrative, 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. You are responsible for reading and complying with the instructions included in HRSA's <u>SF-424 Application Guide</u> except where instructed in the NOFO to do otherwise. You must submit the application in the English language and in the terms of U.S. dollars (45 CFR § 75.111(a)).

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

# Application Page Limit

The total size of all uploaded files included in the page limit 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 NOFO. Standard OMB-approved forms that are included in the workspace application package do not count in the page limit. Please note: If you use an OMB-approved form that is not included in the workspace application package for HRSA-21-045, it may count against the page limit. Therefore, we strongly recommend you only use Grants.gov workspace forms associated with this NOFO to avoid exceeding the page limit. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. It is therefore important to take appropriate measures to ensure your 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.

# Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

- 1. You certify on behalf of the applicant organization, by submission of your proposal, that neither you nor your principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any federal department or agency.
- 2. Failure to make required disclosures can result in any of the remedies described in 45 CFR § 75.371, including suspension or debarment. (See also 2 CFR parts 180 and 376, and 31 U.S.C. § 3321).
- 3. Where you are unable to attest to the statements in this certification, an explanation shall be included in *Attachment 10: Other Relevant Documents*.

See Section 4.1 viii of HRSA's <u>SF-424 Application Guide</u> for additional information on all certifications.

# **Program Expectations**

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

- 1. Build upon and refine the existing WPSI process for developing recommendations to update the Guidelines.
  - a. The process should adhere to the standards of developing trustworthy guidelines established by the National Academy of Medicine.<sup>7</sup>
- 2. Convene a multidisciplinary panel of experts representing women's health professional organizations for the purpose of developing and recommending G
- 3. Guidelines for women's preventive services that are culturally- and linguisticallycompetent.
  - a. The expert panel will be 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, pediatricians, adolescent medicine physicians, internal medicine,

<sup>&</sup>lt;sup>7</sup> <u>https://www.nap.edu/read/13058/chapter/1</u> (accessed on 2/25/2020)

obstetricians and gynecologists, nurse practitioners, nurse-midwives, other nurse organizations, and researchers from organizations that may include women's academic centers.

- b. Convene professional organizations on the expert panel and include, at a minimum those representing women's health, primary care, chronic disease management, obstetrics and gynecology, behavioral health, oral health, gerontology, public health professionals, patients, and consumer organization representatives.
- c. The award recipient will convene and coordinate the expert panel members in the coordination, review, and recommendation development process for the Guidelines.
- 4. Review, update, synthesize, and/or reaffirm existing recommendations, based on emerging scientific evidence, for women's preventive services.
  - a. Develop a process to recruit and onboard review workgroups consisting of a broad range of content experts in adult women's preventive health care across the lifespan. Workgroup members should represent content and methodological experts and researchers.
  - b. Convene and coordinate review workgroups, as necessary, to discuss emerging scientific evidence related to women's preventive services.
  - c. Establish a process to review, update, synthesize, and/or reaffirm existing women's preventive services recommendations.
  - d. Review and synthesize existing Guidelines for women's clinical preventive services, including but not limited to U.S. Preventive Services Task Force recommendations, Bright Futures for adolescents, the HRSA-supported Women's Preventive Services Guidelines, and practice Guidelines recommended by professional organizations that represent providers of adult women's preventive services across the lifespan.
  - e. 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.<sup>8</sup> The review should provide a summary of relevant available evidence, and gaps, including a description of the quality, quantity, and consistency of aggregate available evidence.
  - f. Establish a process to integrate existing Guidelines and new scientific evidence into a comprehensive document that supports women's preventive services across the lifespan.
  - g. By December 1, 2021, the recipient is expected to develop, recommend, and submit initial recommendations for comprehensive Guidelines for women's preventive services based on review and synthesis of existing clinical Guidelines and new scientific evidence to HRSA/MCHB.

<sup>&</sup>lt;sup>8</sup> <u>https://www.uspreventiveservicestaskforce.org/Page/Name/procedure-manual</u> (accessed on 02/25/2020)

- 5. Disseminate HRSA-supported comprehensive Guidelines for use in clinical practice and by patient populations.
  - a. Establish a process for developing consensus among partner organizations to support the comprehensive Guidelines for use in clinical practice and by patient populations.
  - b. Assure that the recommended Guidelines include comprehensive resources for the purpose of dissemination throughout the health care community, including insurers, through multiple channels to reach to health care and public health professionals, patients, health professions educators, payers, and others.
  - c. Maintain and, as needed, recommend updates to the Guidelines for Women's Preventive Services and related materials and tools, in response to changing standards and new scientific knowledge.
- 6. Test utilization of the Guidelines in clinical settings.
  - a. Under the FY 2021 funding opportunity, the award recipient is expected to conduct pilot tests, through the Preventive Service Test Sites/Well-Woman Care Implementation Pilot Program, focused on patient and provider awareness of the Guidelines, as well as implementation and utilization of the recommended screening and services.
  - b. Through the Preventive Service Test Sites/Well-Woman Care Implementation Pilot Program, the award recipient will develop a feasible plan for how to conduct the pilot testing of the recommendations in clinical settings, implement the pilot testing, and share lessons learned to the stakeholder community.
  - c. The award recipient will develop a method/approach to increase the use and application of Guideline implementation into standard practice settings.
- 7. Develop and work to integrate a training strategy on implementation/use of the Guidelines by the health care workforce.
  - a. The award recipient will develop training and continuing education components for medical and nursing students/health professional students, and current practitioners, respectively;
  - b. The intended result of this activity is to increase current and future provider knowledge on women's preventive services and recommendation statements.

# **Program-Specific Instructions**

In addition to application requirements and instructions in Section 4 of HRSA's <u>SF-424</u> <u>Application Guide</u> (including the budget, budget narrative, staffing plan and personnel requirements, assurances, certifications, and abstract), 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, consistent with forms

and attachments, and well-organized so that reviewers can understand the proposed project.

Successful applications will contain the information below. Please use the following section headers for the narrative:

- INTRODUCTION -- Corresponds to Section V's Review Criterion <u>1 Need</u> Briefly describe the purpose of the proposed project. Include discussion points that highlight an expert understanding of preventive health services for women, and the HRSA-supported Guidelines.
  - Demonstrate a clear understanding of the aims, expectations, and timeline of the project.
  - Include a discussion that exhibits an expert understanding of women's health issues, the HRSA-supported Women's Preventive Services Guidelines, and issues related to the Affordable Care Act's preventive services provisions, and, in particular, those related to women's health.
  - 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 <u>1 Need</u> This section helps reviewers understand the need for the Guidelines and the needs of the Guideline's target population/audience. Describe and document the following:
  - The current state of preventive health services for women.
  - The target population's and/or audience's knowledge of recommended preventive services, and delivery or provision of recommended preventive services for women.
  - The limitations of the current recommendations/Guidelines.

Describe and document the preventive health needs of women. Issues of disparity are to be considered and incorporated, such as race, ethnicity, sexual orientation, geography, socioeconomic status, disability status, primary language, health literacy, etc. The needs assessment findings must inform the project activities. Therefore, describe how you will apply the needs assessment findings in the development, implementation, and dissemination of the recommended Guidelines for women's preventive services. Use and cite data sources whenever possible to support the information provided.

 METHODOLOGY -- Corresponds to Section V's Review Criteria <u>2 Response</u> and <u>4 Impact</u>

Propose methods that you will use to address the stated needs and meet each of the previously described program requirements and expectations in this NOFO. Successful applicants will propose projects that include the core functions and activities outlined below. Applications should not duplicate existing activities. Funds for this project are not to be used to supplant current organizational activities.

Address the following program expectations:

# 1. Program Implementation and Recommendation Development

- a. Provide a process for recommendation development that: utilizes health professionals representing multiple disciplines, and is similar to that used by the U.S. Preventive Services Task Force and Bright Futures. Include periods of public comment, transparency, and the ability for the public to nominate topics for consideration.
- b. Describe a plan to identify members to comprise an expert panel of women's health professionals representing multiple disciplines. Include onboarding new members, frequency, process for reviewing members, and addressing conflicts of interest.
- c. Describe a process for obtaining continued participation of the expert panel of multidisciplinary women's health professional organizations aimed at developing recommended Guidelines for women's preventive services that are culturally-and linguistically-competent.
- d. Provide a plan to coordinate evidence reviews of preventive services topics that uniquely affect women by the expert panel. Discuss how the panel will be convened at least annually to review evidence, discuss, develop, and vote on recommendation statements.
- e. Describe the plan to review, recommend updates, synthesize, and/or affirm or reject existing recommendations, based on emerging scientific evidence, for women's preventive services annually beginning December 2021.
- f. Provide a plan to identify gaps in women's preventive services, and investigate new women's health preventive service topics, conduct evidence reviews, develop recommendations, and submit additional recommendations to HRSA for review during Years 3 and 5 of the period of performance.
- g. Identify meaningful support and collaboration with key stakeholders, including state and federal agencies, clinical and non-clinical health care providers, in planning, designing, and implementing activities in this proposal.

# 2. Guidelines Awareness

- a. Describe a plan to expand the 508 compliant, public-facing, freestanding website for project resources, publications, evidence summaries, and recommendation statements, including the expertise required to accomplish this work.
- b. Propose a plan to disseminate the Guidelines that includes materials for both patients and women's health practitioners. Identify any additional appropriate patient and provider audiences and venues to receive project resources. Include criteria for selection of selected audiences. This activity may include the development of publications for peer-reviewed journals, WPSI website, partner websites, mainstream journalism, education materials, trainings, attendance, and participation in health professional conferences, and the creation of tools and needed resources on the HRSA-supported Guidelines.

- c. Develop a communication and dissemination strategy for the Guidelines, reports, products, and/or project outputs to ensure key audiences (e.g., patients and providers) receive project information through venues such as Social Media, Podcasts, and Brochures.
- d. Highlight plans to participate and attend meetings organized, and led by HRSA and other federal agencies (i.e., Annual Maternal Health Learning and Innovation Center Learning Institute and Maternal Health Summit).

# 3. Guideline Adoption

- a. Provide a plan to identify appropriate clinical settings to test the adoption of the Guidelines. The plan should include the criteria for pilot testing selection through the Preventive Service Test Sites/Well-Woman Care Implementation Pilot Program.
- a. Discuss the method to test utilization of the Guidelines in clinical settings; replicate utilization practices at state-level through Preventive Service Test Sites/Well-Woman Care Implementation Pilot Program.
  - i. Describe how pilot tests will be conducted in clinical settings to ascertain the barriers and facilitators to implementation of the Guidelines.
  - ii. Discuss how results of the pilot tests will be compiled and distributed to the field.
- Discuss plans to host a biannual Women's Preventive Services Conference for WPSI Test Sites/Well-Woman Care Implementation Pilot Program.
- c. Describe a plan to develop training and continuing education components for medical and nursing students/health professional students and current practitioners to ensure early and ongoing awareness and proper utilization of the Guidelines that includes issues of cultural and linguistic competence related to the recommendations.

As appropriate, include development of effective tools and strategies for ongoing staff training, outreach, collaborations, clear communication, and information sharing/dissemination with efforts to involve patients, families, and communities. If applicable, include a plan to disseminate reports, products, and/or project outputs so key target audiences receive the project information.

Include a description of any innovative methods that you will use to address the stated needs.

Propose a plan for project sustainability after the period of federal funding ends. HRSA expects recipients to sustain key elements of their 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 <u>2 Response</u> and <u>4 Impact</u>

Describe the activities or steps that you will use to achieve each of the objectives proposed during the entire period of performance in the Methodology section. Use a time line that includes each activity and identifies responsible staff. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing, and implementing all activities, including developing the application. Submit a work plan in table format as *Attachment 1*, and include all of the information and activities detailed in the narrative section of the application.

# Logic Models

Submit a logic model as *Attachment 2* for designing and managing the project. 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 notice, the logic model should summarize the connections between the:

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

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a time line used during program implementation; the work plan provides the "how to" steps. You can find additional information on developing logic models at the following website:

http://www.acf.hhs.gov/sites/default/files/fysb/prep-logic-model-ts.pdf.

# Process Flow Chart

Submit a process flow chart as *Attachment 3*, 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 <u>2 Response</u>

Discuss challenges that you are likely to encounter in designing and implementing the activities described in the work plan, and approaches that you will use to resolve such challenges.

 EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criteria <u>3 Evaluation Measures</u> and <u>5 Resources/Capabilities</u> Describe the plan for the program performance evaluation that will contribute to continuous quality improvement. The program performance evaluation should monitor ongoing processes and the progress towards the goals and objectives of the project. Include descriptions of the inputs (e.g., organizational profile, collaborative partners, key personnel, budget, and other resources), key processes, and expected outcomes of the funded activities.

Describe the systems and processes that will support your organization's performance management requirements through effective tracking of performance outcomes, including a description of how the organization will collect and manage data (e.g., assigned skilled staff, data management software) in a way that allows for accurate and timely reporting of performance outcomes. Describe current experience, skills, and knowledge, including individuals on staff, materials published, and previous work of a similar nature. As appropriate, describe the data collection strategy to collect, analyze, and track data to measure process and impact/outcomes, and explain how the data will be used to inform program development and service delivery. Describe any potential obstacles for implementing the program performance evaluation and your plan to address those obstacles.

 ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion <u>5 Resources/Capabilities</u>

Succinctly describe your organization's current mission and structure, scope of current activities, and how these elements all contribute to the organization's ability to conduct the program requirements and meet program expectations. Include an organizational chart. Discuss how the organization will follow the approved plan, as outlined in the application, properly account for the federal funds, and document all costs to avoid audit findings. Describe past performance managing federal awards/cooperative agreements. Describe how you will routinely assess and improve the unique needs of target populations of the communities served.

Describe your organization's capacity, understanding, and expertise to provide oversight and management in the recommendation development process. At a minimum, address the following:

- State the mission of your organization and describe how WPSI fits within the scope of the organization's mission;
- Demonstrate an understanding of preventive health screenings and services for women;
- Describe the structure of your organization. Include an organizational chart as *Attachment 4* that clearly shows how your organization is

structured;

- Demonstrate that your proposed project will meet the program requirements regarding specific program staff, and describe project personnel, including proposed partners that will be engaged to fulfill the needs and requirements of the proposed project. Include a staffing plan and job descriptions for key personnel in *Attachment 5*. The plan should list staff titles (e.g., program director, program assistant, state coordinator, and data coordinator), number of FTEs fulfilling the role, roles and responsibilities of each position, and biographical sketches of key personnel in *Attachment 6; and,*
- Provide a list of proposed partners, and identify partner roles in responsibilities for program implementation.

Provide information on your ability, capacity, and experience to enhance health care professionals' knowledge and practice of appropriate preventive health services. Specifically, 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 that are both culturally and linguistically relevant to a variety of populations.

Provide information on your 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. Discuss collaborative efforts with health care organizations and medical/health care professional organizations with expertise in women's health. Provide letters of agreement as *Attachment 7* 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 project 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.

### iii. Budget

The directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions in Section 4.1.iv of HRSA's *SF-424 Application Guide* and the additional budget instructions provided below. A budget that follows the Application Guide will ensure that, if HRSA selects the application for

funding, you will have a well-organized plan and, by carefully following the approved plan, may avoid audit issues during the implementation phase.

This program requires a 5-year budget proposal. The SF-424A Budget Form outlines the budget categories for the first 4 years of the project. Applications must include an additional 1-year budget to cover the entire period of performance. This document must be included as *Attachment 8: 5th Year Budget*.

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

The Further Consolidated Appropriations Act, 2020 (P.L. 116-94), Division A, § 202 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." See Section 4.1.iv Budget – Salary Limitation of HRSA's <u>SF-424</u> <u>Application Guide</u> for additional information. Note that these or other salary limitations may apply in the following fiscal years, as required by law.

# *iv.* Budget Narrative

See Section 4.1.v. of HRSA's <u>SF-424 Application Guide</u>. In addition, the Women's Preventive Services Initiative program requires the following:

Reminder: Applications must include the budget narrative for all 5 years of the project. The narrative for Years 2–5 should only include information that changes from the Year 1 budget narrative. The budget narrative portion of the application will be counted towards the application page limit.

# NARRATIVE GUIDANCE

To ensure that you fully address the review criteria, this table provides a crosswalk between the narrative language and where each section falls within the review criteria. Any attachments referenced in a narrative section may be considered during the objective review.

Narrative Section	*Review Criteria
Introduction	(1) Need
Needs Assessment	(1) Need
Methodology	(2) Response and (4) Impact
Work Plan	(2) Response and (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support	(3) Evaluative Measures and
Capacity	(5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities

Budget and Budget Narrative	(6) Support Requested
Budget and Budget Narrative	(0) Support Requested

### v. Program-Specific Forms

Program-specific forms are not required for application.

#### vi. Attachments

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. **Clearly label each attachment**.

#### Attachment 1: Work Plan

Attach the work plan for the project that includes all information detailed in <u>Section IV.2.ii. Project Narrative</u>. If you will make subawards or expend funds on contracts, describe how your organization will ensure proper documentation of funds.

#### Attachment 2: Logic Model

Provide a one-page project logic model that includes all information detailed in <u>Section IV.2.ii. Project Narrative.</u>

#### Attachment 3: Process Flow Chart

Provide a process flow chart, which outlines the steps that will be utilized for developing recommended updates to the women's preventive services Guidelines. 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.

#### Attachment 4: Project Organizational Chart

Provide a one-page figure that depicts the organizational structure of the project.

# Attachment 5: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of HRSA's <u>SF-424 Application Guide</u>)

Keep each job description to one page in length as much as is possible. Include the role, responsibilities, and qualifications of proposed project staff. Also, please include a description of your organization's timekeeping process to ensure that you will comply with the federal standards related to documenting personnel costs.

#### Attachment 6: Biographical Sketches of Key Personnel

Include biographical sketches for persons occupying the key positions described in *Attachment 5*, not to exceed two pages in length per person. In the event that a biographical sketch is included for an identified individual not yet hired, include a letter of commitment from that person with the biographical sketch.

# Attachment 7: Letters of Agreement, Memoranda of Understanding, and/or Description(s) of Proposed/Existing Contracts (project-specific)

Provide any documents that describe working relationships between your organization and other entities and programs cited in the proposal. Documents

that confirm actual or pending contractual or other agreements should clearly describe the roles of the contractors and any deliverable. Make sure any letters of agreement are signed and dated.

Attachment 8: For Multi-Year Budgets--5th Year Budget (NOT counted in page limit) After using columns (1) through (4) of the SF-424A Section B for a 5-year period of performance, you will need to submit the budget for the 5th year as an attachment. Use the SF-424A Section B. See Section 4.1.iv of HRSA's <u>SF-424</u> <u>Application Guide</u>.

### Attachment 9: Progress Report (FOR COMPETING CONTINUATIONS-ONLY)

A well-documented progress report is a required and important source of material for HRSA in preparing annual reports, planning programs, and communicating program-specific accomplishments. The accomplishments of competing continuation applicants are carefully considered; therefore, you should include previously stated goals and objectives in your application and emphasize the progress made in attaining these goals and objectives. HRSA program staff reviews the progress report after the Objective Review Committee evaluates the competing continuation applications.

The progress report should be a brief presentation of the accomplishments, in relation to the objectives of the program during the current period of performance. The report should include:

- (1) The period covered (dates).
- (2) <u>Specific objectives</u> Briefly summarize the specific objectives of the project.
- (3) <u>Results</u> Describe the program activities conducted for each objective. Include both positive and negative results or technical problems that may be important.
- Attachments 10–15: Tables, Charts, and 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 Data Universal Numbering System (DUNS) Number Transition to the Unique Entity Identifier (UEI) and System for Award Management (SAM)

You must obtain a valid DUNS number, also known as the Unique Entity Identifier (UEI), and provide that number in the application. Beginning in December 2020, the \*DUNS number will be replaced by the UEI, a "new, non-proprietary identifier" requested in, and assigned by, the System for Award Management (SAM.gov). For more details, visit the following: <u>Planned UEI Updates in Grant Application</u> <u>Forms</u> and <u>General Service Administration's UEI Update</u> page.

You must also register with SAM and continue to maintain active SAM registration with current information at all times during which you have 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)).

If you are chosen as a recipient, HRSA would not make an award until you have complied with all applicable DUNS (or UEI) and SAM requirements and, if you have not fully complied with the requirements by the time HRSA is ready to make an award, you may be deemed not qualified to receive an award and use that determination as the basis for making an award to another applicant.

If you have 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.

\*Currently, the Grants.gov registration process requires information in three separate systems:

- Dun and Bradstreet (<u>http://www.dnb.com/duns-number.html</u>)
- System for Award Management (SAM) (<u>https://www.sam.gov</u>)
- Grants.gov (<u>http://www.grants.gov/</u>)

For further details, see Section 3.1 of HRSA's SF-424 Application Guide.

**SAM.GOV** ALERT: For your SAM.gov registration, you must submit a <u>notarized</u> <u>letter</u> appointing the authorized Entity Administrator. The review process changed for the Federal Assistance community on June 11, 2018.

In accordance with the Federal Government's efforts to reduce reporting burden for recipients of federal financial assistance, the general certification and representation requirements contained in the Standard Form 424B (SF-424B) – Assurances – Non-Construction Programs, and the Standard Form 424D (SF-424D) – Assurances – Construction Programs, have been standardized federal-wide. Effective January 1, 2020, the forms themselves are no longer part of HRSA's application packages and the updated common certification and representation requirements will be stored and maintained within SAM. Organizations or individuals applying for federal financial assistance as of January 1, 2020, must validate the federally required common certifications annually through SAM located at <u>SAM.gov</u>.

If you fail to allow ample time to complete registration with SAM or Grants.gov, you 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 NOFO is *October 5, 2020 at 11:59 p.m. ET*. HRSA suggests submitting applications to Grants.gov at least **3 calendar days before the deadline** to allow for any unforeseen circumstances. See Section 8.2.5 – Summary of emails from Grants.gov of HRSA's <u>SF-424 Application Guide</u> for additional information.

# 5. Intergovernmental Review

WPSI is not a program subject to the provisions of Executive Order 12372, as implemented by 45 CFR part 100.

See Section 4.1 ii of HRSA's <u>SF-424 Application Guide</u> for additional information.

# 6. Funding Restrictions

You may request funding for a period of performance of up to 5 years, at no more than \$950,000 per year (inclusive of direct and indirect costs). The FY 2021 President's Budget does not request funding for this program. This program notice is subject to the appropriation of funds, and is a contingency action taken to ensure that, should funds become available for this purpose, HRSA can process applications and award funds appropriately. 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 A of the Further Consolidated Appropriations Act, 2020 (P.L. 116-94) 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 the following fiscal years, as required by law.

You are required to have the necessary policies, procedures, and financial controls in place to ensure that your organization complies with all legal requirements and restrictions applicable to the receipt of federal funding including statutory restrictions on use of funds for lobbying, executive salaries, gun control, abortion, etc. Like those for all other applicable grants requirements, the effectiveness of these policies, procedures, and controls is subject to audit.

All program income generated as a result of awarded funds must be used for approved project-related activities. The program income alternative applied to the award(s) under the program will be the addition/additive alternative. You can find post-award requirements for program income at <u>45 CFR § 75.307</u>.

# V. Application Review Information

# 1. Review Criteria

HRSA has procedures for assessing the technical merit of applications to provide for an objective review and to assist you in understanding the standards against which your application will be reviewed. HRSA has critical indicators for each review criterion to assist you in presenting pertinent information related to that criterion and to provide the reviewer with a standard for evaluation.

These criteria are the basis upon which the reviewers will evaluate and score the merit of the application. The entire proposal will be considered during objective review, except for the progress report submitted with a competing continuation application, which will be reviewed by HRSA program staff after the objective review process.

Review criteria are used to review and rank applications. WPSI has six review criteria. See the review criteria outlined below with specific detail and scoring points.

### Criterion 1: NEED (10 points) – Corresponds to Section IV's <u>Introduction</u> and <u>Needs</u> <u>Assessment</u>

The extent to which the application demonstrates the problem and associated contributing factors to the problem.

- The extent to which the application demonstrates an expert understanding of preventive health services for women.
- The extent to which the application provides a detailed plan to address the need for the Guidelines and the needs of the Guideline's target population/audience.

# *Criterion 2: RESPONSE (30 points) – Corresponds to Section IV's <u>Methodology</u>, <u>Work</u> <u><i>Plan, and Resolution of Challenges*</u>

The extent to which the proposed project responds to the "<u>Purpose</u>" included in the program description. 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.

Methodology

• The extent to which the proposed plan provides detailed activities to develop recommendations for preventive health screenings and services for women, and detailed activities to increase the utilization of the recommended preventive services (10 points).

Work Plan

- The extent to which the proposed plan comprehensively describes a thorough process for program implementation and recommendation development, guideline awareness, and guideline adoption (10 points).
- The extent to which the application work plan, logic model, and process flow chart strongly support achievable program goals and objectives (5 points). *Resolution of Challenges*
- The extent to which the application discusses challenges they might encounter in designing and implementing the activities described in the work plan, and

approaches that will be used to resolve such challenges in a timely manner (5 points).

# Criterion 3: EVALUATIVE MEASURES (10 points) – Corresponds to Section IV's <u>Evaluation and Technical Support Capacity</u>

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 <u>Methodology</u> and <u>Work</u> <u>Plan</u>

The extent to which the proposed project has a public health impact and the project will be effective, if funded. This may include: the effectiveness of plans for dissemination of project results, the impact results may have on the community or target population, the extent to which project results may be national in scope, the degree to which the project activities are replicable, and the sustainability of the program beyond the federal funding.

# Criterion 5: RESOURCES/CAPABILITIES (30 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity and 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.

- The extent to which the applicant provides detailed 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 (10 points).
- The extent to which the applicant demonstrates strong partnership and collaboration with appropriate 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 (10 points).
- The extent to which the applicant and staff demonstrates significant experience and expertise in developing and disseminating clinical guidelines, informational materials, and training to health care providers (5 points).
- 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 (5 points).

# *Criterion 6: SUPPORT REQUESTED (10 points) – Corresponds to Section IV's* <u>*Budget*</u> and <u>*Budget Narrative*</u>

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

• The extent to which costs, as outlined in the budget and required resources sections, are reasonable given the scope of work.

 The extent to which key personnel have adequate time devoted to the project to achieve project objectives.

# 2. Review and Selection Process

The objective review process provides an objective evaluation to the individuals responsible for making award decisions. The highest ranked applications receive consideration for award within available funding ranges. HRSA may also consider assessment of risk and the other pre-award activities described in Section 3 below. See Section 5.3 of HRSA's <u>SF-424 Application Guide</u> for more details.

# 3. Assessment of Risk

HRSA 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 (<u>45 CFR § 75.205</u>).

HRSA reviews applications receiving a favorable objective review for other considerations that include past performance, as applicable, cost analysis of the project/program budget, assessment of your management systems, ensuring continued applicant eligibility, and compliance with any public policy requirements, including those requiring just-in-time submissions. HRSA may ask you to submit additional programmatic or administrative information (such as an updated budget or "other support" information) or to undertake certain activities (such as negotiation of an indirect cost rate) in anticipation of an award. However, even at this point in the process, such requests do not guarantee that HRSA will make an award. Following review of all applicable information, HRSA's approving and business management officials will determine whether HRSA can make an award, if special conditions are required, and what level of funding is appropriate.

Award decisions are discretionary and are not subject to appeal to any HRSA or HHS official or board.

HRSA is required to review and consider any information about your organization that is in the <u>Federal Awardee Performance and Integrity Information System (FAPIIS)</u>. You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider your comments, in addition to other information in <u>FAPIIS</u> in making a judgment about your organization's integrity, business ethics, and record of performance under federal awards when completing the review of risk posed as described in 45 CFR § 75.205 HHS Awarding Agency Review of Risk Posed by Applicants.

HRSA will report to FAPIIS a determination that an applicant is not qualified (<u>45 CFR §</u> <u>75.212</u>).

# **VI. Award Administration Information**

# 1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of March 1, 2021. See Section 5.4 of HRSA's <u>SF-424 Application Guide</u> for additional information.

# 2. Administrative and National Policy Requirements

See Section 2.1 of HRSA's SF-424 Application Guide.

# **Requirements of Subawards**

The terms and conditions in the NOA apply directly to the recipient of HRSA funds. The recipient is accountable for the performance of the project, program, or activity; the appropriate expenditure of funds under the award by all parties; and all other obligations of the recipient, as cited in the NOA. In general, the requirements that apply to the recipient, including public policy requirements, also apply to subrecipients under awards, and it is the recipient's responsibility to monitor the compliance of all funded subrecipients. See <u>45 CFR § 75.101 Applicability</u> for more details.

# **Data Rights**

All publications developed or purchased with funds awarded under this notice must be consistent with the requirements of the program. Pursuant to 45 CFR § 75.322(b), the recipient owns the copyright for materials that it develops under an award issued pursuant to this notice, and HHS reserves a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use those materials for federal purposes, and to authorize others to do so. In addition, pursuant to 45 CFR § 75.322(d), the Federal Government has the right to obtain, reproduce, publish, or otherwise use data produced under this award and has the right to authorize others to receive, reproduce, publish, or otherwise use such data for federal purposes, e.g., to make it available in government-sponsored databases for use by others. If applicable, the specific scope of HRSA rights with respect to a particular grant-supported effort will be addressed in the NOA. Data and copyright-protected works developed by a subrecipient also are subject to the Federal Government's copyright license and data rights.

# 3. Reporting

Award recipients must comply with Section 6 of HRSA's <u>SF-424 Application Guide</u> and the following reporting and review activities:

 DGIS Performance Reports. Available through the Electronic Handbooks (EHBs), the Discretionary Grant Information System (DGIS) is where recipients will report annual performance data to HRSA. Award recipients are required to submit a DGIS Performance Report **annually**, by the specified deadline. To prepare successful applicants for their reporting requirements, the listing of administrative forms and performance measures for this program are available at https://grants6.hrsa.gov/MchbExternal/DgisApp/formassignmentlist/UH0.html.

Type of Report	Reporting Period	Available Date	Report Due Date
a) New Competing Performance Report	March 1, 2021 to February 28, 2026 ( <i>administrative data and</i> <i>performance measure</i> <i>projections, as</i> <i>applicable</i> )	Period of performance start date	120 days from the available date
b) Non-Competing Performance Report	March 1, 2022 to February 28, 2023 March 1, 2023 to February 29 2024 March 1, 2024 to February 28, 2025	Beginning of each budget period (Years 2– 4, as applicable)	120 days from the available date
c) Project Period End Performance Report	March 1, 2025 to February 28, 2026	Period of performance end date	90 days from the available date

The type of report required is determined by the project year of the award's period of performance.

The full OMB-approved reporting package is accessible at <a href="https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection">https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection</a> (OMB Number: 0915-0298 | Expiration Date: 06/30/2022).

- 2) Progress Report(s). The recipient must submit a progress report narrative to HRSA annually via the Non-Competing Continuation Renewal in the EHBs, which should address progress against program outcomes (e.g., accomplishments, barriers, significant changes, plans for the upcoming budget year), and include annual data on performance measures identified in the Project Narrative, if not captured by DGIS. Submission and HRSA approval of a progress report will trigger the budget period renewal and release of each subsequent year of funding. Further information will be available in the NOA.
- Integrity and Performance Reporting. The NOA will contain a provision for integrity and performance reporting in <u>FAPIIS</u>, as required in <u>45 CFR part 75</u> <u>Appendix XII</u>.

# **VII. Agency Contacts**

You may request additional information and/or technical assistance regarding business, administrative, or fiscal issues related to this NOFO by contacting:

Hazel N. Booker Grants Management Specialist Division of Grants Management Operations, OFAM Health Resources and Services Administration 5600 Fishers Lane, Mailstop 10SWH03 Rockville, MD 20857 Telephone: (301) 443-4236 Email: <u>NBooker@hrsa.gov</u>

You may request additional information regarding the overall program issues and/or technical assistance related to this NOFO by contacting:

Johannie Escarne Acting Senior Advisor, Division of Healthy Start and Perinatal Services Attn: Women's Preventive Services Initiative Maternal and Child Health Bureau Health Resources and Services Administration 5600 Fishers Lane Rockville, MD 20857 Telephone: (301) 443-0543 Email: wellwomancare@hrsa.gov

You may need assistance when working online to submit your application forms electronically. 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, 7 days a week, excluding federal holidays at:

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

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's EHBs. For assistance with submitting information in the EHBs, contact the HRSA Contact Center, Monday–Friday, 8 a.m. to 8 p.m. ET, excluding federal holidays at:

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

HRSA has scheduled following technical assistance:

### Webinar

Day and Date: Tuesday, August 18, 2020 Time: 3–4 p.m. ET Call-In Number: 1-877-329-5062 Participant Code: 8138038 Weblink: <u>https://hrsa.connectsolutions.com/rnr95mwhwy77/</u>

In an attempt to more effectively utilize our Technical Assistance webinar time, if you have questions about the NOFO, please send them beforehand via email to <u>wellwomancare@hrsa.gov</u>. We will compile and address these questions during the webinar.

HRSA will record the webinar and make it available at: <u>https://mchb.hrsa.gov/fundingopportunities/default.aspx</u>.

# Tips for Writing a Strong Application

See Section 4.7 of HRSA's SF-424 Application Guide.

# **Appendix A: Relevant Websites**

While HRSA does not endorse any other organization/website, the following list, although not exhaustive, may be helpful references:

### Agency for Healthcare Research and Quality

http://www.ahrq.gov/professionals/clinicians-providers/guidelinesrecommendations/index.html

Bright Futures http://brightfutures.aap.org/

### **Clinical Preventive Services for Women: Closing the Gaps**

https://www.nap.edu/catalog/13181/clinical-preventive-services-for-womenclosing-the-gaps

# Healthy People 2020 / Developing Healthy People 2030

http://www.healthypeople.gov/2020/ https://www.healthypeople.gov/2020/About-Healthy-People/Development-Healthy-People-2030

### HRSA/MCHB

http://www.mchb.hrsa.gov/

### **HRSA Women's Preventive Services Guidelines**

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

### Institute of Medicine Standards for Guidelines

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

Logic Models https://www.cdc.gov/eval/tools/logic models/index.html

Making Websites Accessible: Section 508 of the Rehabilitation Act <a href="http://www.section508.gov/">http://www.section508.gov/</a>

National Academy of Medicine <u>https://nam.edu/</u>

National Center for Cultural Competence <a href="http://nccc.georgetown.edu/">http://nccc.georgetown.edu/</a>

U.S. Preventive Services Task Force (USPSTF) <a href="http://www.uspreventiveservicestaskforce.org/">http://www.uspreventiveservicestaskforce.org/</a>

Women's Preventive Services Initiative <a href="https://www.womenspreventivehealth.org/">https://www.womenspreventivehealth.org/</a>

# Appendix B: Key Terms

- Application Guide: HRSA'S SF-424 Application Guide
- GMS: Grants Management Specialist
- Guidelines: Guidelines for Women's Preventive Services
- HRSA: Health Resources and Services Administration
- MCHB: Maternal and Child Health Bureau
- NOFO: Notice of Funding Opportunity
- PO: Project Officer
- USPSTF: United States Preventive Services Task Force
- WPSI: Women's Preventive Services Initiative

# **Appendix C: Existing WPSI Partner Organizations**

The existing WPSI partners are comprised of national professional organizations and patient representatives with expertise in adult women's health. The WPSI organizational representation includes:

- Academy of Women's Health
- American Academy of Pediatrics
- American Academy of Physician Assistants
- American Cancer Society
- American College of Nurse-Midwives
- American College of Preventive Medicine
- American College of Radiology
- American Geriatric Society
- American Osteopathic Association
- American Psychiatric Association
- Association of Maternal & Child Health Programs
- Association of Women's Health, Obstetric and Neonatal Nurses
- National Comprehensive Cancer Network
- National Medical Association
- National Partnership for Women & Families
- National Women's Law Center
- Pacific Northwest Evidence-based Practice Center at Oregon Health & Science University
- Patient Representatives

# **Appendix D: Frequently Asked Questions**

# 1. Why were the Guidelines initially established, and how are they used?

The purpose of the Guidelines is to improve women's health across the lifespan by identifying preventive services and screenings to be used in clinical practice. The Guidelines aim to address practice-based clinical considerations and age-appropriateness in practice settings, such as family history, co-occurring conditions, and other risk factors that influence individual care. Part of the project is to facilitate dissemination of the Guidelines into a clinical setting to enhance the likelihood of effective implementation and utilization into standard practice.

The Guidelines ensure that preventive services and screenings are available to women through their insurance plans without cost sharing. Evidence shows that even minimal cost sharing reduces the utilization of recommended preventive services and screenings, potentially increasing negative health outcomes, morbidity and health care costs.

In 2011, HRSA worked with the National Academies of Science, Engineering, and Medicine (formerly known as the Institutes of Medicine (IOM)) to develop the initial Women's Preventive Services Guidelines (<u>www.hrsa.gov/womensguidelines</u>). Review of the Guidelines now is consistent with IOM's recommendation to provide review and recommended updates at least every 5 years.

Under § 2713 of the Public Health Service Act, as added by the Patient Protection and Affordable Care Act, P.L. 111-148 (42 U.S.C. § 300gg-13), non-grandfathered group health plans and non-grandfathered group and individual health insurance issuers 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. Why are the Guidelines being updated?

In 2010, the Department of Health and Human Services (HHS) commissioned a study by the National Academies of Science, Engineering, and Medicine (formerly known as the Institute of Medicine (IOM)) to review the evidence related to preventive services specific to women's health and well-being and to make recommendations for services to be included in a clinical preventive services benefit for women. IOM conducted a scientific review and provided recommendations on health services that meet the unique health needs of women. In July 2011, HRSA adopted the IOM's recommendations on preventive services to address health needs specific to women and to fill gaps in existing Guidelines.

The IOM, as part of its report, recommended that HHS periodically update the review of women's preventive services. 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 other times (page 159)." Given that the IOM report was published in 2011, the women's Guidelines were updated at the end of 2016 to meet the recommended 5year benchmark, and to remain current with the existing science and evidencebased practices.

3. Where are the current Guidelines published? The HRSA-supported Guidelines are available at <u>http://www.hrsa.gov/womensguidelines/</u>.

# 4. How does this process align with USPSTF work? How will the Women's Guidelines differ from the preventive services Guidelines developed by USPSTF?

The Women's Preventive Services Guidelines will complement the recommendations of USPSTF, Advisory Committee on Immunization Practices (ACIP), and Bright Futures. ACOG, as the award recipient under the previous WPSI, developed a process for making recommendations to update the Guidelines for women's preventive services based on review and synthesis of existing clinical Guidelines and new scientific evidence. Although the recommendations to update the Guidelines will incorporate similar methodological approaches to identifying, reviewing, and analyzing evidence to that of USPSTF, the Women's Guidelines will incorporate additional factors drawn from the clinical setting in making final recommendations. As it relates to potential disagreements across Guidelines, the body of covered preventive services and screenings is additive across the various Guidelines setting groups. In other words, another eligible Guideline setting body may recommend to include a service, which, if supported by HRSA, would result in a requirement for insurance coverage without cost sharing, even though the service may not have an "A" or "B" recommendation by USPSTF.

# 5. What if a recommendation conflicts with guidance or recommendations produced by another agency or professional organization?

If the recommendation conflicts with guidance or recommendations produced by another agency or professional organization, please notify WPSI and submit your agency Guidelines for review during the public comment period. The Women's Preventive Services Guidelines will complement the recommendations of USPSTF, ACIP, and Bright Futures. As it relates to potential disagreements across Guidelines, the body of covered preventive services and screenings is additive across the various Guidelines setting groups.

# 6. When will the updated Guidelines go into effect?

Under the rules implementing § 2713 of the Public Health Service Act, plans and issuers are required to provide coverage without cost-sharing for cover any new or modified preventive services I on the first day of the first plan year (in the individual market, policy year) that begins 1 year after the date of the recommendation. They may do so voluntarily, however, before that time. Thus, if the updated Guidelines are released in early 2020, in general the earliest they would be required to be covered without cost-sharing would be Plan Year (PY) 2021, although some group health plans may begin coverage slightly earlier or later than January 1, 2021, depending on the timing of the plan year.

# Appendix E: Program Logic Model

PROGRAM PROCESS		PROGRAM OUTCOMES	
ACTIVITIES	OUTPUTS / PRODUCTS	SHORT-TERM / INTERMEDIATE	LONG-TERM / IMPACT
Continue convening an expert panel of multidisciplinary women's health professional organizations aimed at developing recommended Guidelines for women's preventive services that are culturally- and linguistically-competent. [Note: Specific membership may change over time.]	Voting body of multidisciplinary women's health clinicians that is convened annually to review & discuss Guidelines.	Increased collaboration and coordination among health professional organizations developing Guidelines for women's preventive services.	Increase/broaden acceptance and sponsorship of the Guidelines by health professional organizations. Increase the capacity of the women's health provider workforce to deliver evidence- based, culturally- and linguistically-appropriate
Review, update, synthesize, and/or reaffirm <u>existing</u> recommendations, based on emerging scientific evidence, for women's preventive services on a 5-year rolling cycle.	Updated evidence summaries and recommendations for HRSA-supported Guidelines.	Maintain the existing, or revised, Guidelines recommendations in alignment with current evidence.	preventive care to women. Increase the number of women's health providers who use/implement the Guidelines and screening recommendations in
Identify gaps in women's preventive services, and investigate <u>new</u> women's health preventive service topics (as needed), conduct evidence reviews, develop recommendations, and submit additional recommendations to HRSA for review during Years 3 and 5 of the period of performance.	Public comment on new topics, new evidence summaries, and new recommendations on women's preventive health topics in Year 3 and 5 of the period of performance.	Increase the number of new women's preventive service topics under review, as appropriate, for the consideration by the voting body to provide comprehensive women's preventive services.	standard clinical practice. Increase patient access to and utilization of the Guidelines. Increase the number of women who receive adequate preventive health care services according to the Guidelines.
Disseminate HRSA-supported comprehensive Guidelines for use in clinical practice and within public health system	Peer-reviewed journal articles, WPSI website, partner website, mainstream journalism, education materials/trainings, attendance	Increase provider awareness and knowledge about the Women's Preventive Service Guidelines.	Increase the number of women who receive appropriate preventive health services for

PROGRAM PROCESS		PROGRAM OUTCOMES	
ACTIVITIES	OUTPUTS / PRODUCTS	SHORT-TERM / INTERMEDIATE	LONG-TERM / IMPACT
Integrate Guidelines implementation training into workforce development of health care providers and public health professionals	and participation in health professional conferences, and tools on the HRSA-supported Guidelines.		specified recommendations (e.g., # of women breastfeeding infants at 6 months, # of women that receive an annual well-woman visit, # of women who receive prenatal care in the first trimester).
Disseminate HRSA-supported Guidelines for patient use (e.g., Social Media, Podcast).	Patient-facing products highlighting the Guidelines. Use of social media.	Increase patient awareness of Women's Preventive Services Guidelines. Increase patient capacity to participate in preventive activities.	
Test utilization of the Guidelines in clinical settings; replicate utilization practices at state-level through Preventive Service Test Sites/Well- Woman Care Implementation Pilot Program.	Biannual Preventive Services Meeting for sites and Stakeholders. Pilot tests conducted; lessons learned compiled.	Increase evidence base on feasibility of Guideline implementation in standard clinical practice.	
Develop training components for medical and nursing students/health professional students and current practitioners to ensure early and ongoing awareness and proper utilization of the Guidelines that includes issues of cultural and linguistic competence related to the recommendations.	Training modules on the Guidelines for medical and nursing students	Increase future provider knowledge on women's preventive services and recommendations. Increase cultural and linguistic competence related to the women's preventive health screenings and recommendations.	