U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

Supporting Fetal Alcohol Spectrum Disorders Screening and Intervention

Funding Opportunity Number: HRSA-20-111
Funding Opportunity Type(s): New
Assistance Listings (CFDA) Number: 93.110

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2020

Application Due Date: June 9, 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: April 10, 2020

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Authority: 42 U.S.C. § 701(a)(2)

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2020 Supporting Fetal Alcohol Spectrum Disorders Screening and Intervention program. This program has two related purposes: to both reduce alcohol use among pregnant women, and to improve developmental outcomes for children and adolescents with a suspected or diagnosed Fetal Alcohol Spectrum Disorder (FASD) in states, U.S. territories, tribes/tribal organizations, or communities that have high rates of binge drinking among pregnant women, especially in rural areas. Specifically, the goals of this program are: 1) to improve the ability of primary care providers (PCPs) serving pregnant women to screen their patient population for alcohol use, provide brief intervention, and refer high-risk pregnant women to specialty care; and, 2) to improve the ability of PCPs serving children and adolescents to screen their patient population for prenatal alcohol exposure among those suspected of FASD, and manage and provide referrals to necessary services for those identified with FASD.[1] PCPs may include, but are not limited to, maternity care, family medicine, pediatric and nursing providers, especially those practicing in rural areas and medically underserved communities. The recipient will use a variety of evidence-based modalities including telehealth approaches, to increase PCP knowledge and provide technical assistance (TA) to implement and sustain practice change among PCPs.

Funding Opportunity Title:	Supporting Fetal Alcohol Spectrum Disorders Screening and Intervention
Funding Opportunity Number:	HRSA-20-111
Due Date for Applications:	June 9, 2020
Anticipated Total Annual Available FY 2020 Funding:	Up to $1,000,000 dependent on the availability of appropriated funds
Estimated Number and Type of Award(s):	Up to one cooperative agreement
Estimated Award Amount:	Up to $1,000,000 per year dependent on the availability of appropriated funds
Cost Sharing/Match Required:	No
Period of Performance:	September 1, 2020 through August 31, 2023 (3 years)

[1] FASDs are difficult to diagnose and require multidisciplinary assessments. There is no one test to diagnose FASDs, and many other disorders can have similar symptoms (https://www.cdc.gov/ncbddd/fasd/diagnosis.html). Therefore, throughout this document, the program goals and objectives related to PCPs screening children and adolescents are articulated as increased knowledge and efficacy in screening for prenatal alcohol exposure among children and adolescents suspected of FASD.

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 Section III.1 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 http://www.hrsa.gov/grants/apply/applicationguide/sf424guide.pdf, except where instructed in this NOFO to do otherwise.

Technical Assistance

HRSA has scheduled the following technical assistance:

Webinar

Day and Date: Thursday, April 30, 2020
Time: 2–3:30 p.m. ET
Call-In Number: 1-877-937-9313
Participant Code: 377-971-87
Weblink: https://hrsa.connectsolutions.com/r95nvy3drg0n

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

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the Supporting Fetal Alcohol Spectrum Disorders Screening and Intervention program. This program has two related purposes: to reduce alcohol use among pregnant women, and to improve developmental outcomes for children and adolescents with a suspected or diagnosed Fetal Alcohol Spectrum Disorder (FASD), in states, U.S. territories, tribes/tribal organizations, or communities that have high rates of binge drinking among pregnant women, especially in rural areas. Specifically, the goals of this program are: 1) to improve the ability of primary care providers (PCPs) serving pregnant women, to screen their patient population for alcohol use, provide brief intervention, and refer high-risk pregnant women to specialty care; and, 2) to improve the ability of PCPs serving children and adolescents to screen their patient population for prenatal alcohol exposure among those suspected of FASD, and manage and provide referrals to necessary services for those identified with FASD.[2] PCPs may include, but are not limited to, maternity care, family medicine, pediatric and nursing providers, especially those practicing in rural areas[3] and medically underserved communities.[4] The recipient will use a variety of evidence-based modalities including telehealth approaches, to increase PCP knowledge and provide technical assistance (TA) to implement and sustain practice change among PCPs.

Program Objectives
To move toward achieving these goals, the recipient will work toward the following objectives by the end of the period of performance in 2023:

1) At least 80 percent of PCPs educated through this program have increased knowledge about the hazards of prenatal alcohol exposure and the options for screening for alcohol use during pregnancy, and prenatal alcohol exposure among children and adolescents suspected of FASD.
2) At least 50 percent of PCPs educated through this program have increased self-efficacy[5] in the recommended approach of screening, intervention, and referral to services, for their respective patient population.
3) At least 30 percent of PCPs educated through this program have increased use of appropriate methods of screening for their respective patient population for alcohol use during pregnancy, and prenatal alcohol exposure among children and adolescents suspected of FASD.

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[2] FASDs are difficult to diagnose and require multidisciplinary assessments. There is no one test to diagnose FASDs, and many other disorders can have similar symptoms (https://www.cdc.gov/ncbddd/fasd/diagnosis.html). Therefore, throughout this document, the program goals and objectives related to PCPs screening children and adolescents are articulated as increased knowledge and efficacy in screening for prenatal alcohol exposure among children and adolescents suspected of FASD.

[3] The Health Resources and Services Administration (HRSA) defines rural here, https://www.hrsa.gov/rural-health/about-us/definition/index.html.

[4] For purposes of this NOFO, a medically underserved community is one which may be designated as a Health Professional Shortage Area, Medically Underserved Area, or Medically Underserved population. For additional information, see https://bhw.hrsa.gov/shortage-designation/types.

[5] Self-efficacy is defined as the confidence to carry out the courses of action necessary to accomplish desired goals. Klassen, RM; Klassen, JRL. Self-efficacy beliefs of medical students: a critical review. Perspect Med Educ. 2018 Apr; 7(2): 76–82. doi: 10.1007/s40037-018-0411-3

See the Program-Specific Instructions in Section IV for a list of key activities.

2. Background

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

Need for Screening, Brief Intervention, and Referral to Treatment
Alcohol use during pregnancy is one of the leading preventable causes of birth defects and developmental disabilities among children in the United States. Between 2015 and 2017, 11.5 percent of pregnant women reported drinking at least one alcohol drink in the past 30 days and 3.9 percent reported binge drinking in the past 30 days.[6,7] The prevalence of binge drinking among pregnant women was highest among those who were aged 18–24 years (5.8 percent) and those who were not married (6.1 percent). Rates of binge drinking among pregnant women also varied by race/ethnicity, with the highest rates reported among non-Hispanic women of other races, including American Indian/Alaska Native, Asian/Pacific Islander, and those reporting multiple races (5.1 percent), followed by Hispanic women (3.5 percent) and non-Hispanic white women (3.4 percent).

FASD is an umbrella term describing a range of physical and neurodevelopmental effects that are associated with prenatal alcohol exposure. These may include congenital physical malformations, developmental delays, learning disorders, and behavioral issues. Challenges for these individuals may include intellectual disability, difficulty with learning, poor reasoning and judgment skills, low attention span, and hyperactive behavior.[8] FASD-related problems make it difficult for the individual to navigate day-to-day life situations. It can cause individuals to trust the wrong people, repeat the same mistakes, and have difficulty understanding the consequences of their actions.[9] Comprehensive early interventions and family therapy/support may reduce the risk that a child with an FASD will require referrals to child welfare, juvenile justice facilities, adult prisons or jails, and homeless shelters.[10] Early identification and linkage to appropriate, integrated support services for children before 6 years of age is associated with better health and life outcomes for individuals with an FASD.[9,11]

While no studies exist that capture the national prevalence of FASDs, CDC studies used medical and other records to identify 0.2 to 1.5 infants with fetal alcohol syndrome (among the most severe diagnoses under the FASD umbrella) for every 1,000 live births in certain areas of the United States.[12] More recent data suggest that the prevalence is

[6] Binge drinking was defined as having consumed four or more drinks on at least one occasion in the past 30 days. The study uses self-reported data collected from the Behavioral Risk Factor Surveillance System (BRFSS), a state-based, landline and cellphone survey of the U.S. population.
[7] Denny CH, Acero CS, Naimi TS, Kim SY. Consumption of Alcohol Beverages and Binge Drinking Among Pregnant Women Aged 18–44 Years — United States, 2015–2017. MMWR Morb Mortal Wkly Rep 2019;68:365–368.
DOI: http://dx.doi.org/10.15585/mmwr.mm6816a1
[8] https://www.cdc.gov/ncbddd/fasd/facts.html
[9] https://www.niaaa.nih.gov/publications/brochures-and-fact-sheets/fetal-alcohol-exposure
[10] Turchi RM, Smith VC, AAP Committee on Substance Use and Prevention, AAP Council on Children with Disabilities. The Role of Integrated Care in a Medical Home for Patients With a Fetal Alcohol Spectrum Disorder. *Pediatrics.* 2018;142(4):e20182333
[11] Streissguth AP, Bookstein FL, Barr HM, Sampson PD, O'Malley K, Young JK. Risk factors for adverse life outcomes in fetal alcohol syndrome and fetal alcohol effects. J Dev Behav Pediatr. 2004 Aug;25(4):228-38.
[12] CDC. Fetal alcohol syndrome-Alaska, Arizona, Colorado, and New York, 1995-1997. MMWR Morb Mortal Wkly Rep. 2002;51(20):433-5.

higher for all FASDs: one study reported that the prevalence of FASDs is between 1.1 – 5 percent among first-graders in four communities within the United States.[13] FASD rates are higher in certain regions of the United States and among vulnerable populations, such as children in foster care, internationally adopted children, and/or some children of American Indian or Alaska Native descent.[14] While no amount or type of alcohol is safe during pregnancy, binge drinking among women of child-bearing age poses the greatest risk for having a child with FASD, as 50 percent of pregnancies in the United States are unplanned, and women may be drinking alcohol before they even realize they are pregnant.

The Critical Role of Primary Care Providers

PCPs, such as maternity care, family medicine, pediatric, and nursing providers, are uniquely positioned to identify alcohol use during pregnancy and prenatal alcohol exposure in pediatric populations. *PCPs serving pregnant women* have a key role in screening and providing brief intervention, patient education, and referral to treatment for patients with at-risk alcohol use, or who have alcohol or substance use disorders.[15] *PCPs serving children and adolescents* build trusted relationships with both their pediatric patients and their patients' parents/caregivers. Therefore, they are in a prime position to screen for prenatal alcohol exposure among those suspected of FASD, and to manage and refer those suspected of or diagnosed with FASD and their families to multidisciplinary assessments and interventions. They can play an important role in preventing future alcohol-exposed pregnancies through education and counseling to mothers with affected children and young female patients of child-bearing age.[16] Similar to the provision of optimal care for children with complex medical or behavioral disabilities, children and adolescents with an FASD and their families benefit from a pediatric medical home approach[17] to provide and coordinate care among available multidisciplinary services (medical, behavioral, social, and educational) across a child's developmental stages: early and middle childhood, adolescence, and young adult/transition age. Pediatric PCPs need appropriate knowledge, resources, referral networks, and self-efficacy to care for patients with a suspected or diagnosed FASD and to provide counseling and support to their families.

Several medical and professional associations recommend universal screening of pregnant and postpartum women for unhealthy alcohol or other substance use and related mental disorders such as depression and anxiety, as well as a brief counseling intervention and appropriate referral as the standard of care.[18] Unfortunately, this has

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[13] May PA, Chambers CD, Kalberg WO, Zellner J, et al. Prevalence of Fetal Alcohol Spectrum Disorders in 4 US Communities *JAMA.* 2018;319(5):474-482. doi:10.1001/jama.2017.21896

[14] Turchi RM, Smith VC, AAP Committee on Substance Use and Prevention, AAP Council on Children with Disabilities. The Role of Integrated Care in a Medical Home for Patients With a Fetal Alcohol Spectrum Disorder. *Pediatrics.* 2018;142(4):e20182333

[15] The American College of Obstetricians and Gynecologists (ACOG) 2011 Committee Opinion (Reaffirmed 2013), At-Risk Drinking and Alcohol Dependence: Obstetric and Gynecologic Implications. Retrieved 3/2020. https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2011/08/at-risk-drinking-and-alcohol-dependence-obstetric-and-gynecologic-implications.pdf

[16] Fetal Alcohol Spectrum Disorders. Janet F. Williams, Vincent C. Smith and the Committee on Substance Abuse. Pediatrics 2015;136;e1395. DOI: 10.1542/peds.2015-3113

[17] In a medical home model, or approach, primary care should be accessible, continuous, comprehensive, family-centered, coordinated, compassionate, and culturally effective. https://www.aap.org/en-us/about-the-aap/aap-facts/AAP-Agenda-for-Children-Strategic-Plan/Pages/AAP-Agenda-for-Children-Strategic-Plan-Medical-Home.aspx

[18] *The U.S. Preventive Services Task Force:* https://www.uspreventiveservicestaskforce.org/uspstf/topic_search_results?topic_status=P&searchterm=depression and https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/unhealthy-alcohol-use-in-adolescents-and-adults-screening-and-behavioral-counseling-interventions *The American College of Obstetricians and Gynecologists:* https://www.acog.org/-

not been achieved universally in practice. Alcohol and other substance use disorders in perinatal women remain largely under-recognized and under-diagnosed.[19] Studies indicate that many PCPs feel they lack the skills and time to effectively screen for prenatal alcohol exposure; as a result, individuals with FASDs often go misdiagnosed or undiagnosed. Pediatric clinicians report that they do not receive sufficient education about the hazards of and the options for screening for prenatal alcohol exposure, and managing an individual with an FASD within the medical home approach.[20] Maternity care providers offer a range of reasons as barriers to routine screening for alcohol use. These include: feeling overwhelmed by the number of conditions for which they must screen; feeling inadequately trained to screen for and assist women with alcohol and other substance misuse; not recognizing that their unique patient population may be at risk; not being convinced of the utility of screening or that patients' alcohol use will change; being concerned about mandatory reporting requirements; not knowing the community resources to whom they can refer; and lastly, being deterred by the lack of reimbursement for evaluation and management services.[21]

Addressing the Needs of Primary Care Providers

Strategies to support provider uptake of clinical guidelines to screen for alcohol use during pregnancy, or prenatal alcohol exposure among children and adolescents suspected of FASD, include the two-pronged approach called for in this program. Strategies should seek to improve PCP knowledge and attitudes to promote practice change, as well as use quality improvement strategies, such as workflow- or provider-focused strategies, to implement and sustain practice change. Strategies may include telehealth and other web-based strategies, audit and feedback, educational meetings, clinical decision supports, reminders, educational outreach visits, peer coaching, primary care practice transformation coaching,[22] continuous quality improvement, and financial incentives. When applying an implementation strategy, it is important to consider potential barriers and incorporate features known to improve the likelihood of successful implementation.[23]

Telehealth is often used as a strategy for equipping the primary health care workforce, particularly those in rural areas and other medically underserved communities, with the necessary education and training for meeting the needs of their patients and families. HRSA defines telehealth as "the use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient, and

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/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2011/08/at-risk-drinking-and-alcohol-dependence-obstetric-and-gynecologic-implications.pdf and https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2015/06/alcohol-abuse-and-other-substance-use-disorders-ethical-issues-in-obstetric-and-gynecologic-practice.pdf and https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2018/11/screening-for-perinatal-depression.pdf. *Women's Preventive Services Initiative:* https://www.womenspreventivehealth.org/recommendations/screening-for-anxiety/ *The American Academy of Pediatrics/Bright Futures:* https://www.aap.org/en-us/Documents/periodicity_schedule.pdf

[19] Wright, T.E., Terplan, M., Ondersma, S.J., Boyce, C., Yonkers, K., et al. (2016). The role of screening, brief intervention, and referral to treatment in the perinatal period. *American Journal of Obstetrics & Gynecology*, 215(5), 539-547.

[20] Turchi RM, Smith VC, AAP Committee on Substance Use and Prevention, AAP Council on Children with Disabilities. The Role of Integrated Care in a Medical Home for Patients With a Fetal Alcohol Spectrum Disorder. *Pediatrics.* 2018;142(4):e20182333

[21] Wright, T.E., Terplan, M., Ondersma, S.J., Boyce, C., Yonkers, K., et al. (2016). The role of screening, brief intervention, and referral to treatment in the perinatal period. *American Journal of Obstetrics & Gynecology*, 215(5), 539-547.

[17] The National Academies of Sciences, Engineering, Medicine. The Role of Telehealth in an Evolving Health Care Environment-Workshop Summary (2010). Retrieved 3/2020. https://www.nap.edu/read/13466/chapter/1.

[22] https://www.ahrq.gov/ncepcr/care/chronic-manual/index.html

[23] Lau R, Stevenson F, Ong BN*, et al* Achieving change in primary care—effectiveness of strategies for improving implementation of complex interventions: systematic review of reviews *BMJ Open* 2015;**5:**e009993. doi: 10.1136/bmjopen-2015-009993)

professional health-related education, public health and health administration."[24] Telehealth technology, such as videoconferencing, allows PCPs to receive face-to-face instruction on diagnosis of FASD, for example, and to demonstrate the skills they have acquired through distance learning. PCPs can receive tele-mentoring, or tele-consultation, from specialists located elsewhere to build their capacity to address complex cases such as FASD, or address alcohol or other substance use among their pregnant patients. Research shows that telehealth can improve access to care, reduce health care costs, improve health outcomes, and address workforce shortages in rural areas and other medically underserved communities.[25] Web-based technology, including distance-learning modalities and technology-enabled collaborative learning models, hold promise for expanding primary care capacity. They permit PCPs who cannot participate in on-site learning sessions to receive on-going education, training, and peer-to-peer exchange. The application of principles and best practices of adult learning, such as case-based discussions and self-directed online learning, can further equip the PCPs with the required knowledge and clinical skills to address FASDs and alcohol use among pregnant women.

Co-morbidities with Alcohol or Substance Use Disorders, and Social Determinants of Health

Research has shown that women with alcohol or substance use disorders have often experienced adverse social determinants of health, such as a history of adverse childhood experiences, intimate partner violence (IPV), other trauma, and/or a co-occurring mental disorder, such as depression, anxiety, or posttraumatic stress disorder.[26] Social determinants of health include factors like socioeconomic status, neighborhood and physical environment, community violence, employment, social support networks, and IPV, as well as access to health care. We know that drinking any alcohol during pregnancy, and especially high-risk alcohol use, increases the risk for FASDs. For women who are unable to stop their alcohol or other substance use during pregnancy (an indicator of a potential substance use disorder), there is the added fear that disclosure of their problem may result in legal consequences. The threat of legal consequences may deter women from seeking health care, prenatal care, and treatment for substance use.[27] Laws that punish or indirectly discriminate against pregnant women are often disproportionately enforced against low-income women and women of color,[28] and this contributes to the mistrust of health care providers by women of color. To be effective in improving PCP knowledge and attitudes and meeting program goals, you should consider how these co-morbidities and social determinants of health will be addressed in the program design detailed in the Project Narrative section.

[24] https://www.hrsa.gov/rural-health/telehealth

[25] The National Academies of Sciences, Engineering, Medicine. The Role of Telehealth in an Evolving Health Care Environment-Workshop Summary (2010). Retrieved 3/2020. https://www.nap.edu/read/13466/chapter/1.

[26] Substance Abuse and Mental Health Services Administration, *Guidance Document for Supporting Women in Co-ed Settings.* HHS Publication No. (SMA) 16-4979. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2016. Retrieved 3/2020. https://store.samhsa.gov/product/guidance-document-supporting-women-co-ed-settings

[27] *State Legislation on Substance Use During Pregnancy, A Self-Study Guide* (2019). Developed by the Alcohol and Substance-Exposed Pregnancy Prevention Initiative (AStEPP), a program of the Healthy Start EPIC Center, and supported by HRSA.

[28] *Criminalizing pregnancy, Policing pregnant women who use drugs in the USA*. Amnesty International (2017). Retrieved 2/2020. https://www.amnesty.org/download/Documents/AMR5162032017ENGLISH.pdf

II. Award Information

1. Type of Application and Award

Type(s) of applications sought: New

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

HRSA program involvement will include:

- Assuring the availability of HRSA personnel to participate in the planning and development of all phases of the project;
- Conducting ongoing reviews of the establishment and implementation of activities, procedures, measures, and tools for accomplishing the goals of the cooperative agreement;
- Participating, as appropriate, in conference calls, meetings and TA sessions that are conducted during the period of the cooperative agreement;
- Ensuring integration into HRSA programmatic and data reporting efforts;
- Assisting with the establishment and facilitation of collaborative relationships with federal and state contacts, HRSA-funded grants, and other entities that may contribute to successful project outcomes;
- Reviewing and providing advisory input on written documents, including information and materials to support the activities conducted through the cooperative agreement, prior to submission for publication or public dissemination; 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:

- Completing activities proposed in response to the Program-Specific Instructions section of this notice of funding opportunity (NOFO);
- Meeting with the federal project officer within 2 weeks after award to review the current strategies and to ensure the project and goals align with HRSA priorities for this activity;
- Providing ongoing, timely communication and collaboration with the federal project officer, including holding regular check-ins with the federal project officer;
- Providing the federal project officer with the opportunity to review, provide advisory input on written documents, including information and materials to support the activities conducted through the cooperative agreement, prior to submission for publication or public dissemination. Such review should start as part of concept development and include review of drafts and final products;

- Establishing contacts relevant to the project's mission such as federal and non-federal partners, and other HRSA projects that may be relevant to the project's mission;
- Collaborating with HRSA on ongoing review of activities, procedures and budget items, and interagency agreements;
- Assuring that all recipient administrative data and performance measure reports, as designated by HRSA, will be completed and submitted on time.

2. Summary of Funding

HRSA expects up to $1,000,000 to be available annually to fund one recipient. You may apply for a ceiling amount of up to $1,000,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The period of performance is September 1, 2020 through August 31, 2023 (3 years). Funding beyond the first year is subject to the availability of appropriated funds for the Supporting Fetal Alcohol Spectrum Disorders Screening and Intervention program 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.

Indirect costs under training awards to organizations other than state, local, or Indian tribal governments will be budgeted and reimbursed at 8 percent of modified total direct costs rather than on the basis of a negotiated rate agreement, and are not subject to upward or downward adjustment. Direct cost amounts for equipment, tuition and fees, and sub-grants and subcontracts in excess of $25,000 are excluded from the direct cost base for purposes of this calculation.

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.

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 Section IV.4 non-responsive and will not consider it for funding under this notice.

NOTE: Multiple applications from an organization are not allowable.
If for any reason (including submitting to the wrong funding opportunity number or making corrections/updates) an application is submitted more than once prior to the application due date, HRSA will only accept 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 Grants.gov using the SF-424 workspace application package associated with this NOFO following the directions provided at http://www.grants.gov/applicants/apply-for-grants.html.

The NOFO is also known as "Instructions" on Grants.gov. You must provide your email address when reviewing or preparing the workspace application package in order to receive notifications including modifications and/or republications of the NOFO on Grants.gov before its closing date. Responding to an earlier version of a modified notice may result in a less competitive or ineligible application. *Please note you are ultimately responsible for reviewing the For Applicants page for all information relevant to desired opportunities.*

2. Content and Form of Application Submission

Section 4 of HRSA's *SF-424 Application Guide* 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 *SF-424 Application Guide* 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 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. Indirect Cost Rate Agreement and proof of non-profit status (if applicable) do not count in the page limit. **We strongly**

urge you 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 to be considered under this notice.

Debarment, Suspension, Ineligibility, and Voluntary Exclusion Certification

1) You, on behalf of the applicant organization certify, 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 9: Other Relevant Documents*.

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

Program-Specific Instructions

Key Activities

To achieve the objectives stated in the Purpose section, you are encouraged to propose innovative strategies through key partnerships and collaborations to:

1) Recruit over the course of the 3-year period of performance to participate in education and TA activities, at least 20 practices[29] comprised of PCPs serving pregnant women and at least 20 practices comprised of PCPs serving children and adolescents, that are located, ideally, in multiple states, U.S. territories, tribes/tribal organizations, or communities that have high rates of binge drinking among pregnant women. As rural adults have higher rates of alcohol misuse than those in metropolitan areas,[30] at least 50 percent of the PCPs educated by this program should be practicing in rural and safety net settings. PCPs may include those participating in other HRSA-supported initiatives. Employ innovative recruitment and retention strategies that may include, but are not limited to, providing maintenance of certification, continuing education credits, certificates of completion, or incentives for participation.

2) Provide education to PCPs serving pregnant women to increase their knowledge and self-efficacy to: discuss avoidance of alcohol during pregnancy, screen pregnant women for alcohol use, provide brief intervention (such as engaging a patient in a short counseling conversation, providing feedback and advice), refer

[29] For the purposes of this NOFO, a practice is defined broadly as an ambulatory clinical setting in which one, two, or more clinicians provide health care in a single-specialty (e.g., primary care) or multispecialty practice (e.g., offering various types of medical specialty care within one organization).

[30] Webpage on *Substance Abuse in Rural Areas* on HRSA's Rural Health Information Hub. Retrieved 2/2020. https://www.ruralhealthinfo.org/topics/substance-abuse

high-risk pregnant women to specialty care, and communicate/collaborate with pediatric providers about known prenatal alcohol exposure.

3) Provide education to PCPs serving children and adolescents to increase their knowledge and self-efficacy to: screen children and adolescents for prenatal alcohol exposure among those suspected of FASD, and manage and provide referrals to necessary services for those identified with FASD, improve effective communication and shared decision making[31] with families caring for a child with a suspected or diagnosed FASD, and provide maternal and family referral, as needed, for alcohol or other substance misuse, mental health, or family support services.

4) Provide TA to participating PCPs and their practices on using quality improvement strategies to implement and sustain practice change on topics such as, but not limited to, integrating evidence-based screening, clinical guidelines, brief intervention, referral, documentation, and clinical decision support tools into practice workflows/electronic health records (EHR); coordinating with specialty and community services; and establishing partnerships for referral networks.

5) Convene a project advisory committee, comprised of individuals and families living with FASDs ("nothing about us without us"[32]), mothers in recovery from alcohol use disorder, and other key stakeholders/experts in the field, to guide project activities.

6) Identify, curate, incorporate, and build on (where appropriate) existing evidence-based education and training materials, tools, clinical guidelines and resources developed by federal agencies, national medical and professional associations, and stakeholders. The recipient shall not duplicate existing public health content, tools, clinical guidelines, or resources.

In addition to application requirements and instructions in Section 4 of HRSA's *SF-424 Application Guide* (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.

[31] Shared decision-making promotes family and clinician collaboration, with ultimate goals of improved health and satisfaction. Adams RC, Levy SE, and AAP Council on Children With Disabilities. Shared Decision-Making and Children With Disabilities: Pathways to Consensus. Pediatrics 2017;139; DOI: 10.1542/peds.2017-0956

[32] *Nothing about us without us* is a slogan used to communicate the idea that no policy should be decided by any representative without the full and direct participation of members the group(s) affected by that policy. This involves national, ethnic, *disability-based*, or other groups that are often thought to be marginalized from political, social, and economic opportunities. Retrieved 3/2020. https://zeroproject.org/nothing-about-us-without-us/

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

INTRODUCTION -- Corresponds to Section V's Review Criterion #1
Briefly describe the purpose of the proposed project.

NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion #1
Use and cite demographic data whenever possible to support the information provided. This section should help reviewers understand the communities and populations that will be served by the proposed project. See Section VIII. Other Information for resources that may be helpful in developing your needs assessments.

- Describe and document the problem to be addressed and supported by the proposed activities. Critically evaluate the need/demand in multiple states, U.S. territories, tribes/tribal organizations, or communities that have high rates of binge drinking among pregnant women for education and TA for PCPs to 1) screen pregnant women for alcohol use, provide brief intervention, and refer high-risk pregnant women to specialty care; and, 2) screen children and adolescents suspected of FASD for prenatal alcohol exposure suspected of FASD, and manage and provide referrals to necessary services for those identified with FASD, improve effective communication and shared decision making with families caring for a child with a suspected or diagnosed FASD, and provide maternal and family referral, as needed, for alcohol or other substance misuse, mental health, or family support services. Demonstrate that providing unmet education needs among these PCPs will contribute to improved health outcomes for their patient populations.

- Provide evidence supporting the selection of the PCP disciplines and geographic locations that the program will target, based on the prevalence of binge drinking among pregnant women, especially in rural areas, as requested in the Key Activities section above.

  Note: for purposes of this program, PCPs may include, but are not limited to, maternity care, family medicine, pediatric and nursing providers, especially those practicing in rural areas and medically underserved communities.

- Identify and describe major health care delivery system issues and conditions impacting the target populations of PCPs, as this will support the proposed plan to address such conditions. Examples include the challenges experienced by PCPs practicing in rural areas and medically underserved communities, developing referral networks, addressing the social determinants of health of their patient populations, etc.

- Demonstrate knowledge of rural and safety net settings serving pregnant women, children, and adolescents that will be reached through the proposed program.

METHODOLOGY -- Corresponds to Section V's Review Criteria #2 and #4

- Propose methods that you will use to address the stated needs and meet each of the program objectives and key activities . To achieve program objectives, you are encouraged to propose innovative strategies through key partnerships and collaborations.
- Include a description of any innovative methods that you will use to address the stated needs.

1) Goals and Objectives

State the overall goal(s) of the proposed project to both reduce alcohol use among pregnant women, and to improve developmental outcomes for children and adolescents with a suspected or diagnosed FASD, in states, U.S. territories, tribes/tribal organizations, or communities that have high rates of binge drinking among pregnant women, especially in rural areas. List the specific objectives that respond to the stated need and purpose of this project. The objectives should be specific, measurable, achievable, relevant, and time-oriented (SMART) with specific outcomes for each project year that are attainable in the stated timeframe.

2) Outreach and Recruitment Strategy

- Provide a detailed plan for how at least 20 practices comprised of PCPs serving pregnant women and at least 20 practices comprised of PCPs serving children and adolescents, that are located, ideally, in multiple states, U.S. territories, tribes/tribal organizations, or communities that have high rates of binge drinking among pregnant women, will be recruited and selected for participation in education and TA over the course of the 3-year period of performance. Describe recruitment plans for PCPs serving pregnant women separately from recruitment plans for PCPs serving children and adolescents. Your target settings, populations, and provider types should be based on the needs identified in the Needs Assessment section. You should propose recruiting PCPs practicing in rural and safety net settings or other HRSA-supported initiatives in rural areas and medically underserved communities.
- Provide a recruitment timeline for the 3-year period of performance. **It is expected that the recruitment of at least 10 practices serving pregnant women and at least 10 practices serving children and adolescents will be complete within the first 6 months of the period of performance**.
- Estimate the numbers and types of learners, and practice settings and locations of those who will participate in this education and TA program, over the course of the 3-year period of performance.
- Describe how you will employ innovative recruitment and retention strategies which may include, providing maintenance of certification, continuing education credits (CECs), certificates of completion, or incentives for participation. If offered, specify how CECs or certificates will be conferred.

- You are encouraged to develop strategic partnerships with any of the following to achieve recruitment or other program goals:
  - HRSA-funded partners to support recruitment of rural and safety net PCPs such as, but not limited to,: *Health Centers*[33]*:* Primary Care Associations (PCAs), HRSA/Bureau of Primary Health Care National Health Center Training and Technical Assistance Partners (NTTAP), Health Center Controlled Networks (HCCNs); *Rural Health*[34]*:* State Offices of Rural Health[35] (SORHs), Rural Health Information Hub[36] (RHIhub), Rural Health Research Gateway[37]; *Maternal and Child Health*[38]*:* Title V Maternal and Child Health Services Block Grant Program state contacts; HIV/AIDS: TargetHIV.[39]
  - National medical and professional associations and stakeholders listed below in 4) Learner Competencies, Education, and TA Content.

3) Education and TA Modalities

- Describe a variety of evidence-based modalities grounded in adult learning principles that you will use to increase the knowledge and self-efficacy of the target populations of PCPs and strategies for optimizing uptake and implementation of evidence-based clinical guidelines and recommendations.

  Interdisciplinary modalities may include, but are not limited to, primary care practice transformation coaching,[40] telehealth approaches such as provider-to-provider tele-consultation, and tele-mentoring such as Project ECHO, didactic, skills-based, peer exchange, and continuous quality improvement approaches, including learning collaboratives. You should propose models that have the best evidence base for sustaining practice change in primary care settings.
- Describe the duration of the modalities and frequency of learning sessions and/or collaboratives (e.g., once a month for 12 months, etc.).
- Describe what technologies you will use to meet the program objectives and key activities for education and TA, including e-learning systems, course management software, web-based conferencing, social media, and social networking tools, among others.

4) Learner Competencies, Education, and TA Content

- Specify the competencies expected of learners at the completion of the education and TA activities. Identify competencies based on the modality and duration of the education received.
- Describe the evidence-based education, training and TA materials, tools, clinical guidelines, curricula (if applicable) and resources you intend to

[33] https://bphc.hrsa.gov/qualityimprovement/strategicpartnerships/index.html
[34] https://www.hrsa.gov/rural-health/index.html
[35] https://nosorh.org/nosorh-members/nosorh-members-browse-by-state/
[36] https://www.ruralhealthinfo.org/
[37] https://www.ruralhealthresearch.org/
[38] https://mchb.tvisdata.hrsa.gov/Home/StateContacts
[39] https://www.hrsa.gov/library/targethiv
[40] https://www.ahrq.gov/ncepcr/care/chronic-manual/index.html

use, or develop, to educate, implement and sustain practice change among:

a) *PCPs serving pregnant women*, and
b) *PCPs serving children and adolescents.*

The program should identify, curate, incorporate, and build on (where appropriate) existing materials developed by federal agencies and national medical and professional associations and stakeholders. **Education and training resources developed under this program should not duplicate existing public health content, tools, clinical guidelines, or resources**.

Federal agencies with training content developed in this area include, but are not limited to, the CDC, the National Institute for Alcohol Abuse and Alcoholism, the Indian Health Service, and the Substance Abuse and Mental Health Services Administration. Professional associations with training content developed in this area include, but are not limited to, the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP), among others. The National Organization on Fetal Alcohol Syndrome (NOFAS) is an organization that works to promote the prevention of FASDs and to improve understanding about individuals living with FASDs and their families.

- Describe how education and training materials will be culturally and linguistically appropriate for the target populations of PCPs and their respective patient populations.
- Describe how education and training materials will help PCPs address the social determinants of health of their respective patient populations.

5) Project Advisory Committee to Guide Program Activities

- Describe your plan to engage a project advisory committee to guide program activities. The advisory committee should be comprised of individuals and families living with FASDs ("nothing about us without us"), mothers in recovery from alcohol use disorder, and other key stakeholders and local and national experts in the field. Describe who and how many people will be on your committee, roles and responsibilities, frequency of meetings (which can be virtual), and how the advisory committee will support the planning and implementation of key activities.
- Include in *Attachment 5*, noting overall page limitations, select copies of letters from proposed advisory members indicating their willingness to perform in accordance with the plan presented in the application.

6) Dissemination Plan

- Provide a plan to disseminate reports, products, and/or project outputs, including peer-reviewed publications, and opportunities for information exchange to ensure key target audiences receive the project information.

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

- 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.

- Propose a timeline that includes each activity and identifies responsible project personnel, including the personnel of any key partners.

- Identify meaningful support and collaboration with key partners or stakeholders in planning, designing, and implementing all activities, including developing the application.

- The work plan's activities should be supported by, aligned with, and appropriate for, the needs assessment, proposed budget, and organizational capacity.

Logic Model

Submit a logic model *(Attachment 2)* supporting the design and management of 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 address the following areas:

- Assumptions (What problem does the program address?);
- Program Purpose (reasons for proposing the intervention; how the program offers a solution);
- Target population(s) (e.g., the individuals to be served by the intervention);
- Inputs (e.g., organizational profile, collaborative partners, key personnel, budget, existing resources);
- Activities (What does the program do?);
- Outputs (i.e., the direct products of program activities); and
- Short-term, Intermediate, Long-term Outcomes (i.e., expected changes in skills, attitudes, knowledge, behavior, health status, health conditions, and/or systems changes).

Although there are similarities, a logic model is not a work plan. A work plan is an "action" guide with a timeline 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.

RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion #2

- 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.
- Discuss potential challenges in recruiting and retaining providers and practices comprised of PCPs serving pregnant women and providers and practices comprised of PCPs serving children and adolescents in multiple states, U.S. territories, tribes/tribal organizations, or communities, especially those practicing in rural areas and medically underserved communities. Describe approaches that you will use to resolve potential challenges.

EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criterion #3

- 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.
- Document a plan for measuring program outcomes including, but not limited to:
    a) increased knowledge of PCPs educated through this program about the hazards of prenatal alcohol exposure and the options for screening for alcohol use during pregnancy and prenatal alcohol exposure among children and adolescents suspected of FASD;
    b) increased self-efficacy of PCPs educated through this program in the recommended approach of screening, intervention, and referral to services, for their respective patient population; and
    c) increased use of appropriate methods of screening for their respective patient populations of PCPs educated through this program, for alcohol use during pregnancy and prenatal alcohol exposure among children and adolescents suspected of an FASD.
- Describe a plan for measuring and evaluating program activities that contribute to population-based outcomes such as reduced alcohol use among pregnant women, and improved developmental outcomes for children and adolescents with a suspected or diagnosed FASD.
- 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 project personnel, data management software) in a way that allows for accurate and timely reporting of performance outcomes.
- Describe your organization's current experience, skills, and knowledge, including project personnel, 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 education and TA 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 #5

- Succinctly describe your organization's current mission and structure, current activities, and how these elements will contribute to the organization's ability to conduct the program requirements and meet program expectations.
- Include an applicant organizational chart that clearly shows how your organization is structured, as *Attachment 6*.
- Describe your organization's capacity and expertise to provide education and TA activities, create linkages among stakeholders, and measure performance for building provider capacity to reduce alcohol use among pregnant women, and to improve developmental outcomes for children and adolescents with a suspected or diagnosed FASD.
- Describe current experience, skills, and knowledge of the proposed program personnel. Describe peer-review publications, other published materials, and previous work of a similar nature.
- Describe expertise and past work in topical areas such as screening, brief intervention, and referral of pregnant women to treatment for substance use and mental disorders; screening children and adolescents for prenatal alcohol exposure, and management and referral of those identified with FASD; the family-centered medical home model; child development; referral network development; trauma informed models and approaches to care, and related topics.
- Demonstrate expertise and past success with quality improvement and delivering TA to implement and sustain practice change in primary care settings.
- Demonstrate expertise and past success with delivering adult education and TA using the modalities you are proposing in this application, including, but not limited to telehealth approaches, primary care practice transformation coaching, and others.
- Discuss how the organization will follow the approved plan, as outlined in the application, properly account for federal funds, and document all costs to avoid audit findings.
- Describe organizations who will partner with yours to fulfill the goals of the program and meet the proposed objectives. Include in Attachment 5, noting overall page limitations, select copies of letters of agreement, memoranda of understanding or similar documents from key organizations/individuals of their willingness to perform in accordance with the plan presented in the application. If applicable:
  - Describe the administrative and organizational structure within which the project will function, including relationships with other relevant departments, institutions, organizations, agencies, or sub-recipients. Overall organizational capacity may be demonstrated through partnerships with these other entities.

- Describe relationships with any organizations or sub-recipients, with which you intend to partner, collaborate, coordinate efforts, or receive assistance from, while conducting project activities.
- Describe your planned oversight of, and frequency of communication with any partners or sub-recipients. All sub-recipients must report to your organization (the award recipient) and are held to the same award requirements.
- A project organizational chart must be included as *Attachment 7*. This is a one-page figure that depicts the organizational structure of the project, including any critical partnerships or other significant key stakeholders, and paths of oversight and communication with other organizations, or sub-recipients. Include the percentage of work your organization will do, as well as that of your partners or sub-recipients.

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 Capacity	(3) Evaluative Measures (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(6) Support Requested – the budget section should include sufficient justification to allow reviewers to determine the reasonableness of the support requested.

iii. Budget

See Section 4.1.iv of HRSA's *SF-424 Application Guide*. Please note: the directions offered in the SF-424 Application Guide may differ from those offered by Grants.gov. Follow the instructions included in the 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 can avoid audit issues during the implementation phase.

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

The 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 SF-424 Application Guide 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 *SF-424 Application Guide*.

Reminder: Applications must include the budget narrative for all 3 years of the project. The narrative for Years 2–3 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.

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. You must clearly label **each attachment**.

Attachment 1: Work Plan

Attach the work plan for the project that includes all information detailed in Section IV.2.ii. Project Narrative.

Attachment 2: Logic Model

Attach the logic model for the project that includes all information detailed in Section IV.2.ii. Project Narrative.

Attachment 3: Staffing Plan and Job Descriptions for Key Personnel (see Section 4.1. of HRSA's *SF-424 Application Guide)*

Keep each job description to one page in length as much as 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 4: Biographical Sketches of Key Personnel

Include biographical sketches for persons occupying the key positions described in *Attachment 2*, not to exceed two pages in length 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 5: 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. Ensure letters of agreement are signed and dated.

Attachment 6: Applicant Organizational Chart

Provide a one-page figure that depicts the organizational structure and where the Supporting Fetal Alcohol Spectrum Disorders Screening and Intervention program will be managed and by whom.

Attachment 7: Project Organizational Chart

Provide a one-page figure that depicts the organizational structure of the project. This is a one-page figure that depicts the organizational structure of the project, including any critical partnerships or other significant key stakeholders, and paths of oversight and communication with other organizations, or sub-recipients. Include the percentage of work your organization will do, as well as that of your partners or sub-recipients

Attachment 8: Tables, Charts, etc.

To give further details about the proposal (e.g., Gantt or PERT charts, flow charts).

Attachments 9–15: Other Relevant Documents

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

3. Dun and Bradstreet Data Universal Numbering System (DUNS) Number and System for Award Management

You must obtain a valid DUNS number, also known as the Unique Entity Identifier, for your organization/agency and provide that number in the application. You must also register with the System for Award Management (SAM) and continue to maintain active SAM registration with current information at all times during which 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))**.**

HRSA may not make an award to an applicant until the applicant has complied with all applicable DUNS and SAM requirements and, if an applicant has not fully complied with the requirements by the time HRSA is ready to make an award, HRSA may determine

that the applicant is not qualified to receive an award and use that determination as the basis for making an award to another applicant.

If 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.

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

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

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

SAM.GOV ALERT: For your SAM.gov registration, you must submit a notarized letter 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 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 and representations annually through SAM located at SAM.gov.

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 *June 9, 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 *SF-424 Application Guide* for additional information.

5. Intergovernmental Review

The Supporting Fetal Alcohol Spectrum Disorders Screening and Intervention program 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 *SF-424 Application Guide* for additional information.

6. Funding Restrictions

You may request funding for a period of performance of up to 3 years, at no more than $1,000,000 per year (inclusive of direct **and** indirect costs). 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 45 CFR § 75.307.

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.

Review criteria are used to review and rank applications. The Supporting Fetal Alcohol Spectrum Disorders Screening and Intervention program 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 Introduction and Needs Assessment

- The strength and completeness of:
  - The applicant's explanation of the problem including the need/demand for education of and TA for the target population of PCPs in multiple states, U.S.

territories, tribes/tribal organizations, or communities that have high rates of binge drinking among pregnant women, especially in rural areas.
    - The description of the 1) clinical educational needs of the target population of PCPs, in the recommended approach of screening, intervention, and referral to services, for their respective patient population and 2) the TA needs of the target population of PCPs to implement and sustain practice change required to address the topics proposed.
- Clear demonstration of knowledge of rural and safety net settings serving pregnant women, children and adolescents, respectively.

Criterion 2: RESPONSE (30 points) – Corresponds to Section IV's Methodology, Work Plan, and Resolution of Challenges

Methodology (10 points)
- The strength, feasibility, completeness, and innovation of the proposed methodology described in the application is capable of addressing the problem and attaining the project objectives.
- The strength and reasonableness of the proposed education and technical assistance modalities and content will meet the education needs and learner competencies of the target populations of PCPs.
- The degree to which the education and TA content is evidence-based, incorporates and builds on existing materials, and does not duplicate existing public health content or resources.
- The strength of the demonstrated understanding of culturally and linguistically appropriate materials, and the extent to which those materials will support PCPs to address the social determinants of health of their respective patient populations.
- The strength of the proposed roles and responsibilities of the Project Advisory Committee to ensure the project will meet the stated goals and objectives with evidence that it will be comprised of individuals and families living with FASDs, mothers in recovery from alcohol use disorder, and other key stakeholders and local and national experts in the field.
- The extent to which the dissemination plan is feasible and complete.

Participant Recruitment and Retention (5 points)
- The degree to which the proposed outreach and recruitment strategies of PCP practices are complete, feasible, innovative, and capable of reaching the target geographic locations, ideally in multiple states, U.S territories, tribes/tribal organizations, or communities, and the specific disciplines with evidence of meeting the required timeframes: 1) the recruitment of at least 10 practices serving pregnant women and at least 10 practices serving children and adolescents will be complete within the first 6 months of the period of performance, and 2) at least 20 practices comprised of PCPs serving pregnant women and at least 20 practices comprised of PCPs serving children and adolescents, over the course of the 3-year period of performance.

Work Plan (10 points)
- The strength and specificity of the work plan including the reasonableness of the timeline, activities, and identification of responsible project personnel, to achieve

each of the objectives proposed in the Methodology section for the entire period of performance.
- The strength and feasibility of the proposed plan to work with strategic partners and collaborate with key stakeholders to plan, design, and implement all project activities, including developing the application.
- The strength and reasonableness of the logic model to demonstrate the relationships among resources, activities, outputs, target population, short- and long-term outcomes, and that proposed activities tie to the intended impact.

Resolution of Challenges (5 points)
- The strength and completeness of the discussion of challenges the applicant is likely to encounter in designing and implementing the activities described in the work plan, including specific challenges in recruiting and retaining practices for participation.
- The feasibility, innovation, and completeness of the approaches the applicant will use to resolve such challenges.
- The strength of the identification and description of potential obstacles for implementing the program performance evaluation and the plan to address those obstacles.

Criterion 3: EVALUATIVE MEASURES (15 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity

- The strength, completeness, and effectiveness of the applicant's evaluation and performance measurement plan.
- Clear demonstration that the program performance evaluation will contribute to continuous quality improvement.
- Clear demonstration that the systems and processes proposed will support the 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., data management software) in a way that allows for accurate and timely reporting of performance outcomes.
- The strength of the plan for measuring program objectives and outcomes including increased knowledge, self-efficacy, and screening for alcohol use during pregnancy and prenatal alcohol exposure among children and adolescents suspected of FASD.
- Clear description of a plan for measuring and evaluating program activities that contribute to population-based outcomes.
- Strength of the proposed data collection strategy to collect, analyze, and track data to measure process and impact/outcomes, and explanation of how the data will be used to inform program development and service delivery.

Criterion 4: IMPACT (15 points) – Corresponds to Section IV's Methodology and Work Plan

- The feasibility and effectiveness of the plan to disseminate reports, products, and/or project outputs and identify opportunities for information sharing to ensure key target audiences receive the project information.
- The feasibility of the plan to attain the project objectives.

- The degree to which the project activities are replicable and can inform public policies and programs.
- The strength and feasibility of the partnerships and collaborations with those doing existing work in the field (e.g., HRSA-funded initiatives described).

Criterion 5: RESOURCES/CAPABILITIES (25 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity and Organizational Information

Technical Support Capacity (13 points)

- The strength of the applicant's technical capability to carry out the proposed project.
- Clear demonstration of current experience, skills, and knowledge, including project personnel, materials published, and previous work of a similar nature.
- Clear demonstration that the project personnel identified on the project responsible for measuring performance and refining, collecting, and analyzing data for evaluation are qualified by training and/or experience to fulfill the proposed data-related and measurement activities.

Organizational Information (12 points)

- The strength and feasibility of the applicant organization, proposed partners, and the expertise and past experience of project staff to address the objectives and goals of the program.
- Clear demonstration that proposed partners, including sub-recipients, are appropriate, and that, in applicable, the applicant described relationships to, roles and responsibilities of program activities, and demonstrates commitments from (e.g., letter of agreement in *Attachment 5*), any entity that is a critical partner in this program.
- Clear demonstration of expertise and past work to provide education and TA, create linkages among stakeholders, and measure performance for building provider capacity in topical areas such as screening, brief intervention, and referral of pregnant women to treatment for substance use and mental disorders; screening children and adolescents for prenatal alcohol exposure, and management and referral of those suspected of FASD; the family-centered medical home model; child development; referral network development; trauma informed models and approaches to care, and related topics.
- Demonstrated expertise and past success to engage pediatric and maternity care practices in measurable improvement to implement and sustain practice change in primary care settings.
- Demonstrated expertise and past success with delivering education and TA using the modalities being described in the application, including, but not limited to telehealth approaches, quality improvement collaboratives, primary care practice transformation coaching, and others.
- Clear discussion of 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.

Criterion 6: SUPPORT REQUESTED (5 points) – Corresponds to Section IV's Budget and Budget Narrative

- The reasonableness of the proposed budget for each year of the period of performance in relation to the objectives, the 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.

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 (45 CFR § 75.205).

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.

Effective January 1, 2016, HRSA is required to review and consider any information about your organization that is in the Federal Awardee Performance and Integrity Information System (FAPIIS). You may review and comment on any information about your organization that a federal awarding agency previously entered. HRSA will consider any of your comments, in addition to other information in FAPIIS 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 (45 CFR § 75.212).

VI. Award Administration Information

1. Award Notices

HRSA will issue the Notice of Award (NOA) prior to the start date of September 1, 2020. See Section 5.4 of HRSA's *SF-424 Application Guide* 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. See 45 CFR § 75.101 Applicability 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.

Human Subjects Protection
Federal regulations (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained. If you anticipate research involving human subjects, you must meet the requirements of the HHS regulations to protect human subjects from research risks.

3. Reporting

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

1) **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/UT9.html. The type of report required is determined by the project year of the award's period of performance.

Type of Report	Reporting Period	Available Date	Report Due Date
a) New Competing Performance Report	September 1, 2020 – August 31, 2023 *(administrative data and performance measure projections, as applicable)*	Period of performance start date	120 days from the available date
b) Non-Competing Performance Report	September 1, 2021 – August 31, 2022	Beginning of each budget period (Years 2–4, as applicable)	120 days from the available date
c) Project Period End Performance Report	September 1, 2022 – August 31, 2023	Period of performance end date	90 days from the available date

The full OMB-approved reporting package is accessible at https://mchb.hrsa.gov/data-research-epidemiology/discretionary-grant-data-collection (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.

3) **Integrity and Performance Reporting.** The NOA will contain a provision for integrity and performance reporting in FAPIIS, as required in 45 CFR part 75 Appendix XII.

VII. Agency Contacts

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

Marc Horner
Grants Management Specialist
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 443-4888
Email: mhorner@hrsa.gov

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

Dawn Levinson, MSW
Behavioral Health Lead, Division of Healthy Start and Perinatal Services
Attn: Supporting Fetal Alcohol Spectrum Disorders Screening and Intervention program
Maternal and Child Health Bureau
Health Resources and Services Administration
5600 Fishers Lane, Room 18N76
Rockville, MD 20857
Telephone: (301) 945-0879
Email: dlevinson@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: support@grants.gov
Self-Service Knowledge Base: https://grants-portal.psc.gov/Welcome.aspx?pt=Grants

Successful applicants/recipients may need assistance when working online to submit information and reports electronically through HRSA's EHBs. For assistance with submitting information in HRSA's 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: Thursday, April 30, 2020
Time: 2–3:30 p.m. ET
Call-In Number: 1-877-937-9313
Participant Code: 377-971-87
Weblink: https://hrsa.connectsolutions.com/r95nvy3drg0n

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

Helpful Resources and Informational Websites

1. Bright Futures (American Academy of Pediatrics (AAP))
   https://brightfutures.aap.org/

2. CDC FASDs: Information for Healthcare Providers
   https://www.cdc.gov/ncbddd/fasd/hcp.html

3. Healthy People 2020
   https://www.healthypeople.gov/2020/topics-objectives

4. HRSA's Health Center Program
   https://bphc.hrsa.gov/about/index.html

5. HRSA's National Consortium of Telehealth Resource Centers
   https://www.telehealthresourcecenter.org/

6. HRSA Strategy to Address Intimate Partner Violence, 2017–2020
   https://www.hrsa.gov/sites/default/files/hrsa/HRSA-strategy-intimate-partner-violence.pdf

7. National Organization on Fetal Alcohol Syndrome (NOFAS)
   https://www.nofas.org/

8. Screening, Brief Intervention, and Referral to Treatment (SBIRT)
   https://www.integration.samhsa.gov/clinical-practice/sbirt

9. The FASD Toolkit, AAP
   https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/fetal-alcohol-spectrum-disorders-toolkit/Pages/default.aspx

10. National Institute on Alcohol Abuse and Alcoholism (NIAAA) Fetal Alcohol Exposure, (NIH)
    https://www.niaaa.nih.gov/publications/brochures-and-fact-sheets/fetal-alcohol-exposure

Tips for Writing a Strong Application

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