U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Federal Office of Rural Health Policy
Office for the Advancement of Telehealth

Evidence Based Telehealth Network Program

Funding Opportunity Number: HRSA-21-082
Funding Opportunity Type: New
Assistance Listings (CFDA) Number: 93.211

NOTICE OF FUNDING OPPORTUNITY

Fiscal Year 2021

Application Due Date: April 2, 2021

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: January 12, 2021

Whitney Wiggins, MA
Public Health Analyst, Office for the Advancement of Telehealth
Telephone: (301) 443-4966
Email: wwiggins@hrsa.gov

Authority: 42 U.S.C. § 254c -14 (§ 330I of the Public Health Service Act)

EXECUTIVE SUMMARY

The Health Resources and Services Administration (HRSA) is accepting applications for the fiscal year (FY) 2021 Evidence Based Telehealth Network Grant Program. The two-fold purpose of this program is (1) to demonstrate how health care systems can increase access to health care services utilizing **Direct-to-Consumer (DTC) Telehealth** technologies and (2) to conduct evaluations of those efforts to establish an evidence base for assessing the effectiveness of Direct-To-Patient Telehealth care for patients, providers, and payers.

Funding Opportunity Title:	Evidence Based Telehealth Network Program
Funding Opportunity Number:	HRSA-21-082
Due Date for Applications:	April 2, 2021
Anticipated Total Annual Available FY 2021 Funding:	$4,900,000
Estimated Number and Type of Awards:	Up to 14 cooperative agreements
Estimated Award Amount:	Up to $350,000 per year
Cost Sharing/Match Required:	No
Period of Performance:	September 01, 2021 through August 31, 2026 (5 years)
Eligible Applicants:	Eligible applicants shall be domestic public or private, non-profit or for-profit entities with demonstrated experience utilizing telehealth technologies to serve rural underserved populations. This includes faith-based, community-based organizations, and federally-recognized tribes and tribal organizations. 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: Tuesday, February 2, 2021
Time: 3 - 4:30 p.m. EST
Call-In Number: 1-888-790-2022
Participant Code: 7490880
Weblink: https://hrsa.connectsolutions.com/nofo_technical_assistance_call/
Playback Number: 1-800-835-3844
Passcode: 20221

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I. Program Funding Opportunity Description

1. Purpose

This notice announces the opportunity to apply for funding under the Evidence Based Telehealth Network Program (EB THNP). The two-fold purpose of this award is (1) to demonstrate how health networks can increase access to health care services utilizing telehealth technologies and (2) to conduct evaluations of those efforts to establish an evidence base for assessing the effectiveness of telehealth care for patients, providers, and payers.

The implementation of telehealth technology is rapidly expanding into health systems.[1] HRSA defines telehealth as the use of electronic information and telecommunication technologies to support and promote long-distance clinical health care, patient and professional health-related education, public health and health administration. Telehealth modalities that support clinical treatment may include video conferencing, the internet, store-and-forward imaging, streaming media, and terrestrial and wireless communications. Rising evidence supports that many health conditions can be addressed with a virtual in home visit from a doctor to his or her patient.[2] In 2015, the American College of Physicians declared their position and support for Direct-to-Consumer (DTC) considering the patient has an established relationship with the providers, and the care meets in person standards of quality.[3]

For this NOFO, applicants must propose to provide **DTC telehealth services to patients within established telehealth networks.** This can be accomplished, in part, by identifying and partnering with local established health care facilities (especially primary care facilities) within the target service area, elevating the trusted patient-provider relationship, access, and quality of care directly to the patient via telehealth. Also, this service will allow for the expansion of access to care in Medically Underserved Areas (MUA) and primary care or mental health defined Health Professional Shortage areas (HPSA). The EB THNP program presents the opportunity for network sites that are currently or have previously utilized telehealth as defined above to efficiently and effectively pilot and/or expand DTC telehealth care. Applicants for this EB THNP Program must utilize synchronous (real-time virtual visits) audio-visual technology and may include remote patient monitoring (RPM) to provide DTC telehealth care to patients (*see Appendix*). This EB THNP program will expand access to health services in three clinical primary focus areas: (1) Primary Care, (2) Acute Care, and (3) Behavioral Health Care (*see Appendix*). In addition, applicants have the option to address one of the following secondary focus areas: Maternal Care, Substance Use Disorder, or Chronic Care Management.

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[1] Elliott, T., & Yopes, M. C. (2019). Direct-to-consumer telemedicine. *Journal of Allergy and Clinical Immunology.in Practice, 7*(8), 2546-2552. doi:http://dx.doi.org.ezproxyhhs.nihlibrary.nih.gov/10.1016/j.jaip.2019.06.027

[2] Gough, Frances & Budhrani, Sunil & Cohn, Ellen & Dappen, Alan & Leenknecht, Cindy & Lewis, Bill & Mulligan, Deborah & Randall, Deborah & Rheuban, Karen & Roberts, Lisa & Shanahan, Terrance & Webster, Kathy & Krupinski, Elizabeth & Bashshur, Rashid & Bernard, Jordana. (2015). *ATA Practice Guidelines for Live, On Demand Primary and Urgent Care.* Telemedicine journal and e-health: the official journal of the American Telemedicine Association. 21. 10.1089/tmj.2015.0008.

[3] Welch, B. M., Harvey, J., O'Connell, N. S., & McElligott, J. T. (2017). Patient preferences for direct-to-consumer telemedicine services: a nationwide survey. *BMC health services research*, *17*(1), 784. https://doi.org/10.1186/s12913-017-2744-8

Changes to reimbursement policies related to in-home telehealth services and RPM in recent years, particularly in the Medicare program, have laid the framework to enable providers to feasibly integrate these technologies into their practices. For example, even prior to COVID-19, Medicare began to allow beneficiaries to receive telehealth services at home for a limited set of services/conditions including home dialysis and the treatment of a substance use disorder or a co-occurring mental health disorder.[4] Home health is also an example of how the Medicare program has expanded the ability of home health agencies (HHAs) to use RPM technologies to augment the health care of the patients they serve. Recently, Medicare explicitly allowed HHAs to provide RPM services to their patients to help foster the adoption of emerging technologies by HHAs and result in more effective care planning.[5,6] Such approaches, to the extent that they strengthen rather than supplant existing patterns and systems of care, reinforce the objectives of this funding opportunity. Namely, a key objective of this program is to demonstrate how providers can use DTC telehealth services in a way that enhances the existing health care infrastructure, as opposed to incentivizing care delivery that circumvents and disadvantages providers in local communities, including rural areas.

Applicants are encouraged to include populations that have historically suffered from poorer health outcomes, health disparities, and other inequities, as compared to the rest of the rural population, when addressing health care needs via telehealth. Examples of these populations include, but are not limited to, racial and ethnic minorities, person/persons experiencing homelessness, pregnant women, disabled individuals, youth and adolescents, etc.

2. Background

This program is authorized by Section 330I(d)(1) of the Public Health Service Act (42 USC §254c-14(d)(1)).

The Federal Office of Rural Health Policy (FORHP) is the focal point for rural health activities within Health and Human Services (HHS). The Office for the Advancement of Telehealth (OAT) is located within HRSA and supports a wide range of telehealth activities, including the EB THNP program.

Rural communities continue to face an increase in disparities for health outcomes compared to their urban counterparts. Often, rural communities are host to "health deserts" with high percentage of deaths from heart disease, stroke, and chronic lower respiratory disease. Moreover, over 6 million individuals suffer from mental health conditions.[7] Telehealth can have several benefits in rural communities. For patients who

[4] Center for Connected Health Policy. (January 2020). Billing for Telehealth Encounters, https://www.cchpca.org/sites/default/files/2020-01/Billing%20Guide%20for%20Telehealth%20Encounters_FINAL.pdf
[5] Medicare and Medicaid Programs; CY 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations, Final Rule with Comment Period. 83 Federal Register 56406. (2018, November 13). https://www.federalregister.gov/documents/2018/11/13/2018-24145/medicare-and-medicaid-programs-cy-2019-home-health-prospective-payment-system-rate-update-and-cy
[6] Centers for Medicare & Medicaid Services. (2018, October 31). CMS Takes Action to Modernize Medicare Home Health. https://www.cms.gov/newsroom/press-releases/cms-takes-action-modernize-medicare-home-health-0
[7] Baird M. & Larson D. (2020, February 7) Telehealth's untapped potential in rural America, Medical Economics. https://www.medicaleconomics.com/view/telehealths-untapped-potential-rural-america

reside in these communities, having increased access to virtual visits can reduce the distance traveled and time required to receive care, increase access to health care specialist, and increase privacy and confidentiality especially for patients overcoming stigma surrounding certain medical conditions.[8]

The recent Public Health Emergency revealed that DTC telehealth is a way to leverage value-based care for patients.[9] For example, Accountable Care Organizations (*see Appendix*) continued to proactively engage patients utilizing DTC to conduct annual wellness visits. In this case, the patients are protected, the elements of the comprehensive assessment are performed, and lastly the value of the conversation and the patient provider relationship is maintained.[10]

DTC telehealth ideally allows patients to receive care on their own time and in an accessible way. Therefore, in efforts to ensure continuity of care and further reduce telehealth inequities, community health workers should have an essential role in program navigation and implementation.[11] These individuals build the networks capacity to address health issues by creating connections between vulnerable populations and healthcare providers and help patients navigate healthcare and social service systems.

The EB THNP program supports and encourages projects that address the needs of a wide range of population groups, including, but not limited to, low-income populations, the elderly, pregnant women, youth, adolescents, ethnic and racial minorities, homeless populations, and individuals with special health care needs. It is important to note that rural racial and ethnic minority populations face even greater challenges in terms of access to care and related health care challenges that are often overlooked. Recognizing that within ethnic minority populations have a lower rate of participation in telemedicine, applicants are encouraged to identify and bridge the gap between social determinants of health and other systemic issues that could contribute to achieving health equity with regards to participating in telehealth services.[12]

You must base your proposed project on established practices. Applicants are encouraged to work with your National and Regional Telehealth Resource Center to identify best or promising practices in effectively integrating your proposed project into your existing health care practice. Applicants are also encouraged to visit the HHS Telehealth website, to find resources and best practices for providers. In addition, applicants may visit the HRSA Training and Technical Assistance Hub website, which houses all HRSA training and technical assistance resources to extend the reach of our training and technical assistance resources and further the impact of HRSA award recipients and stakeholders. Resources are organized by topic and some resources may be listed under multiple topics.

[8] Majerol M., Nadler J., Schulte A. (2019, November 27), Narrowing the rural urban health divide: bringing virtual health to rural communities, Deloitte https://www2.deloitte.com/us/en/insights/industry/public-sector/virtual-health-telemedicine-rural-areas.html
[9] Baile et al, 2020 Confronting Rural America's Health Care Crisis, https://bipartisanpolicy.org/report/confronting-rural-americas-health-care-crisis/
[10] https://caravanhealth.com/CaravanHealth/media/Resources-Page/Telehealth_AWV_AWV-033-20200406-APP.pdf
[11] https://www.ruralhealthinfo.org/toolkits/community-health-workers/1/introduction
[12] https://www.healthtechmagazines.com/telehealth-and-addressing-health-equity/

Lastly, all award recipients will have the opportunity to work closely with technical assistance (TA) providers throughout the five-year period of performance. The targeted TA will assist award recipients with achieving desired project outcomes, sustainability and strategic planning, and will ensure alignment of the awarded project with the EB THNP Program goals. The TA is provided to award recipients at no additional cost. This support is an investment made by HRSA in order to ensure the success of the awarded projects. HRSA has found that most award recipients benefit greatly from the support provided through these collaborations. If funded, award recipients will learn more about the targeted technical assistance and evaluation support.

II. Award Information

1. Type of Application and Award

Type of applications sought: New

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

HRSA program involvement will include:

- Reviewing and providing recommendations on the final work plan;
- Ongoing review of award activities and input on content or approach;
- Participating in conference calls or meetings with the award recipients;
- Supporting collaboration between the EB THNP program award recipients and the Telehealth-Focused Rural Health Research Center award recipient;
- Providing common measures that must be reported by all recipients;
- Reviewing products or publications before dissemination;
- Reviewing reimbursement requests for telehealth services that cannot be reimbursed by third party payers; and
- Reviewing and providing recommendations regarding additional uses of the telehealth beyond DTC services. This may include using related telehealth technologies for provider education, or to provide clinical services for patients, beyond the award's primary focus of care.

The cooperative agreement recipient's responsibilities will include:

- Adhering to HRSA guidelines pertaining to acknowledgement and disclaimer on all products produced by HRSA award funds, per Section 2.2 of the Application Guide (**Acknowledgement of Federal Funding**);
- Completing activities included in the final approved work plan, specifically data collection on measures identified by HRSA;
- Actively participating in efforts to contribute to the telehealth evidence- base;
- Participating in conference calls or meetings with HRSA and technical assistance provider;
- Networking with telehealth stakeholders;
- Engaging in webinars presented by TA providers (e.g., program best practices, sustainability, etc.);

- Identifying professional opportunities to present, exhibit, or publish program findings that contribute to the telehealth evidence-base;
- Collaborating with HRSA in ongoing review of activities and budgets; and
- Responding timely to requests for information, including requests for data submissions, from HRSA or the Telehealth-Focused Rural Health Research Center award recipient (*see Appendix*).

2. Summary of Funding

HRSA estimates approximately $4,900,000 to be available annually to fund up to 14 recipients. You may apply for a ceiling amount of up to $350,000 total cost (includes both direct and indirect, facilities and administrative costs) per year. The period of performance is September 1, 2021 through August 31, 2026 (5 years). Funding beyond the first year is subject to the availability of appropriated funds for the EB THNP 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.

The limitation on indirect cost rates is 15 percent (42 U.S.C. §254c-14(k)(7)).

III. ELIGIBILITY Information

1. Eligible Applicants

Eligible applicants shall be domestic public or private, non-profit or for-profit entities with demonstrated experience utilizing telehealth technologies to serve rural underserved populations. Faith-based, community-based organizations, and federally recognized tribes and tribal organizations are eligible to apply. **Services must be provided to rural areas**, although the applicant can be located in an urban area.

A. Geographic Requirements:
The applicant organization may be located in an urban or rural area. Applicants must include at least two distant sites located in rural areas and no more than two urban distant sites. HRSA encourages applicants in urban areas that choose to focus their program on providing primary care services, to collaborate with rural established providers as distant sites. **For the purposes of this award, the originating site** is the location of the patient at the time the service being furnished via a telecommunications system occurs. The originating site is required to be **solely located in HRSA-defined rural areas in order to receive funds through this award. Urban originating site service areas are NOT eligible to receive funding through this award.** Specifically, the applicant's proposed service area must be located in a non-metropolitan county or in a rural census tract of a metropolitan county. All services must be provided in a non-metropolitan county or rural census tract. To ascertain rural eligibility, please refer to HRSA's Rural Health Grants Eligibility Analyzer. This webpage allows you to search by county or street address and determine your rural eligibility.

In addition to the 50 states, only organizations in Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, American Samoa, the U.S. Virgin Islands, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau are eligible. If you are located outside the 50 states, you must still meet eligibility requirements.

B. Composition of the Telehealth Network:
The telehealth network shall include at least three (3) of the following entities as distant sites (at least one of which shall be a community-based health care provider):

a. Community or migrant health centers or other Federally Qualified Health Centers.
b. Health care providers, including pharmacists, in private practice.
c. Entities operating clinics, including Rural Health Clinics
d. Local health departments.
e. Nonprofit hospitals, including Critical Access Hospitals.
f. Other publicly funded health or social service agencies.
g. Long-term care providers.
h. Providers of health care services in the home.
i. Providers of outpatient mental health services and entities operating outpatient mental health facilities.
j. Local or regional emergency health care providers.
k. Institutions of higher education.
l. Entities operating dental clinics.

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.

Multiple applications from an organization are not allowable. HRSA recognizes a growing trend towards greater consolidation within the rural health care industry and the possibility that multiple organizations with the same EIN and/or DUNS number could be located in different rural service areas that have a need for telehealth services. Please refer to Attachment 11 for information on how to request an exception to this policy.

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.

Current Evidence Based Tele-behavioral Health Network Program recipients are eligible to apply for funds through this notice for the FY 2021 cycle if the proposed project is a new proposal (entirely new project). **If previously funded through the Evidence Based Tele-behavioral Health Network Program, then the new Evidence Based Telehealth Network Program proposed project should not supplant an existing program.** The proposal should differ significantly from the previous projects by expanding the service area of the project to rural communities.

In order to apply, if the applicant organization has a history of receiving funds under the Evidence- Based Tele-behavioral Health Network Program award, they must propose a project that is different from the previously funded project and have at least two (2) new health care partners. Applicants must submit abstracts from the previous Evidence Based Tele-behavioral Health Network Program award in Attachment 10.

Each state has a State Office of Rural Health (SORH), and HRSA recommends making every effort to contact the SORH entity early in the application process to advise them of your intent to apply. The SORH may be able to provide consultation to you regarding model programs, data resources, and technical assistance for consortiums, evaluation, partner organizations, or support of information dissemination activities. An EB THNP applicant should make every effort to seek consultation from its State Office of Rural Health.

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 notice of funding opportunity (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 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 *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 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-21-082, 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 13: Other Relevant Documents*.

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

Temporary Reassignment of State and Local Personnel during a Public Health Emergency

Section 319(e) of the Public Health Service (PHS) Act provides the Secretary of the Department of Health and Human Services (HHS) with discretion upon request by a state or tribal organization to authorize the temporary reassignment of state, tribal, and

local personnel during a declared federal public health emergency. The temporary reassignment provision is applicable to state, tribal, and local public health department or agency personnel whose positions are funded, in full or part, under PHS programs and allows such personnel to immediately respond to the public health emergency in the affected jurisdiction. Funds provided under the award may be used to support personnel who are temporarily reassigned in accordance with § 319(e). Please reference detailed information available on the HHS Office of the Assistant Secretary for Preparedness (ASPR) website via http://www.phe.gov/Preparedness/legal/pahpa/section201/Pages/default.aspx.

Program-Specific Instructions

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*.

ABSTRACT HEADING CONTENT
Applicant Organization Information **Applicant organization name; Applicant organization address (street, city, county, state, ZIP code); Applicant organization website, if applicable;**
Designated Project Director Project Director Name & Title, Contact Phone Number and E-Mail Address
EB THNP Project Project Title Requested Award Amount for each project year (1-5)
ABSTRACT BODY CONTENT
Applicant Organization Facility Type (See Section III.1.B for examples)
Primary Focus Area (must select at least one) *Primary Care, Acute Care, Behavioral Health* **Secondary Focus Area (optional)** *Maternal Care, Substance Use Disorder, Chronic Care Management*
Target Service Area Briefly identify the geographic service area that the health care system and partners serve or will serve, including its size and population. Note how many full and partial HPSAs and full and partial MUAs the service area contains. Also, note any mental health and/or dental HPSAs. Note any other critical characteristics of the service area and its population.
Needs, Objectives, and Projected Outcomes Briefly describe the identified needs and expected demand for services, project objectives, and expected outcomes.
Clinical Services to be provided List proposed clinical services.
Actual Patients/Persons Served Specify the actual number of unduplicated patients/persons served throughout 2020

(January 1 – December 31, 2020) at the distant sites proposed. Estimate (by distant site and year) the number of unduplicated patients/persons to receive DTC services at each distant site during the first year of the program and in subsequent years 2, 3, 4, and 5.
Self-Assessment Briefly describe how the applicant plans to measure their progress achieving the goals stated in their application.
Expected Outcome(s) Provide a brief description on the expected outcome(s) of the proposed services.
Sustainability Briefly describe activities to sustain the telehealth DTC services once federal funding ends.
Previous EB THNP Funding Indicate if you are a recipient of a current EB THNP award, and whether you serve/d as the applicant organization or a Originating Site; Indicate whether you have applied for an EB THNP award, and whether you applied as the applicant organization or an Originating Site.
How the applicant learned about funding (e.g., Telehealth Resource Centers, SORH, Grants.gov, HRSA news release, FORHP weekly announcements, etc.)

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(a) #1 (Need)*

  Succinctly (1-2 pages) describe the purpose of the proposed project. Include an overview of the telehealth network partners and collaborative plans for addressing the identified health care need in the rural communities in your proposed service area, including a list of the specific DTC telehealth services that will be offered. You must include a data-driven estimate of the projected number of distant sites (including comparison sites) and unduplicated patients that will receive services and for whom data (including clinical and cost data) will be collected for research/evaluation purposes for each year of the period of performance.

  Do not include information about network sites or patients who would not be active contributors or beneficiaries under this cooperative agreement. For example, if your health care system includes ten network sites but only eight distant sites will be actively participating/providing data in the proposed project, you should only discuss those eight distant sites in your application.

  You are required to utilize HRSA's Evidence Based Telehealth Network Program

measures (also commonly referred to as Performance Improvement Measurement System (PIMS) measures) to help monitor your project progress. You are also required to utilize HRSA's evaluation measures (to be identified upon award along with the Rural Telehealth-Focused Research Center) to collect evidence based data. In addition to the HRSA measures, applicants are encouraged to develop their own project specific measures that they can track throughout the period of performance.

Applicants should list the proposed project-specific measures and the projected impact in this section. Details about the proposed measures must be explained in the "Evaluation and Technical Support Capacity" section of the Project Narrative. Please see the "Evaluation and Technical Support Capacity" section below for further instructions.

- *NEEDS ASSESSMENT -- Corresponds to Section V's Review Criterion #1 (Need)*

This section outlines the needs of the community and/or organization. Describe and document the target population and its unmet health needs. Use and cite demographic data whenever possible to support the information provided. Discuss any relevant barriers in the service area that the project hopes to overcome. This section will help reviewers understand the community and/or organization that you will serve with the proposed project. Please use the following sub-headings (1) Target Population Details, (2) Target Area Details, (3) Stakeholder Involvement, (4) DTC Evidence Base, (5) Community and Provider Need for DTC Services

Target Population Details

A. Describe the target population. Consider disparities based on race, ethnicity, gender identity, sexual orientation, geography, socioeconomic status, disability status, primary language, health literacy, and other relevant elements. You should also consider people with disabilities; non-English speaking populations; minority populations; people with limited health literacy; or populations that may otherwise be overlooked when identifying target populations. The needs assessment should focus on telehealth needs in HRSA designated rural areas, including tribal entities.
B. Describe the associated unmet health needs of the target population of the proposed project (if funded, this is the population that you will monitor and track). Describe the entire population of the service area and its demographics in relation to the population you will serve. When possible, incorporate any national and/or local rankings data to aid in illustrating the community's need. Cite data for factors that are relevant to the project, such as: specific national, state, and regional health status indicators and unmet health need (as it relates to your primary focus area); percentage of target population with health insurance coverage and estimated proportion of major payers within this population (e.g., any commercial health plan, Medicare, Medicaid, dual Medicare-Medicaid, CHIP, TRICARE, Indian Health Service, uninsured/self-pay, etc.); percentage of target population without health insurance coverage that is likely eligible for health insurance coverage; and percentage of target population living below the federal poverty line, etc. Also, include information regarding the

social determinants of health and health disparities affecting the population or communities served

C. Within your proposed service area, identify and describe the presence of any racial and ethnic minority subpopulations. Explain how your project will meet the needs of these populations in terms of racial and ethnic health disparities and barriers (social, cultural, infrastructure etc.) that affect their health status. If your organization has not historically served the identified racial and ethnic minority subpopulations in your proposed service area, describe the vehicles, data points and/or partnerships needed to make the project successful. If your service area does not include any racial and ethnic minority subpopulations, describe your population demographics and any unique disparities they face.

Target Service Area Details

A. Identify the target service area(s) for the proposed project. Describe any relevant geographical features of the service area that affect access to health care services.
B. Describe the health care services available in or near the target service area and any gaps in services. Keep in mind that it is important for reviewers to understand the number and types of relevant health and social service providers that are located in and near the service area of the project as well as their relation to the project. How does the proposed project incorporate and leverage the current services in the community?
C. Describe the existing primary health care providers, home health agencies, or other health networks in the region that are serving the area that you are incorporating as a part of your proposed program. Detail how this project would foster or/and enhance collaboration.
D. Provide details how the project will not compete with other regional health care service providers (e.g., changes in referral patterns, practice patterns, provider reimbursement impact, etc.).

Direct-to-Consumer (DTC) Telehealth Evidence Base

A. Describe how the proposed DTC health services can contribute to or add to the existing evidence-base around the effectiveness of DTC telehealth as a modality of health care for patients, providers, and payers. Specifically, briefly describe what you see as the gaps or weaknesses in the existing evidence-base for DTC health services.
B. Discuss how information collected in this program could be analyzed to address the identified gaps and impact the field of telehealth. The target population of the project must be sufficiently large to permit rigorous data analysis (e.g., projects should not propose limited services to small demographic groups or uncommon clinical conditions). Quantitative data must be used when describing the demand for DTC telehealth services (specifically as it relates to your selected primary focus: Primary Care, Acute Care, or Behavioral Health Care).

Community and Provider Need for Direct-to-Consumer (DTC) Telehealth Services

Describe the community and provider needs for DTC telehealth services in your proposed rural service area. Present evidence of the significant demand for DTC care health services among patients and existing providers in the proposed service area, the challenges existing primary care and other clinicians are facing in offering DTC services, and how they will be able to do so through the collaboration of this project.

- *METHODOLOGY -- Corresponds to Section V's Review Criterion(a) #2 (Response) and #4 (Impact)*

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. Include a description of any innovative methods that you will use to address the stated needs. Please address these headings (1) Goals and objectives, (2) Delivery of services and, (3) Sustainability.

Goals and Objectives

Define the specific goals and objective. The stated goals and objectives should be measurable, align with the intent to the EB THNP program, and achievable within the period of performance.

Delivery of Services

You must describe how DTC telehealth services will be delivered to the target population in the proposed project in a manner that permits rigorous analysis and data collection but also promotes increased access to care. Include a discussion of the following:

A. Based on the information provided in the "Needs Assessment" section, describe the DTC telehealth services that you will offer under this award and the technical means by which they will be delivered;
B. Please describe how the identified practice model is appropriate for your proposed project, and effective in meeting the rural target population's need. Detail how the model will address the Health Professional Shortage and/or amplify effective care provided by existing health care providers in the targeted rural area;
C. Provide a clear explanation and justification of how proposed network partners (distant sites) were selected and build on existing patterns and systems of care for face-to-face services for this application and how they will collaborate with you to maximize the number of DTC patient encounters and individuals for whom data can be collected and analyzed in a statistically rigorous manner;
D. Provide a clear explanation and justification of how proposed comparison sites (*see Appendix*) were selected for this application and how they will collaborate with you to maximize the number of patient encounters and individuals for whom data can be collected and analyzed in a statistically rigorous manner;

E. Describe how your EB THNP network sites will maintain rural commitment throughout the period of performance;
F. Describe the patient level data collection capabilities of the distant sites
G. Discuss and demonstrate the willingness of the administrators, providers, and community members to deliver/receive DTC telehealth care using telehealth technology (if applicable, including RPM devices);
H. Discuss the telehealth reimbursement environment for DTC health care services and if Medicare, Medicaid, and/or private insurance in the applicant state(s) cover the proposed services. HRSA encourages applicants to reach out to the state Medicaid office and include any specific information received regarding reimbursement for project activities;
I. Describe the technology requirements and each type of equipment that will be employed along with its relevance to the project, how it contributes to cost-effective and quality care, and ease of use; and
J. Describe plans and activities to implement the technology with assurances that the technology complies with existing federal and industry standards, that the technologies are interoperable, and that the proposed technology can be easily integrated into health care practice.

Sustainability

A. Describe the methods by which you will sustain program activities beyond the period of performance; and
B. Describe some of the potential sources of support for achieving sustainability. Sources of support could include but are not limited to financial, in-kind, or the absorption of activities by your network.

- *WORK PLAN -- Corresponds to Section V's Review Criterion(a) #2 (Response) and #4 (Impact)*

Submit this section as Attachment 6. This section should describe the specific activities or steps that you will take to: (1) increase access to health care services via DTC in rural and frontier communities in a way that complements the existing prevailing patterns of care; (2) how local primary care practices and other local community providers were incorporated into the network and ensure that the project will not be bringing new primary care providers into the service region to offer DTC in a way that would supplant or put at risk the existing clinicians serving the area; (3) contribute to the evidence base assessing the effectiveness of DTC health care services for patients, providers, and payers; and (4) effectively manage the project. A work plan is an "action" guide with a time line used during program implementation; the work plan provides the "how to" steps. As appropriate, identify meaningful support and collaboration with key stakeholders in planning, designing, and implementing all activities, including developing the application. The timeline should include goals, objectives, and the following:

Increase Access to Health Care Services

A. Describe how telehealth care services will be implemented at the patients location (originating site) (e.g., scheduling, identifying potential patients, educating staff and providers on how to integrate telehealth services into existing workflows, etc.); and

B. Provide a timeline with specific milestones for each network site.

Contribute to the Evidence Base

A. Provide a detailed explanation of how data will be collected from the originating sites (e.g., manual chart abstraction, extraction from electronic health records, etc.);
B. Provide an explanation of data quality control processes; and
C. Provide an explanation of internal review board and/or data use agreement processes.

Project Management

A. Provide a detailed explanation of how your organization will actively manage this project to ensure that all aspects of the project (both care delivery and data collection) are proceeding effectively; and
B. Provide a detailed explanation of specific responsibilities for data management key personnel.

- *RESOLUTION OF CHALLENGES -- Corresponds to Section V's Review Criterion #4 (Impact)*

This section should identify challenges that you may encounter in designing and implementing the activities described in your work plan and the approaches that you will use to resolve those challenges. These challenges may include those related to: (1) the provision and operation of DTC telehealth care services in conjunction with existing primary clinics, home health agencies, etc., or (2) the required data collection and cross-program evaluation and analysis. You should consider scenarios including:

A. Staff turnover and/or loss of telehealth champion(s) at your applicant site and distant sites;
B. Broadband and other infrastructural issues related to providing telehealth services directly to patient;
C. Addressing underutilization of DTC telehealth services in the proposed network and incorporating into local existing distant sites pattern of health care delivery;
D. Data collection throughout distant sites; and
E. Need for technical assistance at the distant sites and patients location to optimize the provision of DTC telehealth care services.

- *EVALUATION AND TECHNICAL SUPPORT CAPACITY -- Corresponds to Section V's Review Criterion #3 (Evaluative Measures) and #5 (Resources/Capabilities)*

Technical Support Capacity

A. This section should demonstrate your organization's capability to collaborate (including data sharing) with the Telehealth-Focused Rural Health Research Center on across-award recipient program evaluation/analyses designed to contribute to the DTC telehealth care evidence base. HRSA will collaborate with the Telehealth-Focused Rural

Health Research Center and award recipients to establish a full list of required measures at the beginning of the performance.

B. Describe how each distant sites will be supported, through financial and resources, to ensure quality data collection.
C. Include details in Attachment 5 Letters of Agreement/Memorandum of Understanding identifying clear responsibilities of each distant sites to provide quality data in a timely manner.

Evaluation Capacity

For the purposes of your application, you must demonstrate the ability and capacity to report on measures for DTC patients and control/comparison patients in the following domains:

A. Clinical outcomes (e.g., symptom reduction, health status improvement, higher response to treatment in behavioral health);
B. Cost and cost-effectiveness/minimization (e.g., reduced treatment costs relative to non-telehealth treatment based on fixed and variable costs and reduced travel time; reduced utilization of other health services such as emergency departments or hospitalizations);
C. Quality of care (e.g., impact on value-based care, and effectiveness of DTC telehealth care in health care system); and
D. Access (e.g., reduced wait time until appointment and increased receipt of follow-up specialty services; reduced travel time for patients).

NOTE: EB THNP award recipients will be expected to work with a HRSA-funded technical assistance provider and Rural Telehealth Focused Research Center during the period of performance (and potentially share project updates and information with them after the period of performance ends). HRSA will provide additional guidance on the technical assistance components of the project throughout the period of performance.

- *ORGANIZATIONAL INFORMATION -- Corresponds to Section V's Review Criterion #5 (Resources/Capabilities)*

This section should describe your organization's structure and the proposed staffing plan for activities conducted under this notice.

A. Describe your organization's experience (including materials published) successfully conducting work of a similar nature;
B. Demonstrate previous experience successfully executing data-sharing and/or research activities that required your organization to gather data, either through manual chart abstractions or electronic health records, from the distant sites;
C. Describe the availability of health providers available, either directly employed by your organization or employed via contract with your organization, that have the capacity to provide DTC telehealth services within 1 year of the project start date;

D. Describe the ability of the network to implement the project, including their ability to expand on local existing provider and community support for proposed DTC telehealth services;
E. Describe the network governance, including the ability of your organization (distant site) to hold partner distant sites accountable for data delivery and other project deliverables; and
F. Describe how the information provided in the Project Organizational Chart (*Attachment 7)* contributes to the ability of the network to conduct the program requirements and meet program expectations.

In addition, each distant site (Section III) within the project should:

A. Have a clearly defined role and specific set of responsibilities for the project;
B. Have a signed and dated Memoranda of Agreement (*Attachment 5*) that delineates the member's role and resource contribution, data collection commitment, and decisions on equipment placement and responsibility for maintenance throughout the funding period and beyond.
C. Demonstrate clinician support from new and existing health care providers, and describe the commitment, involvement and support of senior management and clinicians in developing and operating the project. In addition, the clinicians' understanding of the challenges in project implementation and their competence and willingness to meet those challenges. This would include a thorough explanation of how funds will flow to each distant site to support data collection.
D. Given the respective roles of various members, document the technical and organizational ability to implement the proposed project in the following areas: (a) Telehealth network development, i.e., the ability to build partnerships and community support; (b) governance, including effective coordination of network member activities in the project; (c) operation and management**. Start-up projects with no demonstrable telehealth experience will not be competitive. Projects with prospective partners not committed to the project will not be funded.**
E. Describe strength, capacity and value of your telehealth network. Describe how your telehealth network has the capacity, and collective mission and vision to collaborate effectively to achieve the goals of the EB THNP program. Detail the history of collaboration among your telehealth network members and detail the strengths of your partnership; and
F. Staffing needs should have a direct link to the activities proposed in the project narrative and budget portion of the application. You should:
    - have at least one permanent staff at the time an award is made; and
    - If there will not be a permanent Project Director at the time of the award, recipients should make every effort to hire a Project Director in a timely manner and applicants should discuss the process and timeline for hiring.

If the Project Director serves as a Project Director for other federal awards, please list the federal awards as well as the percent full-time equivalent (FTE) for that respective federal award. Project staff cannot bill more than 1.0 FTE across federal awards.

Community Health Worker/Patient Coordinator: You should detail how the Community Health Worker will facilitate coordination with the distant site and the patients to implement the proposed project activities in the work plan and HRSA-required reporting requirements. **You should have at least .50 FTE devoted to the Community Health Worker/Patient Coordinator position.** These individuals act as a liaison or advocate and assist in implementation of programs.[13]

- Create connections between vulnerable populations and healthcare providers
- Help patients navigate healthcare and social service systems
- Collect data and relay information to stakeholders to inform programs and policies
- Provide informal counseling, health screenings, and referrals
- Build community capacity to address health issues

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.

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.

In addition, the Evidence-Based Telehealth Network Program requires that you submit a separate program-specific *Detailed Budget* (described below) for each year of the period of performance (September 1, 2021 to August 31, 2026) and upload it as *Attachment 9*. The detailed budget should reflect allocations for each 12-month budget period. More information on the detailed budget is described in the following section:

Allowable Costs: [42 U.S.C. § 254c-14(k)] [Section 330l(k) of the Public Health Service Act]

[13] https://www.ruralhealthinfo.org/toolkits/community-health-workers/1/roles

Use of Award Funds:
Award funds may be used for salaries, limited equipment, and operating or other costs, including the cost of:

A. Developing and delivering clinical telehealth services that enhance access to community-based health care services in rural areas, frontier communities, or medically underserved areas, or for medically underserved populations;
B. Developing and acquiring, through lease or purchase, computer hardware and software, audio and video equipment, computer network equipment, interactive equipment, data terminal equipment, and other equipment that furthers the objectives of the Evidence Based Telehealth Network Program;
C. Developing and providing distance education, in a manner that enhances access to care in rural areas, frontier communities, or medically underserved areas, or for medically underserved populations; or
D. Mentoring, preceptorship, or supervising health care providers and students seeking to become health care providers, in a manner that enhances access to care in the areas and communities, or for the populations described above.
E. Developing and acquiring instructional programming;
F. Providing for transmission of medical data, and maintenance of equipment;
G. Providing for compensation (including travel expenses) of specialists, and referring health care providers, who are providing telehealth services through the network, if no third party payment is available for the telehealth services delivered through the network. The award recipient will be required to consult with project officer first to discuss amount of compensation allowable;
H. Developing projects to use telehealth technology to facilitate collaboration between health care providers; and
I. Collecting and analyzing usage statistics and data to document the cost-effectiveness of the telehealth services.

The Consolidated Appropriations Act, 2021 (P.L. 116-260), Division H, § 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*.

In addition, the Evidence Based Telehealth Network Program requires the following:

Detailed Budget
The detailed budget should be included as *Attachment 9*. Detailed budget information is required to capture information specific to the proposed telehealth activities. It provides a detailed breakout of how each network site will expend funds requested

for each object class category. The Detailed Budget allows you to identify how you will use federal funds for each proposed distant site.

Applicant must include details showing how the allocation of funds directly support the collection of data analysis at each distant site.

The initial budget period for this funding opportunity is from September 1, 2021 to August 31, 2022. You must provide a budget for each year of requested funding for each object class category that reflects the cost of proposed activities for each distant site. Based on the budget for each object class category, you will develop a consolidated budget.

Each object class category should be reported on a separate page (or multiple pages if needed based on the number of distant sites). Report the object class categories as follows:

A. Personnel/Fringe Benefits;
B. Travel;
C. Equipment;
D. Supplies;
E. Subcontracts;
F. Other; and
G. Indirect Costs.

Travel should include sufficient funds to support travel costs for up to three (3) individuals to attend at least two (2) recipient partnership meetings for award recipients. One will be held in the Washington, D.C. metropolitan area.

Combined Object Class Totals: On one page, using the identical format for the detailed budget discussed above, summarize federal and non-federal costs for combined costs of all object classes for the Applicant and each distant site. Please include indirect costs in the summary worksheets when calculating these totals. We recommend that you present your line-item budget in table format, listing each object class category for each facility (starting with your organization as the applicant site and the subsequent network sites) on the left side of the document, and the program corresponding costs (OAT- Federal Dollars, Other Federal Dollars, Federal Subtotal, Applicant/ Partners Non-Federal Dollars, State Non- Federal Dollars, Other Non-Federal Dollars, Non-Federal Subtotal Dollars, and Total Dollars) across the top. Please label each network site as being rural or urban.

As a reminder, only network sites that will be actively participating and contributing data should be listed. Under Personnel, please list each position by the position title and name, with annual salary, FTE, percentage of fringe benefits paid, and salary charged to the award for each network site. Equipment should be listed under the name of the distant site where the equipment will be placed. List the types of equipment to be funded at each distant site. Only equipment costs should be listed here (personnel costs for equipment installation should be listed in the “Other” category).

Equipment expenditures under this funding opportunity are limited to a 40 percent cap per year.[14] Clinician payments should be listed in the "Other" category and should only be included for patients for whom no alternate reimbursement is available.

Clinician Reimbursement: Award applicants must bill all services covered by a third party reimbursement plan and should demonstrate plans to make every effort to obtain payments throughout all five (5) years of the period of performance. All the general claims data will be a critical part of the EB THNP program evaluation. More than 40 state Medicaid programs now reimburse some level of telehealth services. In addition, some states have instituted "parity laws" for telehealth, meaning that if an insurer covers a service face-to-face it must provide the same reimbursement for the service via telehealth. Applicants for EB THNP services that could be reimbursed by Medicaid, Children's Health Insurance Programs (CHIP), Medicare or private insurance should **highlight their ability to catalyze a sustainable network through their state's reimbursement environment**. More information about state-specific telehealth reimbursement can be found here: https://www.umtrc.org/updated-state-telehealth-laws-and-reimbursement-policies.

Note: At the same time, award recipients may not deny services to any individuals because of an inability to pay. If awarded, the applicant may allocate funding from the award to pay practitioners for telehealth services **only after documenting that the award recipient has attempted to seek third-party reimbursement** and/or why it is not possible to receive third party reimbursement. If at any time post-award the award recipient seeks to use award dollars to reimburse practitioners for telehealth services, they will be required to receive approval from the project officer first. **Approved utilization of funds will be limited** to a percentage of the amount awarded within the budget period the request is made.

Indirect costs For this program, **indirect costs are limited to 15 percent of the total award** funds and must apply to the activities funded under this program [42 U.S.C. §254c-14(k)(7)]. A copy of the most recent indirect cost agreement must be provided. It is recommended that *Attachment 9* be converted to a PDF to ensure page count does not change when the document is uploaded into https://www.grants.gov.

For Revenues by Network Site (for the budget period): On a single separate page, report as two vertical columns. The left column should list each network site starting with the applicant site on the top followed downward by each distant site; and the right column should list the anticipated revenue total corresponding to each Applicant/Network site. Include this document in *Attachment 9*.

Treatment of Program Income: Under the EB THNP Program, any program income, including reimbursements from third party claims per *Section IV.2.iv*. Budget Narrative, is expected to be added to funds committed to the project and used to further eligible program objectives and make the project sustainable.

[14] This restriction is consistent with similar programs funded through HRSA.

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
Work Plan	(2) Response and (4) Impact
Resolution of Challenges	(2) Response
Evaluation and Technical Support Capacity	(3) Evaluative Measures and (5) Resources/Capabilities
Organizational Information	(5) Resources/Capabilities
Budget and Budget Narrative	(6) Support Requested

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

Keep each job description to one page in length. Include the role, responsibilities, amount of FTE dedicated on project, 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 2: Biographical Sketches of Key Personnel (Required)

Include biographical sketches for persons occupying the **key positions** described in *Attachment 2*, not to exceed one page 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 3: Rural Identification (ID) Eligibility (Required)

All applicants are required to submit information regarding each rural originating sites within their target service area. For purposes of this funding opportunity, "rural" means all counties that are not designated as parts of Metropolitan Areas (MAs) by the Office of Management and Budget (OMB). In addition, HRSA uses the Rural Urban Commuting Area Codes (RUCAs), developed by the WWAMI Rural Research Center at the University of Washington and the Department of Agriculture's Economic Research Service, to designate "Rural" areas within MAs. This rural definition can be accessed via HRSA's Rural Health Grants Eligibility Analyzer weblink.[15] If the county is not entirely rural or urban, then follow the link for "Check Rural Health Grants Eligibility by Address" to determine if a specific originating site service area qualifies as rural based on its specific census tract within an otherwise urban county.

Rural ID Eligibility Headings-- *HEADINGS REQUIRING RESPONSES:*

a. **Name of Site –** List the name of Distant Site. If Originating Site Service Area, list as Originating Site Service Area #1, Originating Site Service Area #2, etc.
b. **Street Address –** Include city, state and ZIP Code.
c. **County –** List name of County
d. **Map of Originating Site Service Area**
e. **Do application attachments 5 & 12 contain evidence that each distant site is committed to the project for Year 1?** Yes/No

Attachment 4: Network Identification Information (Required)

A. You are required to submit the following information about your organization and the network sites included in your application.
The applicant site (your organization):
   a. **Site name and address**
   b. **Designation as a hub/distant site**
   c. **Participating in the Federal Communication Commission Lifeline Program-** Yes/No
   d. **National Provider Identifier and Primary Taxonomy** (if the distant site bills for services)[16]
   e. **HCP number** (if the distant site receives Universal Service funding)[17]
   f. **County where the organization is located**
   g. **Geographic Destination-** Rural/Urban[18]
   h. **Do application attachments 5 & 12 contain evidence that each distant site is committed to the project for Year 1?** Yes/No
   i. **Description of facility**

[15] Follow the link for "Check Rural Health Grants Eligibility by Address" to determine if a specific originating site area qualifies as rural based on its specific census tract within an otherwise urban county.
[16] If the distant site name or address does not match the National Provider Identifier registry, please provide an explanation for the discrepancy. See https://npiregistry.cms.hhs.gov/.
[17] See https://www.usac.org/rhc.
[18] The applicant organization and any other hub/distant sites may be located in urban areas but all network originating site areas must be located in rural areas. Urban originating sites are not eligible to receive support under this funding opportunity.

i. Federally Qualified Health Center or other Community Health Center
ii. Entity operating a clinic, including a Rural Health Clinic
iii. Hospital, including Critical Access Hospitals
iv. Local health department
v. Other publically funded health or social service agency
vi. Long term care provider
vii. Provider of outpatient mental health services or entity operating an outpatient mental health facility
viii. Local or regional emergency health care provider
ix. Institution of higher education
x. Other entity not otherwise described (please provide description)

B. Successive partner sites

Successive pages of information should be used to identify each individual distant site by including the information listed above for the applicant site. Label the top of each distant site as appropriate (e.g., site #2 of total # of sites, site #3 of total # of sites, etc.).

Attachment 5: Letters of Agreement, Memoranda of Agreement, and/or Description(s) of Proposed/Existing Contracts (project-specific) (Required)

Provide documentation that describes the working relationships between the applicant organization and each distant site included in the application for this NOFO. Each memorandum of agreement (MOA) shall be executed by the listed contact in the application or other appropriate official from the partner distant site with authority to obligate the partner distant site to the project. The MOA will include a cover page on the letterhead of each respective partner distant site. The MOA should be tailored to the particular partner distant site and contain, at minimum, the following:

A. Clearly defined roles and a specific set of responsibilities for the project (including decisions about equipment placement, ownership and maintenance of equipment throughout the period of performance, and data collection)
B. Clearly defined resources (e.g., space, staff, access to data, etc.)
C. Past and current activities in planning and implementing telehealth projects with your (the applicant) organization
D. All MOAs must be dated and contain original signatures from the authorized representatives. MOAs containing generic information not referencing and relevant to the proposed EB-THNP project are not acceptable.

Note: Evidence must be provided that all partners are committed to the project and are ready to begin implementing the project on September 1, 2021. Applicants failing to submit verifiable information with respect to the commitment of partners, including specific roles, responsibilities, and services being provided, will be deemed incomplete and will not be considered for funding.

Attachment 6: Work Plan (Required)

Attach the work plan for the project that includes all information detailed in Section IV.2.ii. Project Narrative. If you will make subawards or expend funds on contracts, describe how your organization will ensure proper documentation of funds. This attachment will count towards the 80-page limit.

Attachment 7: Project Organizational Chart (Required)

Provide a one-page figure that depicts the organizational structure of the project, including subcontractors and other significant collaborators (including HRSA and HRSA's Telehealth Focused Rural Health Research Center). The chart should illustrate where project staff are located and reporting lines for each component of the project.

Attachment 8: Proof of Existing Telehealth Services (Required)

Provide proof (e.g., administrative data) showing the history your organization has provided telehealth services for at least 6 months and a significant number of rural patients (defined as 15 or more patients per month).

Attachment 9: Detailed Budget Information (Required)

Include the program-specific line-item budget (see Section IV.2.iii. Budget for additional information). ***It is recommended that this attachment be converted to a PDF to ensure that the page count does not change when the document is uploaded*** to www.grants.gov.

For Multi-Year Budgets--5th Year Budget

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, which does not count in the page limit: however, any related budget narrative does count. See Section 4.1.iv of HRSA's *SF-424 Application Guide*.

NON-FEDERAL EXPENDITURES	
FY Prior to Application (Actual) *Actual prior FY non-federal funds, including in-kind, expended for activities proposed in this application.* *Amount: $_____*	*Current FY of Application (Estimated)* *Estimated current FY non-federal funds, including in-kind, designated for activities proposed in this application.* *Amount: $_____*

Attachment 10: Evidence Based Tele-behavioral Health Network Program Funding History Information (If applicable)

Current recipients of the Evidence Based Tele-behavioral Health Network Program are eligible to apply if the proposed project is a new proposal (entirely new project) or an expansion or enhancement of the previous award. The proposal should differ from the previous projects by expanding the service area of the project, serving a new population, providing a new service or expanding the scope of the previous award activities.

Current Evidence Based Tele-behavioral Health Network award recipients must include: dates of any prior award(s) received; award number assigned to the previous project(s); a copy of the abstract or project summary that was submitted with the previously awarded funding application(s); description of the role of the applicant telehealth site in the previous award; and a brief statement of how the current proposal is different from the previously awarded Evidence Based Tele-behavioral Health Network Program award(s).

Attachment 11: EIN/DUNS Number Exception Request (If Applicable)

In general, multiple applications associated with the same DUNS number and/or EIN are not allowable. However, HRSA recognizes a growing trend towards greater consolidation within the rural health care industry and the possibility that multiple organizations with the same EIN and/or DUNS number could be located in different rural service areas that have a need for telehealth services. Therefore, at HRSA discretion, separate applications associated with a single DUNS number and/or EIN may be considered for this funding opportunity if the applicants provide HRSA with the following information in Attachment 11:

1. **Names, street addresses, EINs, and DUNS numbers of the applicant organizations;**
2. **Name, street address, EIN, and DUNS number of the parent organization;**
3. **Names, titles, email addresses, and phone numbers for points of contact at each of the applicant organizations and the parent organization;**
4. **Proposed EB THNP service areas for each applicant organization** (these should not overlap**);**
5. **Justification for why each applicant organization must apply to this funding opportunity separately as the applicant organization, as opposed to serving as consortium members on other applications;**
6. **Assurance that the applicant organizations will each be responsible for the planning, program management, financial management, and decision making of their respective projects, independent of each other and/or the parent organization; and**
7. **Signatures from the points of contact at each applicant organization and the parent organization**.

Applications associated with the same DUNS number or EIN should be independently developed and written. HRSA reserves the right to deem applications that provide insufficient information in Attachment 11, or are nearly identical in content, to be ineligible. In this instance, assuming all other eligibility criteria are met, HRSA will only accept the last submitted application associated with the EIN or DUNS number.

Attachment 12: Letters of Support (optional)

Only include letters of support that specifically indicate a commitment to the project/program (in-kind services, dollars, staff, space, equipment, etc.). List all other support letters on one page. A letter of support cannot take the place of a memorandum of agreement as required in *Attachment 5*.

Attachment 13: Other Relevant Documents

Include 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. At a future, to-be-determined date, 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 pages: Planned UEI Updates in Grant Application Forms and General Service Administration's UEI Update.

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:

1. Dun and Bradstreet (http://www.dnb.com/duns-number.html)
2. System for Award Management (SAM) (https://www.sam.gov)
3. 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 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 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 *April 2, 2021 at 11:59 p.m. ET*. HRSA suggests submitting applications to Grants.gov at least **three (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 EB THNP Program is 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 5 years, at no more than $350,000 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 H of the Consolidated Appropriations Act, 2021 (P.L. 116-260) 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 following fiscal years, as required by law.

You cannot use funds under this notice for the following purposes:

1) To acquire real property;
2) For expenditures to purchase or lease equipment, to the extent that the expenditures would exceed 20 percent of the total award funds;
3) In the case of a project involving a telehealth network, to purchase or install transmission equipment (such as laying cable or telephone lines, or purchasing or installing microwave towers, satellite dishes, amplifiers, or digital switching equipment);
4) To pay for any equipment or transmission costs not directly related to the purposes for the award;
5) To purchase or install general purpose voice telephone systems;
6) For construction; or
7) For expenditures for indirect costs, to the extent that the expenditures would exceed 15 percent of the total award funds.

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 awards requirements, the effectiveness of these policies, procedures, and controls is subject to audit.

Be aware of the requirements for HRSA recipients and subrecipients at 2 CFR § 200.216 regarding prohibition on certain telecommunications and video surveillance services or equipment. For details, see the HRSA Grants Policy Bulletin Number: 2021-01E.

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.

Criterion 1: NEED (10 points) – Corresponds to Section IV's (Introduction and Needs Assessment)

Sub Criterion- Target Service Area Details (5 points)

The extent to which the application:

1. Provides a clear overview of the proposed network's unmet health needs and thoroughly responds to how the project will be used to address the health care needs in rural communities within its service area.
2. Thoroughly illustrates the demographics of the service area, disparities, and target population. The applicant should compare local data versus state and national data to demonstrate disparity and need.
3. Describes significant demand for DTC telehealth services in the proposed service area, including a realistic and data-driven estimate of existing health care delivery to support the number of distant sites and unduplicated patients that will receive services AND for whom clinical and financial data can be collected.
4. Includes a clear discussion of the current gaps or weaknesses in the existing evidence base for the DTC health services proposed, including how data collected in this program can be used to address the identified gaps.

Sub Criterion- Community and Provider Collaboration for Direct-to-Consumer services (5 points)

The extent to which the applicant demonstrates a thorough understanding of the relevant health services currently available in the targeted service area including:

1. Includes a clear discussion and evidence of the project specific impact of the DTC services to enhance collaboration with existing health care infrastructure in the rural region.
2. Manner and extent to which the proposed project will meaningfully fill gaps in existing telehealth services related to the purpose of this award funding opportunity and healthcare need.
3. The potential impact of the project on current providers (especially those that are not included in the proposed project);
4. Includes a clear overview of the stakeholder involvement in meeting community and provider DTC needs in order to enhance existing health care infrastructure

Criterion 2: RESPONSE (25 points) – Corresponds to Section IV's (Methodology and Work plan)

Sub Criterion: Methodology (15 points)

1. The extent to which the proposed project responds to the "Purpose" included in the program description.
2. The strength of the proposed goals and objectives and their relationship to the identified project.
3. Clearly outlines the DTC telehealth services that, will be offered at each network site, the technical means, and appropriateness by which they will be offered.
4. The extent to which the proposed project provides a clear and thorough explanation and justification of how proposed distant sites and control/comparison sites were selected for this application and how they will collaborate with existing health care providers local to the target service area to maximize the number of patient encounters and individuals served.
5. Clearly describes the use of telehealth technologies that provide accurate, cost-effective care and are easy to use for patients and providers.
6. Effectively describes how the proposed technology(ies) comply with existing federal and industry standards and can easily be integrated into the health care practices at the distant sites.
7. The strength and feasibility of the plan for sustainability after the period of federal funding ends.
8. Provides a thorough overview of the reimbursement environment in the proposed service area for DTC telehealth services and how that environment will impact the applicant's ability to bill Fee for Services to successfully implement the proposed project.
9. Clearly demonstrates how providers can use DTC telehealth services in a way that enhances the existing health care infrastructure
10. Proposes plan and methods to optimize reimbursement for services across insurance types; and facilitate the health insurance process for eligible uninsured patients

Sub Criterion: Work plan (10 points)

1. The clarity with which the work plan addresses the project activities, responsible parties, the timeline of the proposed activities, anticipated outputs, and the necessary processes associated with achieving project goals.
2. Describes in detail how telehealth services will be implemented at the patient's location (originating site) and how the organization will actively manage all aspects of the project.
3. The extent to which the applicant demonstrates that the completion of work plan activities is a collaborative approach across the telehealth network members (including local primary care practices or local community providers), as demonstrated by the shared responsibilities of work plan activities and the integration of the activities within the member's operational activities.
4. Proposes quality control processes that ensure the data collected is accurate and complete.

5. The extent to which the applicant demonstrates meaningful support and collaboration with key stakeholders in planning, designing, and implementing all activities, including developing the application

Criterion 3: EVALUATIVE MEASURES (20 points) – Corresponds to Section IV's Evaluation and Technical Support Capacity

Sub Criterion: Evaluation Capacity (10 points)

The extent to which the application:

1. Documents the capacity to collect patient-level data in the following domains:
    a. Clinical outcomes (e.g., symptom reduction, chronic care management health status improvement, higher response to treatment in behavioral health);
    b. Cost and cost-effectiveness/minimization (e.g., reduced treatment costs relative to non-telehealth treatment based on fixed and variable costs and reduced travel time; reduced utilization of other health services such as emergency departments or hospitalizations);
    c. Quality of care (e.g., impact on value-based care, and effectiveness of DTC telehealth care in health care system); and
    d. Access (e.g., reduced wait time until appointment and increased receipt of follow-up specialty services; reduced travel time for patients).
2. Clearly demonstrates that the applicant organization and their proposed partners have the willingness and ability to implement data collection protocols based on the measures provided at the beginning of the period of performance on both users of the telehealth services and an appropriate comparison group who do not use the telehealth services.
3. Describes the ability of the network to implement project and/or ability to expand on local existing provider and community support for DTC telehealth services
4. Includes discussion about the project organizational abilities to conduct program requirements and meet program expectations

Sub Criterion: Technical Support Capacity (10 Points)

1. Provides clear detail of how each distant site will be supported through financial and other resources to contribute to data analysis.
2. Provides a clear and detailed explanation of how data will be collected from the distant sites and the patients they serve.
3. Clearly describes the existing data sharing capabilities between the applicant organization and the distant network sites.
4. For distant sites that do not currently share data, the extent to which the application includes a clear plan for how the applicant organization will obtain patient level data within year of start date.
5. Includes an explanation of an internal review board and/or data use agreement processes that demonstrates a thorough understanding the process for the impacted institutions/organizations involved in the proposed project.

Criterion 4: IMPACT (30 points) – Corresponds to Section IV's Methodology, Work plan, Resolution of Challenges, and Attachment #8

Sub Criterion- Ability to Maximize Number of Individuals Receiving Services and Contributing Data (10 points)

The extent to which the applicant organization:

1. Clearly demonstrates in the work plan their ability to provide DTC telehealth services in collaboration with the identified partner distant sites (especially local existing health care providers). Begins collecting data with little to no ramp up time or clearly details plan to begin within 1 year of start date.
2. Has identified a target population that is sufficiently large to permit rigorous data analysis (e.g., the proposed project is not limited to small demographic groups or uncommon clinical conditions).
3. Provides a clear explanation/justification for how distant sites were selected to collaborate in this project, how they will ensure that services are provided to a sufficient number of patients, and how they will sufficiently support each distant site to collect patient level data and perform rigorous data analysis.
4. Provides evidence (e.g., administrative data) of a significant number of rural patients (defined as 15 or more) already receiving telehealth services through the applicant organization.
5. The feasibility and effectiveness of the proposed approach for widely disseminating information regarding results of the project.

Sub Criterion: Community and Provider Support for DTC Telehealth Services (10 points)

The extent to which the application:

1. Provides evidence of provider, health care facility administrator and community support to deliver/receive health care services using telehealth technology.
2. Clearly describes how the implementation of DTC telehealth will promote increase access to care at the distant sites.
3. Clearly discusses how local primary care practices and other local community providers were incorporated into the network and ensure that the project will not be bringing new primary care providers into the service region to offer DTC in a way that would supplant or put at risk the existing clinicians serving the area.
4. Provides clear explanation the distant sites will maintain rural commitment throughout the period of performance.

Sub Criterion: Project Management (5 points)

The extent to which the application:

Includes a detailed project management plan that conveys how the applicant will actively manage the proposed activities to ensure that delivery of care and data collection are progressing effectively throughout the lifespan of federal funding.

Sub Criterion: Resolution of Challenges (5 points)

The extent to which the application:

Provides clear and action-oriented responses that addresses and resolves challenges and anticipated barriers that may arise related to data collection or provision of care. This discussion should include (but is not limited to):

a. Staff turnover/loss of telehealth champions
b. Broadband/infrastructure issues
c. Underutilizing of DTC telehealth services in the proposed network and incorporating into local existing primary care sites pattern of health care delivery
d. Data collection from distant sites
e. Optimizing provision of technical assistance for tele-behavioral health services at distant sites and patients location

Criterion 5: RESOURCES/CAPABILITIES (10 points) – Corresponds to Section IV's Organizational Information and Evaluation and Technical Support Capacity

The extent to which the applicant organization:

1. Demonstrates previous experience successfully implementing high volume telehealth services in rural communities.
2. Demonstrates access to and collaboration with local existing health care providers with the capacity to provide telehealth services to patients in rural communities through this telehealth program.
3. List project staff including one permanent staff and .50 FTE devoted to Community Health Worker/Patient coordinator position. If project director is not hired includes details on hiring process and timeline.
4. Demonstrates previous experience successfully executing data-sharing and/or research activities that required the applicant organization to gather data, through either manual chart abstractions or electronic health records, from partner distant sites.
5. Has a governance structure that allows the applicant organization to hold distant sites accountable for data delivery and other project deliverables.
6. Clearly defines the roles and specific responsibilities of the distant partner sites.
7. Includes signed and dated Memoranda of Agreement (Attachment 5) that clearly demonstrate commitment to the proposed project.

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

The extent to which the budget, including the detailed budget (*Attachment 9)* and the budget justification:

1. Provides a clear justification for costs with respect to project goals and proposed activities and maximizes the use of HRSA funding for service delivery and data collection.
2. Documents a realistic, necessary, and justifiable number of FTEs including Project Director, Community Health Worker/Patient Coordinator, and expertise necessary to implement and maintain the project.

3. Is complete and detailed in supporting each line item and allocating resources for each year of the period of performance.
4. Includes details showing the allocation of funds directly support the collection of data analysis at each distant site
5. Demonstrates in detail plans to make every effort to bill services covered by a third party reimbursement plan

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.

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 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, 2021. 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*.

If you are successful and receive a Notice of Award, in accepting the award, you agree that the award and any activities thereunder are subject to all provisions of 45 CFR part 75, currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

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 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.

- Please refer to instructions provided in HRSA's *SF-424 R&R Application Guide*, Appendix Supplemental Instructions for Preparing the Protection of Human Subjects Section of the Research Plan and Human Subjects Research Policy for specific instructions on preparing the human subjects section of the application.
- Please refer to HRSA's *SF-424 R&R Application Guide* to determine if you are required to hold a Federal Wide Assurance (FWA) of compliance from the Office of Human Research Protections (OHRP) prior to award. You must provide your Human Subject Assurance Number (from the FWA) in the application. If you do not have an assurance, you must indicate in the application that you will obtain one from OHRP prior to award.
- In addition, you must meet the requirements of the HHS regulations for the protection of human subjects from research risks, including the following: (1) discuss plans to seek IRB approval or exemption; (2) develop all required documentation for submission of research protocol to IRB; (3) communicate with IRB regarding the research protocol; (4) communicate about IRB's decision and any IRB subsequent issues with HRSA.

IRB approval is not required at the time of application submission but must be received prior to initiation of any activities involving human subjects. Do not use the protection of human subjects section to circumvent the page limits of the Methods portion of the Project Narrative section.

3. Reporting

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

1. **Progress Report**(s).
   Award recipients must submit a Non Competitive Continuation (NCC) progress report to HRSA on an annual basis. Submission and HRSA approval of your Progress Report(s) triggers the budget period renewal and release of subsequent year funds. This report demonstrates award recipient progress on program-specific goals. Further information will be provided in the award notice.

2. **Performance Measures**. A performance measures report is required for continued funding after the end of each budget period in the Performance Improvement Measurement System (PIMS). Upon award, recipients will be notified of specific performance measures required for reporting.

3. **Final Report**. A final report is due within 90 days after the end of the period of performance. The final report must be submitted online in the Electronic Handbooks (EHBs) system at https://grants.hrsa.gov/webexternal/home.asp. Further information will be provided in the Notice of Award for the final year of funding.

4. **Patient Level Data.** Cooperative agreement recipients will be required to collaborate with HRSA and the HRSA-funded Telehealth Focused Rural Health Research Center (RTRC) to contribute to the tele-behavioral health evidence base through systematic collection of patient-level data. By aggregating data from the entire cohort of award recipients, researchers at the RTRC will have a sufficient sample size to conduct statistically sound analyses. EB-THNP recipients will be required to report on data in the following domains:
    A. Clinical outcomes (e.g., symptom reduction, health status improvement, higher response to treatment in behavioral health);
    B. Cost and cost-effectiveness/minimization (e.g., reduced treatment costs relative to non-telehealth treatment based on fixed and variable costs and reduced travel time; reduced utilization of other health services such as emergency departments or hospitalizations);
    C. Quality of care (e.g., impact on value-based care, and effectiveness of DTC telehealth care in health care system); and
    D. Access (e.g., reduced wait time until appointment and increased receipt of follow-up specialty services; reduced travel time for patients).

    Additional information, including the specific measures, will be provided at the beginning of the period of performance.

Other required reports and/or products

5. **Federal Financial Status Report (FFR).** A Federal Financial Report (FFR) is required at the end of each budget period. The report is an accounting of expenditures under the project that year. Financial reports must be submitted electronically. More specific information will be included in the Notice of Award.
6. **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 XII45 CFR part 75 Appendix XII.

Please note that the OMB revisions to Guidance for Grants and Agreements termination provisions located at 2 CFR § 200.340 - Termination apply to all federal awards effective August 13, 2020.

VII. Agency Contacts

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

India Smith
Division of Grants Management Operations, OFAM
Health Resources and Services Administration
5600 Fishers Lane, Mailstop 10SWH03
Rockville, MD 20857
Telephone: (301) 443-2096
Email : ismith@hrsa.gov

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

Whitney Wiggins
Public Health Analyst, Office for the Advancement of Telehealth
Federal Office of Rural Health Policy
Health Resources and Services Administration
5600 Fishers Lane, Room 17N 166A
Rockville, MD 20857
Telephone: (301) 443-4966
Email: wwiggins@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 Electronic Handbooks (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, February 2, 2021
Time: 3 - 4:30 p.m. EST
Call-In Number: 1-888-790-2022
Participant Code: 7490880
Weblink: https://hrsa.connectsolutions.com/nofo_technical_assistance_call/
Playback Number: 1-800-835-3844
Passcode: 20221

Tips for Writing a Strong Application

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

Appendix: Common Definitions

ACCOUNTABLE CARE ORGANIZATION (ACO): A healthcare organization characterized by a payment and care delivery model that seeks to tie provider reimbursements to quality metrics and reductions in the total cost of care for an assigned population of patients.

ACUTE CARE: secondary healthcare field for patients who are suffering from serious injuries, illnesses, or medical conditions, or who are recovering from major surgery. Acute care is **short-term and services** designed and implemented with the goal of discharging patients once they have rehabilitated to the point of stability. Acute care is the opposite of chronic care, which involves ongoing treatment for long-term illnesses and conditions. While acute care may involve intensive treatment, this pattern of care is usually short in duration.

BEHAVIORAL HEALTH SERVICES: Refers to prevention, screening, intervention, assessment, diagnosis, treatment, and follow-up of common mental health disorders, such as depression, anxiety, and Attention Deficit Disorder with Hyperactivity (ADHD). Behavioral Health Services also include the treatment and follow-up of patients with severe mental illnesses (e.g., schizophrenia, bi-polar disorder, psychotic depression) who have been stabilized and are treatment compliant on psychiatric/psychotropic medications. Clinical and support services may include individual and group counseling/psychotherapy, cognitive-behavioral therapy or problem solving therapy, psychiatric/psychotropic medications, self-management groups, psycho-educational groups, and case management.

COMPARISON GROUP: Data are to be collected on all patients where telehealth services are used as part of the award (Telehealth group) and on a 1-to-1 comparison sample of patients who receive comparable services in-person (Non-telehealth comparison group). Collecting data on Non-telehealth comparison groups is an important component of the research design and will enable important research questions to be answered using a more rigorous research approach. Ideally, award recipients will be able to identify treatment sites that provide in-person services that are comparable to those delivered through telehealth, and to patients who are similar to those receiving telehealth services. The type of services should be roughly comparable in terms of delivering similar diagnostic and treatment services to patients with similar acuity (for example, an urgent care clinic). Likewise, the patient characteristics (e.g., rural location, age, sex, race, ethnicity, insurance coverage, principle diagnosis, and presenting complaint) should be similar for the two groups – Telehealth group and Non-telehealth comparison group. The most important matching variables are comparable services and presenting complaint and/or principle diagnosis. Following those, the patients should be matched, as a group, on the remaining patient characteristics.

DIRECT -TO -CONSUMER TELEHEALTH: Direct-to-Consumer (DTC) care is defined as patient initiated telehealth care, typically from their home. In DTC telemedicine, no clinician is physically present with the patient as he or she interacts with the distant telemedicine clinician.

DISTANT OR HUB SITE: Site at which the physician or other licensed practitioner delivering the service is located at the time the service is provided via telecommunications.

HEALTH SYSTEM: Based on three types of arrangements between two or more health care provider organizations: (1) organizations with common ownership, (2) contractually integrated organizations (e.g., accountable care organizations), and (3) informal care systems, such as common referral arrangements. Systems include organizations combined horizontally (e.g., a hospital system) or vertically (e.g., a multihospital system also owning physician practices and post-acute care facilities).

ORIGINATING OR SPOKE SITE: Location of the patient at the time the service being furnished via a telecommunications system occurs.

PRIMARY CARE: Health services that cover a range of prevention, wellness, and treatment for common illnesses. Primary care providers include doctors, nurses, nurse practitioners, and physician assistants. They often **maintain long-term relationships** with you and advice and treat you on a range of health related issues. They may also coordinate your care with specialists.

REMOTE MONITORING: type of ambulatory healthcare where patients use mobile medical devices to perform a routine test and send the test data to a healthcare professional in real-time. Remote monitoring includes devices such as glucose meters for patients with diabetes and heart or blood pressure monitors for patients receiving cardiac care.

RURAL TELEHEALTH FOCUSED RESEARCH CENTER: Supports the HRSA Office for the Advancement of Telehealth (OAT) to build the evidence base for telehealth, especially in rural settings. This includes working with OAT and EB THNP Program award recipients to identify a core set of measures applicable to each award recipient program, building a data collection tool, fielding the tool and collecting patient-level data, analyzing the pooled data, and publishing findings.

TELEHEALTH NETWORK: is defined as an organizational arrangement among three or more separately owned domestic public and/or private entities, including the applicant organization. For purposes of this award, HRSA recognizes a growing trend towards greater consolidation within the rural health care industry and the possibility that multiple organizations with the same EIN and/or DUNS number could be located in different rural service areas that have a need for telehealth services. Please refer to Attachment 11 for information on how to request an exception to this policy.