DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFDA 93.153 COORDINATED SERVICES AND ACCESS TO RESEARCH FOR WOMEN, INFANTS, CHILDREN, AND YOUTH (Ryan White HIV/AIDS Program Part D Women, Infants, Children, and Youth (WICY) Program)

I. PROGRAM OBJECTIVES

The objective of this program is to provide family-centered care in an outpatient or ambulatory care setting (directly or through contracts or memoranda of understanding) for low income, uninsured, and medically underserved women, infants, children, and youth with HIV.

II. PROGRAM PROCEDURES

The Department of Health and Human Services (HHS) administers the Ryan White HIV/AIDS Program (RWHAP) Part D Coordinated Services for Women, Infants, Children, and Youth (WICY) through the Health Resources and Services Administration (HRSA)'s HIV/AIDS Bureau (HAB). The RWHAP Part D WICY programs provide family-centered outpatient or ambulatory care setting (directly or through contracts or memoranda of understanding) for low income, uninsured and medically underserved women, infants, children, and youth with HIV. Recipients can also provide additional support services to patients and affected family members.

Grants under the RWHAP Part D WICY are awarded to public and non-profit private entities, including health facilities operated by or pursuant to a contract with the Indian Health Service (42 USC 300ff-71(a)). Services may be provided directly by the recipient or through contractual agreements or memoranda of understanding with other service providers.

Source of Governing Requirements

The RWHAP Part D WICY is authorized under Section 2671 of Title XXVI of the PHS Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. No. 111-87) and is codified at 42 USC 300ff-71. The Minority AIDS Initiative (MAI) is authorized under Section 2693(b)(2)(D) of the PHS Act (42 USC 300ff-121(b)(2)(D)).

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. No. 116- 136, 134 Stat. 562) provided one-time funding to help current Ryan White HIV/AIDS Program (RWHAP) recipients prevent, prepare for, and respond to the novel coronavirus disease 2019 (COVID-19).

The RWHAP Part D WICY has no program-specific program regulations.

Availability of Other Program Information

Further information about the RWHAP Part D WICY is available at http://www.hab.hrsa.gov/.

Additional information on allowable uses of funds under the RWHAP Part D WICY is contained in policy notices and standards found at

http://www.hab.hrsa.gov/manageyourgrant/policiesletters.html.

CARES Act information is available at https://hab.hrsa.gov/program-grants-management/coronavirus-covid-19-response.

III. COMPLIANCE REQUIREMENTS

In developing the audit procedures to test compliance with the requirements for this federal program, the auditor must determine, from the following summary (also included in Part 2, "Matrix of Compliance Requirements"), which of the 12 types of compliance requirements have been identified as subject to the audit (noted with a "Y" in the summary matrix below), and then determine which of the compliance requirements that are subject to the audit are likely to have a direct and material effect on the federal program at the auditee. For each such compliance requirement subject to the audit, the auditor must use Part 3 (which includes generic details about each compliance requirement other than Special Tests and Provisions) and this program supplement (which includes any program-specific requirements) to perform the audit. When a compliance requirement is shown in the summary below as "N," it has been identified as not being subject to the audit. Auditors are not expected to test requirements that have been noted with an "N." See the Safe Harbor Status discussion in Part 1 for additional information.

A	B	C	E	F	G	H	I	J	L	M	N
Activities Allowed or Unallowed	Allowable Costs/Cost Principles	Cash Management	Eligibility	Equipment/ Real Property Management	Matching, Level of Effort, Earmarking	Period Of Performance	Procurement Suspension & Debarment	Program Income	Reporting	Subrecipient Monitoring	Special Tests and Provisions
Y	Y	Y	N	N	N	N	Y	Y	Y	N	N

A. Activities Allowed or Unallowed

1. *Activities Allowed*

   a. Funds may be used for family-centered care involving outpatient or ambulatory care, directly or through contracts or memoranda of understanding, for women, infants, children, and youth with HIV. This includes provision of professional, diagnostic, and therapeutic services by a primary care provider, or a referral to and provision of specialty care; and services that sustain program activity and contribute to or help improve those services (42 USC 300ff-71(a) and (h)(3)).

Funds are not required to be used for primary care services when payments are available for such services from other sources (including Titles XVIII, XIX and XXI of the Social Security Act) (42 USC 300ff-71(i)).

b. Funds may be used for the following support services for patients: (1) family-centered care, including case management; (2) referrals for additional services, including inpatient hospital services, treatment for substance abuse and mental health services, and other social and support services as appropriate; (3) additional services necessary to enable the patient to participate in the RWHAP Part D WICY, including services to recruit and retain youth with HIV; and (4) provision of information and education on opportunities to participate in HIV/AIDS-related clinical research (42 USC 300ff-71(b)). Affected family members (people not identified with HIV) may be eligible for RWHAP support services in limited situations, but these services for affected individuals must always benefit people with HIV. Examples include, but are not limited to, mental health services, and respite care. Services to non-affected family members who meet these criteria may not continue subsequent to the death of the RWHAP client. Refer to HAB Policy Clarification Notice #16-02: Ryan White HIV/AIDS Program Services: Eligible Individuals & Allowable Uses of Funds for further information on circumstances in which affected family members may be eligible to receive RWHAP funded support services.

c. Funds must be used for the establishment of a clinical quality management program to assess the extent to which HIV health services are consistent with the most recent Public Health Service guidelines for the treatment of HIV/AIDS and related opportunistic infections, and, as applicable, to develop strategies for ensuring that such services are consistent with the guidelines for improvement in the access to and quality of HIV health services (42 USC 300ff-71(f)(2)). Policy Clarification Notice #15-02 https://hab.hrsa.gov/sites/default/files/hab/Global/HAB-PCN-15-02-CQM.pdf.

d. Funds may be used for administrative expenses, which are defined as funds used by recipients for grant management and monitoring activities, including costs related to any staff or activity other than provision of services. Indirect costs included in a federally negotiated indirect rate are considered part of administrative costs (see III.G.3, “Matching, Level of Effort, Earmarking – Earmarking,” for a limitation on expenditures for administrative costs) (42 USC 300ff-71(f)(1), (h)(1), and (h)(2)). Funds may be used for administrative expenses; no more than 10 percent on administrative expenses.

2. *Activities Unallowed*

a. Funds may not be used for AIDS programs or to develop materials, designed to promote or encourage, directly, intravenous drug abuse or sexual activity, whether homosexual or heterosexual (42 USC 300ff-84).

b. Funds may not be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug (Consolidated Appropriations Act, 2016 (Pub. L. No. 114-113), Division H, Title V, Section 520, and subsequent appropriations, as applicable). Other elements of syringe services programs may be allowable if in compliance with applicable HHS and HRSA-specific guidance.

c. Funds may not be used to purchase or improve land or to purchase, construct, or make permanent improvement to any building (Funding Opportunity Announcement, Section IV.6).

d. Funds may not be used to make cash payments to intended recipients of RWHAP services (Policy Clarification Notice #16-02, Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds https://hab.hrsa.gov/sites/default/files/hab/program-grants-management/ServiceCategoryPCN_16-02Final.pdf).

e. Charges that are billable to third party payors (e.g., private health insurance, prepaid health plans, Medicaid, Medicare, HUD, other RWHAP funding including ADAP).

f. To directly provide housing or health care services (e.g., HIV care, counseling, and testing) that duplicate existing services.

g. PrEP or non-occupational Post-Exposure Prophylaxis (nPEP) medications or the related medical services. As outlined in the June 22, 2016 RWHAP and PrEP program letter, the RWHAP legislation provides grant funds to be used for the care and treatment of PLWH, thus prohibiting the use of RWHAP funds for PrEP medications or related medical services, such as physician visits and laboratory costs. RWHAP Part D funds can be used toward Psychosocial Support Services, a component of family-centered care, which may include counseling and testing and information on PrEP to eligible clients' partners and affected family members, within the context of a comprehensive PrEP program.

h. Fundraising expenses.

i. Lobbying activities and expenses.

j. International travel.

J. Program Income

The Notice of Award provides guidance on the use of program income. The addition method is used for the Ryan White HIV/AIDS Program Part D. Program income must be used for activities described in III.A.1, "Activities Allowed."

L. Reporting

1. Financial Reporting

a. *SF-270, Request for Advance or Reimbursement* – Applicable

b. *SF-271, Outlay Report and Request for Reimbursement for Construction Programs* – Not Applicable

c. *SF-425, Federal Financial Report* – Applicable

2. Performance Reporting

Not Applicable

3. Special Reporting

Not Applicable

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFDA 93.461 COVID-19 TESTING FOR THE UNINSURED

I. PROGRAM OBJECTIVES

The COVID-19 Testing for the Uninsured program is also referred to as the COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured program. This program is administered by the Health Resources and Services Administration to provide claims reimbursements to health care providers for conducting COVID-19 testing for the uninsured and to support healthcare related expenses attributable to the treatment of uninsured individuals with COVID-19.

II. PROGRAM PROCEDURES

This program is administered as a claims reimbursement program for health care providers. Health care providers who have conducted COVID-19 testing or provided treatment for uninsured individuals with a COVID-19 diagnosis on or after February 4, 2020, can electronically request claims reimbursement through the program and will be reimbursed generally at Medicare rates, subject to available funding. Steps involve enrolling as a provider participant (recipient), signing the terms and conditions of the program, checking patient eligibility, submitting patient information, submitting claims electronically, and receiving payment via direct deposit.

This program does not provide coding guidance to providers. Rather, the program provides billing guidance to allow providers to identify and submit only claims eligible for reimbursement under this program, which is exclusively for reimbursing providers for COVID-19 testing of uninsured individuals and treatment for uninsured individuals when COVID-19 is the primary reason for treatment.

Source of Governing Requirements

This program has the following two components:

1. Testing – The reimbursement for COVID-19 testing services is authorized via:

    - Families First Coronavirus Response Act (Pub. L. No. 116-127) (FFCRA) [Division A, Title V, Office of the Secretary, Public Health and Social Service Emergency Fund 134 Stat. 182].

    - Paycheck Protection Program and Health Care Enhancement Act (Pub. L. No. 116-139) [134 Stat. 626] (PPPHCA).

2. Treatment – The reimbursement for COVID-19 treatment services is authorized via:

    - The Coronavirus Aid, Relief, and Economic Security Act (CARES) (Pub. L. No. 116-136, 134 Stat. 563).

- Paycheck Protection Program and Health Care Enhancement Act (Pub. L. No. 116-139).

Availability of Other Program Information

The following websites provide additional information about COVID Uninsured Claims.

Overview:
https://www.hrsa.gov/CovidUninsuredClaim

Frequently Asked Questions:
https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions
https://coviduninsuredclaim.linkhealth.com/frequently-asked-questions.html

Claims Reimbursement Procedures:
https://coviduninsuredclaim.linkhealth.com/

Testing – Terms and Conditions of the award:
https://www.hhs.gov/sites/default/files/terms-and-conditions-ffcra-relief-fund.pdf

Treatment – Terms and Conditions of the award:
https://www.hhs.gov/sites/default/files/terms-and-conditions-uninsured-relief-fund.pdf

III. COMPLIANCE REQUIREMENTS

In developing the audit procedures to test compliance with the requirements for this federal program, the auditor must determine, from the following summary (also included in Part 2, "Matrix of Compliance Requirements"), which of the 12 types of compliance requirements have been identified as subject to the audit (noted with a "Y" in the summary matrix below), and then determine which of the compliance requirements that are subject to the audit are likely to have a direct and material effect on the federal program at the auditee. For each such compliance requirement subject to the audit, the auditor must use Part 3 (which includes generic details about each compliance requirement other than Special Tests and Provisions) and this program supplement (which includes any program-specific requirements) to perform the audit. When a compliance requirement is shown in the summary below as "N," it has been identified as not being subject to the audit. Auditors are not expected to test requirements that have been noted with an "N." See the Safe Harbor Status discussion in Part 1 for additional information.

A	B	C	E	F	G	H	I	J	L	M	N
Activities Allowed or Unallowed	Allowable Costs/Cost Principles	Cash Management	Eligibility	Equipment/ Real Property Management	Matching, Level of Effort, Earmarking	Period Of Performance	Procurement Suspension & Debarment	Program Income	Reporting	Subrecipient Monitoring	Special Tests and Provisions
Y	Y	N	Y	N	N	N	N	N	N	N	N

A. Activities Allowed or Unallowed

1. *Activities Allowed*

   Required primary health services as described in the terms and conditions of the award for uninsured individuals:

   a. Reimbursement of payments for COVID-19 testing and testing-related items for individuals who do not have coverage through an individual or employer-sponsored plan, a federal healthcare program, or the Federal Employees Health Benefits Program at the time the services were rendered.

   b. Reimbursements of payments for COVID-19 treatment as determined by the program for individuals who do not have any health care coverage at the time the services were rendered.

2. *Activities Unallowed*

   As described in the terms and conditions of the award.

   a. Funds provided will not be used to reimburse expenses that have been reimbursed from other sources or that other sources are obligated to reimburse. The recipient will not include costs for which payment was received in cost reports or otherwise seek uncompensated care reimbursement through federal or state programs for items or services for which payment was received.

   b. The recipient will not engage in “balance billing” or charge any type of cost sharing for any COVID-19 testing, testing-related items and services provided, or treatment for which the recipient receives a payment from this program. The recipient shall consider payment received under this program to be payment in full for such care or treatment.

c. If the recipient, prior to signing these terms and conditions, charged any uninsured individuals a fee for COVID-19 testing, testing-related items and services, or treatment for which the recipient subsequently received a payment from this program, the recipient will communicate to the uninsured individuals they do not owe recipient any money for that care or treatment. If an uninsured individual paid the recipient for any portion of such care or treatment, the recipient must return the payment to the uninsured individual in a timely manner.

E. Eligibility

Services must be for individuals who at the time the services were provided were uninsured as described in the terms and conditions of the award.

IV. Other Information

Guidance documents on HRSA webpages on the HHS.gov website, such as those listed under "Availability of Other Program Information," are provided only to clarify the applicable laws, regulations, and terms and conditions of the award. Such guidance documents do not create new compliance requirements. However, non-federal entities in substantial compliance with the guidance applicable in these guidance documents at the time of a transaction are considered in compliance with the underlying compliance requirements.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFDA 93.498 PROVIDER RELIEF FUND

Note: As discussed in "IV. Other Information, 2. *Schedule of Expenditures of Federal Awards (SEFA) Reporting*," for fiscal years ending in 2020 on or before December 30, 2020, the entity reports no PRF expenditures (including no lost revenue). Therefore, this program's expenditures will first be reported in the SEFA and audited under the Uniform Guidance in a fiscal year ending on or after December 31, 2020.

I. PROGRAM OBJECTIVES

The Provider Relief Fund (PRF) is administered by the Health Resources and Services Administration (HRSA) and provides relief funds to hospitals and other healthcare providers, including those on the front lines of the coronavirus response. The funding supports healthcare-related expenses or lost revenue attributable to COVID-19 and ensures that uninsured Americans can get treatment for COVID-19.

II. PROGRAM PROCEDURES

The PRF includes the following components and may include additional components established after the date of this Supplement:

General Distribution – The first round of Phase 1 funds was distributed to providers based on their portion of 2019 Medicare-Fee-For-Service (MFFS) payments. These distributions included $30 billion distributed April 10, 2020 and April 17, 2020. The second round of Phase 1 funds of $20 billion were distributed to providers beginning on April 24, 2020, and were based on revenues from CMS cost report data and submissions to the provider portal.

In June 2020, Phase 2 General Distribution funds of $18 billion were made available to Medicaid, CHIP, Dental providers, and providers who missed the Phase 1 distribution.

Targeted Distributions – Funds were allocated for targeted distribution to providers in areas particularly impacted by the COVID-19 outbreak: rural providers, providers of services with lower shares of Medicare reimbursement, or providers who predominantly serve the Medicaid population. Distributions were made in the following areas:

High Impact Area Distribution

Skilled Nursing Facility Distribution

Skilled Nursing Facility Infection Control Distribution

Safety Net Hospital Distribution

Indian Health Service Distribution

Rural Distribution

Most payments were sent out to providers without application, with requirement for recipients to accept the terms and conditions through an online portal or return funds. Recipients were required to either accept the terms and conditions or return the funds. The CFDA numbers were not provided at time of payments or included in initial terms and conditions.

Source of Governing Requirements

Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. No. 116-136, 134 Stat. 563)

Paycheck Protection Program and Health Care Enhancement Act (Pub. L. No. 116-139, 134 Stat. 622)

Availability of Other Program Information

The following HHS.gov webpages provide additional information:

CARES Act Provider Relief Fund
https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/index.html

CARES Act Provider Relief Fund General Information
https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/general-information/index.html

CARES Act Provider Relief Fund: For Providers which includes copies of terms and conditions.
https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/for-providers/index.html

CARES Act Provider Relief Fund Frequently Asked Questions
https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/faqs/index.html

The following HHS.gov webpages provide the applicable terms and conditions:

General Distribution
https://www.hhs.gov/sites/default/files/terms-and-conditions-provider-relief-30-b.pdf
https://www.hhs.gov/sites/default/files/terms-and-conditions-provider-relief-20-b.pdf

Medicaid, CHIP, and Dental Distribution
https://www.hhs.gov/sites/default/files/terms-and-conditions-phase-2-general-distribution-relief-fund.pdf

High Impact Area Distribution
https://www.hhs.gov/sites/default/files/terms-and-conditions-high-impact-relief-fund.pdf

Skilled Nursing Facility Distribution
https://www.hhs.gov/sites/default/files/terms-and-conditions-skilled-nursing-facility-relief-fund.pdf

Skilled Nursing Facility Infection Control Distribution
https://www.hhs.gov/sites/default/files/provider-relief-fund-nf-infection-control-payment-terms-and-conditions.pdf

Safety Net Hospital Distribution
https://www.hhs.gov/sites/default/files/terms-and-conditions-safety-net-relief-fund.pdf

Indian Health Service Distribution
https://www.hhs.gov/sites/default/files/terms-and-conditions-indian-health-service-relief-fund.pdf

Rural Distribution
https://www.hhs.gov/sites/default/files/terms-and-conditions-rural-relief-fund.pdf

III. COMPLIANCE REQUIREMENTS

In developing the audit procedures to test compliance with the requirements for this federal program, the auditor must determine, from the following summary (also included in Part 2, "Matrix of Compliance Requirements"), which of the 12 types of compliance requirements have been identified as subject to the audit (noted with a "Y" in the summary matrix below), and then determine which of the compliance requirements that are subject to the audit are likely to have a direct and material effect on the federal program at the auditee. For each such compliance requirement subject to the audit, the auditor must use Part 3 (which includes generic details about each compliance requirement other than Special Tests and Provisions) and this program supplement (which includes any program-specific requirements) to perform the audit. When a compliance requirement is shown in the summary below as "N," it has been identified as not being subject to the audit. Auditors are not expected to test requirements that have been noted with an "N." See the Safe Harbor Status discussion in Part 1 for additional information.

A	B	C	E	F	G	H	I	J	L	M	N
Activities Allowed or Unallowed	Allowable Costs/Cost Principles	Cash Management	Eligibility	Equipment/ Real Property Management	Matching, Level of Effort, Earmarking	Period Of Performance	Procurement Suspension & Debarment	Program Income	Reporting	Subrecipient Monitoring	Special Tests and Provisions
Y	Y	N	N	N	N	N	N	N	Y	N	N

A. Activities Allowed or Unallowed

1. *Activities Allowed (All distributions except Skilled Nursing Facility Infection Control Distribution)*

   Law (HR 748-283 and Pub. L. No. 116-139, 134 Stat. 622)

   To prevent, prepare for, and respond to coronavirus, domestically or internationally, for necessary expenses to reimburse, through grants or other mechanisms, eligible health care providers for health care related expenses or lost revenues that are attributable to coronavirus.

   That funds appropriated under this paragraph in this Act shall be available for building or construction of temporary structures, leasing of properties, medical supplies and equipment, including personal protective equipment and testing supplies, increased workforce and trainings, emergency operation centers, retrofitting facilities, and surge capacity.

   Payment means a pre-payment, prospective payment, or retrospective payment.

   Terms and Conditions

   a. The recipient certifies that the payment will only be used to prevent, prepare for, and respond to coronavirus, and that the payment shall reimburse the recipient only for health care related expenses or lost revenues that are attributable to coronavirus.

   b. The secretary has concluded that the COVID-19 public health emergency has caused many healthcare providers to have capacity constraints. As a result, patients that would ordinarily be able to choose to receive all care from in-network healthcare providers may no longer be able to receive such care in-network. Accordingly, for all care for a presumptive or actual case of COVID-19, recipient certifies that it will not seek to collect from the patient out-of-pocket expenses in an amount greater than what the patient would have otherwise been required to pay if the care had been provided by an in-network recipient.

   c. The recipient certifies that retaining the payment for at least 90 days without contacting HHS regarding remittance of those funds, is deemed to have accepted the Terms and Conditions.

   d. The recipient must provide or have provided after January 31, 2020, diagnoses, testing, or care for individuals with possible or actual cases of COVID-19 or prevented in the spread of COVID-19. The Department of Health and Human Services (HHS) broadly views every patient as a possible case of COVID-19.

2. *Activities Unallowed* (**All distributions**)

Law (HR 748-283 and Pub. L. No. 116-139, 134 Stat. 622)

That these funds may not be used to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse.

Terms and Conditions

Payments may not be used to reimburse expenses or losses that have been reimbursed from other sources or that other sources are obligated to reimburse.

3. *Activities Allowed (Skilled Nursing Facility Infection Control Distribution)*

Terms and Conditions

Funds may only be used to reimburse the recipient for costs associated with the following items and services ("Infection Control Expenses"):

a. Costs associated with administering COVID-19 testing, which means an in vitro diagnostic test defined in section 809.3 of title 21, *Code of Federal Regulations* (or successor regulations) for the detection of SARS-CoV-2 or the diagnosis of the virus that causes COVID-19, and the administration of such a test, that:

- Is approved, cleared, or authorized under section 510(k), 513, 515, or 564 of the Federal Food, Drug, and Cosmetic Act (21 USC 360(k), 360c, 360e, 360bbb-3);
- The developer has requested, or intends to request, emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 USC 360bbb-3), unless and until the emergency use authorization request under such section 564 has been denied or the developer of such test does not submit a request under such section within a reasonable timeframe;
- Is developed in and authorized by a state that has notified the secretary of HHS of its intention to review tests intended to diagnose COVID-19; or
- Other test that the secretary determines appropriate in guidance.

b. Reporting COVID-19 test results to local, state, or federal governments.

c. Hiring staff, whether employees or independent contractors, to provide patient care or administrative support.

d. Expenses incurred to improve infection control, including activities such as implementing infection control "mentorship" programs with subject matter experts or changes made to physical facilities.

e. Providing additional services to residents, such as technology that permits residents to connect with their families if the families are not able to visit in person.

L. Reporting

1. Financial Reporting

a. *SF-270, Request for Advance or Reimbursement* – Not Applicable

b. *SF-271, Outlay Report and Request for Reimbursement for Construction Programs* – Not Applicable

c. *SF-425, Federal Financial Report* – Not Applicable

2. Performance Reporting

Not Applicable

3. Special Reporting – Applicable only to audits of fiscal years ending on or after December 31, 2020

Recipients must report for the calendar year ending December 31, 2020, and the six months ending June 30, 2021, as described in the General and Targeted Distribution Post-Payment Notice of Reporting Requirements issued September 19, 2020 (https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/reporting-auditing/index.html) and guidance issued by HRSA subsequent to the date of this Supplement.

At the time of issuance of this addendum, the report and reporting portal were under development and not expected to be available before January 15, 2021. By February 1, 2021, a notice will be placed on OMB's Office of Federal Financial Management website (https://www.whitehouse.gov/omb/management/office-federal-financial-management/) providing key line items and other information from the report that are subject to audit for audits of fiscal years ending on or after December 31, 2020. Auditors performing audits of December 31, 2020 year-ends are expected to test this special reporting even though it will not be able to be submitted by recipients until early in the next fiscal year.

IV. Other Information

1. *Webpage Guidance*

Guidance documents accessed by links on the HHS.gov website such as those listed under "Availability of Other Program Information" are provided only to clarify the applicable laws,

regulations, and terms and conditions of the award and do not create new compliance requirements. However, non-federal entities in substantial compliance with the guidance applicable in these guidance documents in effect at the time of the activity or transaction are considered in compliance with the underlying compliance requirements.

2. *Schedule of Expenditures of Federal Awards (SEFA) Reporting*

SEFA reporting for this program (including lost revenue) is based upon the PRF report in "L.3 Special Reporting – Applicable only to audits of fiscal years ending on or after December 31, 2020."

For fiscal years ending (FYE) in 2020 on or before December 30, 2020, the entity reports no PRF expenditures (including no lost revenue).

For a FYE December 31, 2020, the entity reports on the SEFA as expenditures (including lost revenue) based upon the PRF report for calendar year ending December 31, 2020, and discloses in the footnotes to the SEFA that the amount included on the SEFA is based upon the December 31, 2020 PRF report.

For fiscal years ending in 2021 on or before June 29, 2021, the entity reports on the SEFA as expenditures (including lost revenue) based upon the PRF report for calendar year ending December 31, 2020, and discloses in the footnotes to the SEFA that the amount included on the SEFA is based upon the December 31, 2020 PRF report.

SEFA reporting guidance for fiscal years ending on or after June 30, 2021, will be provided in the 2021 Compliance Supplement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFDA 93.914 HIV EMERGENCY RELIEF PROJECT GRANTS (RYAN WHITE HIV/AIDS PROGRAM PART A)

I. PROGRAM OBJECTIVES

The objective of this program is to improve access to a comprehensive continuum of high-quality, community-based primary medical care and support services in metropolitan areas that are disproportionately affected by the incidence of Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS). The statute refers to both people with HIV and those who have AIDS (as reported to and confirmed by the Centers for Disease Control and Prevention (CDC)). These terms are used interchangeably in this compliance supplement but refer to this total universe of eligible individuals.

Emergency financial assistance in the form of formula-based funding, supplemental project-based funding, and formula-based Minority AIDS Initiative (MAI) funding is provided to eligible metropolitan areas (EMAs) and transitional grant areas (TGAs) to develop, organize, and operate health and support services programs for people with HIV and their care givers.

The supplemental grants are discretionary awards and are awarded, following competition, to EMAs and TGAs that demonstrate need beyond that met through the formula award. They must also demonstrate the ability to use the supplemental amounts quickly and cost effectively. Other criteria contained in annual application guidance documents may also apply. All EMAs and TGAs that are receiving formula assistance are also receiving supplemental assistance and will continue to receive such assistance unless they fail to meet the legislative requirements related to unobligated balances.

II. PROGRAM PROCEDURES

The Health Resources and Services Administration (HRSA), a component of the Department of Health and Human Services (HHS), administers the HIV emergency relief programs. Eligibility for Ryan White HIV/AIDS Program (RWHAP) Part A grants depends, in part, on the number of confirmed AIDS cases within a statutorily specified "metropolitan area." The secretary of HHS uses the Office of Management and Budget's (OMB) census-based definitions of a Metropolitan Statistical Area (MSA) in determining the geographic boundaries of a RWHAP metropolitan area. HHS relies on the OMB geographic boundaries in effect when a jurisdiction was or is (if newly eligible) initially funded under RWHAP Part A. A metropolitan area is not eligible if it does not have an overall population of 50,000 or more.

HRSA uses data reported to and confirmed by CDC to determine eligibility. An EMA is a metropolitan area for which there has been reported to, and confirmed by, the director of the CDC a cumulative total of more than 2,000 cases of AIDS for the most recent five calendar-year periods for which data are available. A TGA is a metropolitan area for which there has been reported to, and confirmed by, the director of the CDC a cumulative total of at least 1000, but fewer than 2000, cases of AIDS during the most recent period of five calendar years for which data are available. MAI funding is awarded using a formula that is based on the distribution of HIV/AIDS cases among racial and ethnic minorities.

After subtracting the amount available for MAI project assistance, HRSA must make at least two-thirds (66 2/3 percent) of the appropriated amount available for the EMAs' and TGAs' formula allocation and award the remainder as supplemental funding on the basis of demonstrated need and other factors. EMAs and TGAs are funded from the formula, supplemental, and MAI allocation on the basis of a single application and a combined award.

Funds are made available to the chief elected official of the EMA or TGA in accordance with statutory requirements and program guidelines. Day-to-day responsibility for the grant is ordinarily delegated to the jurisdiction's public health department, and some administrative functions may be outsourced to a private entity. The chief elected official of the jurisdiction is also required to establish or designate an HIV health services planning council, which carries out a planning process, coordinating with other state, local, and private planning and service organizations, and establishes the priorities for allocating funds. Newly eligible areas designated as TGAs in fiscal year (FY) 2007 and beyond are exempt from the requirement to establish and use an HIV health services planning council but must provide a process for obtaining community input as prescribed in the RWHAP Part A legislation.

Consistent with funding and service priorities established through the public planning process, the receiving jurisdiction uses the funds to provide assistance to public entities or private non-profit or for-profit entities to deliver or enhance HIV/AIDS-related core medical and support services and, within established limits, for associated administrative and clinical quality management activities. Administrative activities include EMA or TGA oversight of service provider performance and adherence to their subrecipient obligations. Most of these service providers are non-profit organizations.

Source of Governing Requirements

This program is authorized under sections 2601–2610 of Title XXVI of the Public Health Service Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. No. 111-87), and is codified at 42 USC 300ff-11 through 300ff-20. The MAI is authorized under Section 2693(b)(2)(A) of the Public Health Service Act, 42 USC 300ff- 121(b)(2)(A).

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. No. 116-136, 134 Stat. 562) provided one-time funding to help current RWHAP recipients prevent, prepare for, and respond to the novel coronavirus disease 2019 (COVID-19).

All HRSA awards are subject to the Uniform Administrative Requirements, Cost Principles, and Audit Requirements at 45 CFR part 75. As per 45 CFR part 75.201 and 301, recipients may use a fixed-award instrument to obtain services based on a reasonable estimate of actual cost and based on performance and results related to improvement of program outcomes.

There are no program regulations specific to this program.

Availability of Other Program Information

Additional information about this program is available at http://hab.hrsa.gov/.

Additional information on allowable uses of funds under this program is contained in policy notices and standards found at http://www.hab.hrsa.gov/manageyourgrant/policiesletters.html and http://hab.hrsa.gov/manageyourgrant/files/fiscalmonitoringparta.pdf.

CARES Act information is available at https://hab.hrsa.gov/program-grants-management/coronavirus-covid-19-response.

III. COMPLIANCE REQUIREMENTS

In developing the audit procedures to test compliance with the requirements for this federal program, the auditor must determine, from the following summary (also included in Part 2, "Matrix of Compliance Requirements"), which of the 12 types of compliance requirements have been identified as subject to the audit (noted with a "Y" in the summary matrix below), and then determine which of the compliance requirements that are subject to the audit are likely to have a direct and material effect on the federal program at the auditee. For each such compliance requirement subject to the audit, the auditor must use Part 3 (which includes generic details about each compliance requirement other than Special Tests and Provisions) and this program supplement (which includes any program-specific requirements) to perform the audit. When a compliance requirement is shown in the summary below as "N," it has been identified as not being subject to the audit. Auditors are not expected to test requirements that have been noted with an "N." See the Safe Harbor Status discussion in Part 1 for additional information.

A	B	C	E	F	G	H	I	J	L	M	N
Activities Allowed or Unallowed	Allowable Costs/Cost Principles	Cash Management	Eligibility	Equipment/ Real Property Management	Matching, Level of Effort, Earmarking	Period Of Performance	Procurement Suspension & Debarment	Program Income	Reporting	Subrecipient Monitoring	Special Tests and Provisions
Y	Y	Y	Y	N	N	N	N	Y	N	Y	N

A. Activities Allowed or Unallowed

1. *Activities Allowed*

Funds may be used only for core medical services, support services, clinical quality management, and administrative expenses (42 USC 300ff-14(a)).

a. Core medical services with respect to people with HIV (including co-occurring conditions, i.e., one or more adverse health conditions of an individual with HIV, without regard to whether the individual has AIDS or whether the conditions arise from HIV) means (1) outpatient and

ambulatory health services; (2) AIDS Drug Assistance Program treatments; (3) AIDS pharmaceutical assistance; (4) oral health care; (5) early intervention services meeting the requirements of 42 USC 300ff-14(e); (6) health insurance premium and cost sharing assistance for low-income individuals; (7) home health care; (8) medical nutrition therapy; (9) hospice services; (10) home and community-based health services; (11) mental health services; (12) substance abuse outpatient care; and (13) medical case management, including treatment adherence services (42 USC 300ff-14(c)(3)).

b. Support services means services that are needed for people with HIV to achieve their medical outcomes (those outcomes affecting the HIV-related clinical status of an individual with HIV) (for example, respite care for persons caring for people with HIV, outreach services, medical transportation, linguistic services, referrals for health care and support services, and such other services specified by HRSA) (42 USC 300ff-14(d)).

c. Clinical quality management means assessing the extent to which HIV health services provided to patients under the grant are consistent with the most recent Public Health Service guidelines for the treatment of HIV/AIDS and related opportunistic infections, and as applicable, developing strategies for ensuring that such services are consistent with the guidelines for improvement in the access to and quality of HIV health services (42 USC 300ff-14(h)(5)(A)). Policy Clarification Notice #15-02 https://hab.hrsa.gov/sites/default/files/hab/Global/CQM-PCN-15-02.pdf.

d. Administrative expenses at the recipient level include (1) activities related to routine grant administration and monitoring (for example, development of applications, receipt and disbursal of program funds, development and establishment of reimbursement and accounting systems, development of a clinical quality management program, preparation of routine programmatic and financial reports, and compliance with grant conditions and audit requirements); (2) contract development, solicitation review, award, monitoring, and reporting; and (3) activities carried out by the HIV health services planning council (42 USC 300ff-14(h)(3) and 300ff-12(b)).

e. Subrecipient administrative expenses include usual and recognized overhead activities, including those that are reimbursed through approved indirect cost rates; management oversight of funded activities; and other types of program support such as quality assurance, quality control, and related activities (42 USC 300ff-14(h)(4)).

2. *Activities Unallowed*

a. Funds may not be used to make payment for any item or service if payment has already been made or can reasonably be expected to be made

under any state compensation program, under an insurance policy or any federal or state health benefits program, or by an entity that provides health services on a pre-paid basis except for programs administered by or providing the services of the Indian Health Service (42 USC 300ff-15(a)(6)).

b. Funds may not be used to purchase or improve land or to purchase, construct, or make permanent improvement to any building. Minor remodeling is allowed (42 USC 300ff-14(i)).

c. Funds may not be used to make cash payments to intended recipients of RWHAP services (42 USC 300ff-14(i)) and Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds, Policy Clarification Notice #16-02 https://hab.hrsa.gov/sites/default/files/hab/program-grants-management/ServiceCategoryPCN_16-02Final.pdf.

d. Funds may not be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug (Consolidated Appropriations Act, 2016, Division H, Title V, Section 520 (Pub. L. No. 114-113) and subsequent appropriations, as applicable). Other elements of syringe services programs may be allowable if in compliance with applicable HHS and HRSA-specific guidance.

e. Funds may not be used for AIDS programs or to develop materials, designed to promote or encourage, directly, intravenous drug use or sexual activity, whether homosexual or heterosexual (42 USC 300ff-84).

E. Eligibility

1. Eligibility for Individuals

Eligible beneficiaries are low-income individuals or families of people with HIV. To the maximum extent practicable, services are to be provided to eligible individuals regardless of their ability to pay for the services and their current or past health condition (42 USC 300ff-15(a)(7)(A)).

The requirement related to people with HIV is waived for the COVID-19 CARES Act funding only in the extremely limited instances of household members living with RWHAP clients, and only for COVID-19 testing and the provision of personal protective equipment (PPE). Part D recipients are able to use funds for this purpose in the absence of a waiver (section 2683 of the PHS Act).

2. Eligibility for Group of Individuals or Area of Service Delivery

Not Applicable

3. Eligibility for Subrecipients

The EMA or TGA may make funds available to public or private non-profit entities or to private for-profit entities if they are the only available providers of quality HIV care in the area (42 USC 300ff-14(b)(2)).

J. Program Income

The Notice of Award provides guidance on the use of program income. The addition method is used for this program. Program income must be used for activities described in III.A.1, "Activities Allowed."

M. Subrecipient Monitoring

1. The HHS Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards *(*45 CFR Part 75) requires pass-through entities: (1) to evaluate each subrecipient's risk of noncompliance in order to determine the appropriate monitoring level; (2) to monitor the activities of subrecipient organizations to ensure that the subaward is in compliance with applicable federal statutes and regulations and terms of the subaward; and (3) to verify that subrecipients are audited as required under this guidance. Specifically, the grantee must conduct monitoring activities in accordance with sections 75.351 through 75.353 of Subpart D of 45 CFR Part 75.

2. Grantees must ensure that all requirements imposed by the federal government are passed down to subrecipients so that the HHS award is used in accordance with federal statutes, regulations, and the terms and conditions of the award.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFDA 93.917 HIV CARE FORMULA GRANTS (RYAN WHITE HIV/AIDS PROGRAM PART B)

I. PROGRAM OBJECTIVES

The objective of this program is to assist states and territories in improving the quality, availability, and organization of healthcare and support services for low-income, uninsured, and underinsured people with Human Immunodeficiency Virus (HIV).

II. PROGRAM PROCEDURES

The Department of Health and Human Services (HHS) administers the Ryan White HIV/AIDS Program (RWHAP) Part B through the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB). Grants are awarded annually, on a formula basis, to all 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands following submission of an application to, and approval by, HAB. The responsible state agency, usually the state health department, is designated by the governor.

The application addresses how the state plans to address each of the six specified program components: (1) HIV care consortia, (2) home and community-based care, (3) health insurance continuation program, (4) provision of treatments, (5) state direct services, and (6) Minority AIDS Initiative (MAI). This includes the state's plans for the AIDS Drug Assistance Program (ADAP). ADAP funding is provided to the state as a separate formula amount in addition to the base formula grant amount and can only be used for ADAP services.

States may use a variety of service delivery mechanisms. States may provide some or all services directly or may enter into subawards with local HIV care consortia, associations of public and non-profit healthcare and support service providers, and community-based organizations that plan, develop, and deliver services for low-income, uninsured, and underinsured people with HIV. The state also may delegate some of its authority to monitor provider agreements to a "lead agency" (fiscal agent), with specific responsibilities contained in a formal agreement between the state and that agency. Finally, the state may provide subawards to healthcare or other service providers.

Source of Governing Requirements

The RWHAP Part B formula grant program is authorized under Sections 2611-2623 of Title XXVI of the Public Health Service Act as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. No. 111-87) and codified at 42 USC 300ff-21 through 300ff-31b. The MAI is authorized under Section 2693(b)(2)(B) of the Public Health Service Act, 42 USC 300ff-121(b)(2)(B).

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. No. 116- 136, 134 Stat. 562) provided one-time funding to help current RWHAP recipients prevent, prepare for, and respond to the novel coronavirus disease 2019 (COVID-19).

There are no regulations specific to the RWHAP Part B.

Availability of Other Program Information

Further information about the RWHAP Part B is available at http://www.hab.hrsa.gov.

Additional information on allowable uses of funds under this program is contained in policy notices and standards found at http://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters and http://hab.hrsa.gov/sites/default/files/hab/Global/fiscalmonitoringpartb.pdf.

CARES Act information is available at https://hab.hrsa.gov/program-grants-management/coronavirus-covid-19-response.

III. COMPLIANCE REQUIREMENTS

In developing the audit procedures to test compliance with the requirements for this federal program, the auditor must determine, from the following summary (also included in Part 2, "Matrix of Compliance Requirements"), which of the 12 types of compliance requirements have been identified as subject to the audit (noted with a "Y" in the summary matrix below), and then determine which of the compliance requirements that are subject to the audit are likely to have a direct and material effect on the federal program at the auditee. For each such compliance requirement subject to the audit, the auditor must use Part 3 (which includes generic details about each compliance requirement other than Special Tests and Provisions) and this program supplement (which includes any program-specific requirements) to perform the audit. When a compliance requirement is shown in the summary below as "N," it has been identified as not being subject to the audit. Auditors are not expected to test requirements that have been noted with an "N." See the Safe Harbor Status discussion in Part 1 for additional information.

A	B	C	E	F	G	H	I	J	L	M	N
Activities Allowed or Unallowed	Allowable Costs/Cost Principles	Cash Management	Eligibility	Equipment/ Real Property Management	Matching, Level of Effort, Earmarking	Period Of Performance	Procurement Suspension & Debarment	Program Income	Reporting	Subrecipient Monitoring	Special Tests and Provisions
Y	Y	Y	Y	N	Y	N	N	Y	N	Y	N

A. Activities Allowed or Unallowed

1. *Activities Allowed*

a. Grant funds (and required matching funds) may be used for core medical services, support services, planning and evaluation, clinical quality management, and administrative expenses (42 USC 300ff-22(a); 42 USC 300ff-28(b)).

(1) Core medical services with respect to people with HIV (including the co-occurring conditions of the individual) means (1) outpatient and ambulatory health services; (2) AIDS Drug Assistance Program treatments; (3) AIDS pharmaceutical assistance; (4) oral healthcare; (5) early intervention services meeting the requirements of 42 USC 300ff-22(d); (6) health insurance premium and cost sharing assistance for low-income individuals; (7) home healthcare; (8) medical nutrition therapy; (9) hospice services; (10) home and community-based health services; (11) mental health services; (12) substance abuse outpatient care; and (13) medical case management, including treatment adherence services (42 USC 300ff-22(b)(3)).

(2) Support services means services that are needed for people with HIV to achieve their medical outcomes (those outcomes affecting the HIV-related clinical status of people with HIV) (for example, respite care for persons caring for people with HIV, outreach services, medical transportation, linguistic services, referrals for healthcare and support services, and such other services specified by HRSA). Expenditures for or through consortia are considered support services (42 USC 300ff-22(c); 42 USC 300ff-23(f)).

(3) Clinical quality management means assessing the extent to which HIV health services provided to patients under the grant are consistent with the most recent Public Health Service guidelines for the treatment of HIV/AIDS and related opportunistic infections, and as applicable, developing strategies for ensuring that such services are consistent with the guidelines for improvement in the access to and quality of HIV health services (42 USC 300ff-28(b)(3)(E)(i)). Policy Clarification Notice #15-02 https://hab.hrsa.gov/sites/default/files/hab/Global/HAB-PCN-15-02-CQM.pdf.

(4) Administrative expenses at the recipient level include activities related to (1) routine grant administration and monitoring (for example, development of applications, receipt and disbursal of program funds, development and establishment of reimbursement and accounting systems, development of a clinical quality

management program, preparation of routine programmatic and financial reports, and compliance with grant conditions and audit requirements); (2) contract development, solicitation review, award, monitoring, and reporting; and (3) planning and evaluation activities (42 USC 300ff-28(b)(3)(C)).

(5) Subrecipient administrative expenses include usual and recognized overhead activities, including those that are reimbursed through approved indirect cost rates; management oversight of funded activities; and other types of program support, such as quality assurance, quality control, and related activities (42 USC 300ff-28(b)(3)(D)).

b. Any drug rebates received on drugs purchased from funds provided to establish a program of therapeutics must be used to support the types of activities otherwise eligible for funding under RWHAP Part B, with priority given to activities related to providing therapeutics (42 USC 300ff-26(g)). To assess whether a state or subrecipient is giving priority to activities related to providing therapeutics, the state (or subrecipient) should be able to demonstrate, that, before undertaking any type of activities other than ADAP purchases for medications or insurance that are allowed under paragraph 1.a. above it (1) has no waiting list for ADAP services; (2) the ADAP formulary includes the required classes of HIV antiretroviral medications and opportunistic infection-related medications; and (3) the financial eligibility to access the ADAP is established at no less than 200 percent of the federal poverty level (the poverty guidelines are available at https://aspe.hhs.gov/poverty-guidelines and are also published each year in the *Federal Register*).

c. Rebates may be used for allowable RWHAP Part B services that exceed the recipient's RWHAP Part B implementation work plan. Rebates are not part of the recipient's RWHAP Part B award, and, therefore, are not subject to the 10 percent administrative cost cap nor to the requirement to spend 75 percent on core medical services (see III.G.3.b and h, "Matching, Level of Effort, and Earmarking – Earmarking" below). Rebates can be used to meet both a recipient's state matching and maintenance of effort (MOE) requirements (42 USC 300ff-26(g) and Policy Clarification Notice #15-04, Utilization and Reporting of Pharmaceutical Rebates, https://hab.hrsa.gov/sites/default/files/hab/Global/pcn_15-04_pharmaceutical_rebates.pdf).

2. *Activities Unallowed*

a. Funds may not be used to purchase or improve land, or to purchase, construct, or permanently improve (other than minor remodeling) any building or other facility (42 USC 300ff-28(b)(6)).

b. Funds may not be used to make cash payments to intended recipients of RWHAP services. Where direct provision of the service is not possible or effective; store gift cards, vouchers, coupons, or tickets that can be exchanged for a specific service or commodity (e.g., food or transportation) must be used. Recipients are advised to administer voucher and store gift card programs in a manner which assures that vouchers and store gift cards cannot be exchanged for cash or used for anything other than the allowable goods or services, and that systems are in place to account for disbursed vouchers and store gift cards (42 USC 300ff-28(b)(6)) and Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds, Policy Clarification Notice #16-02, https://hab.hrsa.gov/sites/default/files/hab/program-grants-management/ServiceCategoryPCN_16-02Final.pdf).

c. Funds may not be used to make payments for any item or service to the extent that payment has been made or can reasonably be expected to be made for that item or service under any state/territory compensation program, under an insurance policy, or under any federal or state health benefits program or by an entity that provides health services on a prepaid basis except for a program administered by or providing the services of the Indian Health Service (42 USC 300ff-27(b)(7)(F)).

d. Funds may not be used for inpatient hospital services, or nursing home or other long-term care facilities (42 USC 300ff-24(c)(3)).

e. Funds may not be used to pay any costs associated with creation, capitalization, or administration of a liability risk pool (other than those costs paid on behalf of individuals as part of premium contributions to existing liability risk pools) or to pay any amount expended by a state/territory under Title XIX of the Social Security Act (Medicaid) (42 USC 300ff- 25(b)).

f. Funds may not be used to develop materials designed to promote or encourage, directly, intravenous drug use or sexual activity, whether homosexual or heterosexual (42 USC 300ff-84).

g. Funds may not be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug (Consolidated Appropriations Act (Pub. L. No. 114-113), 2016, Division H, Title V, Section 520 and subsequent appropriations, as applicable). Other elements of syringe services programs may be allowable if in compliance with applicable HHS and HRSA-specific guidance.

h. ADAP rebates cannot be shared with other entities including, but not limited to, RWHAP Part A recipients, high-risk insurance pools, Marketplace plans, Medicaid, or any other state or federal program (42 USC 300ff- 31(b)).

i. International travel.

E. Eligibility

1. Eligibility for Individuals

a. To be eligible to receive assistance in the form of therapeutics, an individual must have a medical diagnosis of HIV/AIDS and be (a) a low-income individual (as defined by the state), (b) a resident of the state, and (c) uninsured or underinsured (42 USC 300ff-26(b)).

b. The requirement to serve only people with HIV is waived for the COVID-19 CARES Act funding only in the extremely limited instances of household members living with Ryan White HIV/AIDS Program clients, and only for COVID-19 testing and the provision of personal protective equipment (PPE). Part D recipients are able to use funds for this purpose in the absence of a waiver (42 USC 300ff-83).

2. Eligibility for Group of Individuals or Area of Service Delivery

A state must use Emerging Communities funding in the geographic area specified as an Emerging Community, as defined in 42 USC 300ff-30(d)—a metropolitan area for which there has been reported to and confirmed by the Centers for Disease Control and Prevention a cumulative total of at least 500, but fewer than 1,000, cases of AIDS during the most recent period of five calendar years for which such data are available (42 USC 300ff-32(b)(1) and 300ff-30).

3. Eligibility for Subrecipients

a. To receive funding from the state under a consortium agreement, an applicant consortium must agree to provide, directly or through agreements with other service providers, essential health services, and essential support services, and must meet specified application and assurance requirements. These include conducting a needs assessment within the geographic area served and developing a plan (consistent with the state's comprehensive plan required by 42 USC 300ff-27(b)(5)) to meet identified service needs following a consultation process (42 USC 300ff-23(c)(2)).

b. For consortia otherwise meeting these requirements, the state shall give priority first to consortia that are receiving assistance from HRSA for adult and pediatric HIV-related care demonstration projects and then to any other existing HIV care consortia (42 USC 300ff-23(e)).

G. Matching, Level of Effort, Earmarking

1. Matching

a. States and territories (excluding Puerto Rico) with greater than one percent of the aggregate number of national cases of HIV/AIDS in the two-year period preceding the federal fiscal year in which the state is applying for a grant must, depending on the number of years in which this threshold requirement has been met, provide matching funds as follows (42 USC 300ff-27(d)):

Year(s) in Which Matching Required	Minimum Percentage of Non-Federal Matching	Ratio of Non-Federal to Federal Expenditures
First	16 2/3	$1 non-Federal/$5 Federal
Second	20	$1 non-Federal/$4 Federal
Third	25	$1 non-Federal/$3 Federal
Fourth and subsequent	33 1/3	$1 non-Federal/$2 Federal

b. All recipients are subject to a matching requirement for ADAP supplemental funds in an amount equal to $1 for every $4 of federal funds (42 USC 300ff-28(a)(2)(F)(ii)(III)). Those recipients that are required to match the base formula funds may request and receive a waiver from this additional matching requirement.

c. Activities Waived (specific to fiscal year (FY) 2020 CARES Act (Pub. L. No. 116- 136)).

The requirements that recipients with more than one percent of national HIV cases must match the award, and that recipients match the ADAP supplemental award are waived for the COVID-19 CARES Act funding. 42 USC 300ff-83.

2. Level of Effort

2.1 Level of Effort – *Maintenance of Effort*

The state/territory will maintain HIV-related activities at a level that is equal to not less than the level of such expenditures by the state/territory for the 1-year period preceding the fiscal year for which the state/territory is applying for RWHAP Part B funds (42 USC 300ff-27(b)(7)(E)).

The requirement that the recipient must maintain expenditures for HIV-related activities at a level which is not less than the level of expenditures for such activities during the one-year period preceding the fiscal year for which the applicant is applying to receive the grant is waived for the COVID-19 CARES Act funding (42 USC 300ff-83).

2.2 Level of Effort – *Supplement Not Supplant*

Funds awarded under a grant must supplement and not supplant other funds available to the entity for the provision of early intervention services for the fiscal year involved (42 USC 300ff-22(d)(2)(B)).

3. Earmarking

a. The state may not use more than 10 percent of the amounts received under the grant for planning and evaluation activities (42 USC 300ff-28(b)(2)).

b. The state may not use more than 10 percent of the amounts received under the grant for administration (42 USC 300ff-28(b)(3)(A)).

c. A state may not use more than a total of 15 percent of the amounts received for the combined costs for administration, planning and evaluation and clinical quality management (42 USC 300ff-28(b)(4)). States and territories that receive a minimum allotment (between $50,000 and $500,000) may expend up to the amount required to support one full-time equivalent employee for any or all of these purposes (42 USC 300ff-28(b)(5)).

d. The aggregate of expenditures for administrative expenses by subrecipients may not exceed 10 percent of the total amount of grant funds subawarded by the state (without regard to whether particular entities spend more than 10 percent for such purposes) (42 USC 300ff-28(b)(3)(B)).

e. Unless waived by the secretary, for the purpose of providing health and support services to women, youth, infants, and children with HIV, including treatment measures to prevent the perinatal transmission of HIV, a state shall use for each of these populations not less than the percentage of RWHAP Part B funds in a fiscal year constituted by the ratio of the population involved (women, youth, infants, or children) in the state with AIDS to the general population in the state of individuals with AIDS (42 USC 300ff-22(e)). This information is provided to the state by HRSA with reporting requirements (i.e., annual progress report) as listed on the Notice of Award (NoA). Recipients demonstrate compliance with the WICY expenditure requirement in their annual progress report and may request a waiver as part of the annual progress report.

   The requirement that the recipient must allocate funding in accordance with WICY ratios is waived for the COVID-19 CARES Act funding (42 USC 300ff-83).

f. A state shall use a portion of the funds awarded to establish a program to provide therapeutics to treat HIV/AIDS or prevent the serious

deterioration of health arising from HIV/AIDS in eligible individuals, including measures for the prevention and treatment of opportunistic infections. The specific amount for ADAP will be provided in the grant agreement. Of the specific amount in the grant agreement for this purpose, the state may use not more than 5 percent to encourage, support, and enhance adherence to, and compliance with, treatment regimens (including related medical monitoring) unless the secretary (or designee) approves a 10 percent limit (42 USC 300ff-26(c)).

The statutory limitation on the use of ADAP funds to 5 percent for access, adherence, and monitoring is waived for the COVID-19 CARES Act funding, permitting allocations for these activities (42 USC 300ff-83).

g. A state shall establish a clinical quality management program to determine whether the services provided under the grant are consistent with the most recent Public Health Service guidelines for the treatment of HIV disease and related opportunistic infection and, as applicable, to develop strategies for bringing these services into conformity with the guidelines. Funds used for this purpose may not exceed the lesser of 5 percent of the amount received under the grant or $3,000,000 and are not considered administrative expenses for purposes of the limitation under paragraph 3.b above (42 USC 300ff-28(b)(3)(E)).

h. Unless waived by the secretary, HHS (or designee), not less than 75 percent of the amount remaining after reserving amounts for state administration and a clinical quality management program shall be used to provide core medical services to eligible people with HIV (including services regarding the co-occurring conditions of those individuals) (42 USC 300ff-22(b)).

The requirement that the recipient must spend at least 75 percent of the amount remaining after reserving amounts for administration, planning and evaluation, and/or clinical quality management on core medical services is waived for the COVID-19 CARES Act funding (42 USC 300ff-83).

J. Program Income

1. The NoA provides guidance on the use of program income. Generally, the addition method is used for this program; program income may also be used to satisfy all or part of the state matching requirements. Program income must be used for activities described in III.A.1, “Activities Allowed.”

2. The terms and conditions of award under the RWHAP Part B regarding program income do not apply to drug rebates. Rather, drug rebates must be used as specified in III.A.1.b and c, “Activities Allowed or Unallowed – Activities Allowed.”

M. Subrecipient Monitoring

1. HHS Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards (45 CFR Part 75) requires pass-through entities: (1) to evaluate each subrecipient's risk of noncompliance in order to determine the appropriate monitoring level; (2) monitor the activities of subrecipient organizations to ensure that the subaward is in compliance with applicable federal statutes and regulations and terms of the subaward; and (3) verify that subrecipients are audited as required under this guidance. Specifically, the grantee must conduct monitoring activities in accordance with sections 75.351 through 75.353 of Subpart D of 45 CFR Part 75.

2. Grantees must ensure that all requirements imposed by the federal government are passed down to subrecipients so that the HHS award is used in accordance with federal statutes, regulations, and the terms and conditions of the award.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

CFDA 93.918 GRANTS TO PROVIDE OUTPATIENT EARLY INTERVENTION SERVICES WITH RESPECT TO HIV DISEASE (RYAN WHITE HIV/AIDS PROGRAM PART C)

I. PROGRAM OBJECTIVES

The objective of the Ryan White HIV/AIDS Program (RWHAP) Part C Early Intervention Services (EIS) is to provide outpatient, high-quality, early intervention services and primary care related to the Human Immunodeficiency Virus (HIV) and the Acquired Immune Deficiency Syndrome (AIDS).

II. PROGRAM PROCEDURES

The Department of Health and Human Services (HHS) administers the RWHAP Part C EIS through the Health Resources and Services Administration's (HRSA) HIV/AIDS Bureau (HAB). Grants are awarded to public and non-profit private entities, including federally qualified health centers under Section 1905(1)(2)(B) of the Social Security Act (42 USC 1396d (l)(2)(B)).

Grants also are awarded to (1) grantees under Section 1001 (regarding family planning) other than states, (2) comprehensive hemophilia diagnostic and treatment centers, (3) rural health clinics, (4) health facilities operated by or pursuant to a contract with the Indian Health Service, (5) community-based organizations, clinics, hospitals, and other health facilities that provide early intervention services to those people with HIV, or (6) non-profit private entities that provide comprehensive primary care services to populations at risk for HIV/AIDS, including faith-based and community-based organizations. Providers must be qualified Medicaid-participating providers unless an exception is granted by HRSA (42 USC 300ff-52(a)(1)(A) through (G) and 42 USC 300ff-52(b)).

The RWHAP Part C EIS enables provision of a comprehensive primary health care and support services in an outpatient setting, including (1) HIV counseling and testing, (2) periodic medical evaluation, clinical, and diagnostic services, (3) provision of therapeutic measures for preventing and treating the deterioration of the immune system and for preventing and treating conditions arising with HIV/AIDS; and (4) referrals to appropriate providers of health care and support services. RWHAP Part C EIS recipients work with their community and public health partners to improve outcomes across the HIV care continuum so that individuals diagnosed with HIV are linked and engaged in care and started on ART as early as possible.

Minority AIDS Initiative (MAI) funds are provided to recipients based on the percentage of the RWHAP Part C EIS populations served within racial/ethnic minority communities.

Services may be provided directly by the recipient or through contractual agreements with other service providers/subrecipients.

Source of Governing Requirements

The RWHAP Part C EIS is authorized under sections 2651–2667 of Title XXVI of the Public Health Service (PHS) Act, as amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. No. 111-87) and is codified at 42 USC 300ff-51 through 300ff-67. The MAI is authorized under Section 2693(b)(2)(C) of the Public Health Service Act (42 USC 300ff-121(b)(2)(C)).

The Coronavirus Aid, Relief, and Economic Security Act (Pub. L. No. 116-136, Division B, Title VIII) (CARES Act) provided one-time funding to help current RWHAP recipients prevent, prepare for, and respond to the novel coronavirus disease 2019 (COVID-19).

The RWHAP Part C EIS has no specific program regulations.

Availability of Other Program Information

Further information about the RWHAP Part C EIS is available at http://www.hab.hrsa.gov/.

Additional information on allowable uses of funds under the RWHAP Part C EIS is contained in policy notices and standards found at http://www.hab.hrsa.gov/manageyourgrant/policiesletters.html.

CARES Act information is available at https://hab.hrsa.gov/program-grants-management/coronavirus-covid-19-response.

III. COMPLIANCE REQUIREMENTS

In developing the audit procedures to test compliance with the requirements for this federal program, the auditor must determine, from the following summary (also included in Part 2, "Matrix of Compliance Requirements"), which of the 12 types of compliance requirements have been identified as subject to the audit (noted with a "Y" in the summary matrix below), and then determine which of the compliance requirements that are subject to the audit are likely to have a direct and material effect on the federal program at the auditee. For each such compliance requirement subject to the audit, the auditor must use Part 3 (which includes generic details about each compliance requirement other than Special Tests and Provisions) and this program supplement (which includes any program-specific requirements) to perform the audit. When a compliance requirement is shown in the summary below as "N," it has been identified as not being subject to the audit. Auditors are not expected to test requirements that have been noted with an "N." See the Safe Harbor Status discussion in Part 1 for additional information.

A	B	C	E	F	G	H	I	J	L	M	N
Activities Allowed or Unallowed	Allowable Costs/Cost Principles	Cash Management	Eligibility	Equipment/ Real Property Management	Matching, Level of Effort, Earmarking	Period Of Performance	Procurement Suspension & Debarment	Program Income	Reporting	Subrecipient Monitoring	Special Tests and Provisions
Y	Y	Y	N	N	N	Y	Y	Y	Y	N	N

A. Activities Allowed or Unallowed

1. *Activities Allowed*

   a. Funds may be used for counseling (whether or not associated with HIV testing) and testing for HIV (42 USC 300ff-51(e)(1)(A) and (B) and 42 USC 300ff-62(f)).

   b. Funds may be used to provide clinical and diagnostic services regarding HIV/AIDS and periodic medical evaluations of individuals with HIV. Funds also may be used for providing therapeutic measures for preventing and treating the deterioration of the immune system and related conditions (including STD, hepatitis C, and tuberculosis) (42 USC 300ff- 51(e)(1)(D) and (E)).

   c. Funds may be used to refer people with HIV to providers of health and support services, as appropriate. This includes recipients of funding under the RWHAP Part A and Part B for the provision of health and support services; biomedical research facilities of institutions of higher education that offer experimental treatment for such disease; community-based organizations or other entities that provide such treatment; and, in the case of pregnant women, recipients of funding under RWHAP Part D (42 USC 300ff-51(e)(1)(C) and -51(e)(2)(A-C)).

   d. At least 75 percent of funds must be used for core medical services for an individual with HIV, including the co-occurring conditions of the individual. Core medical services encompass the following services: (1) outpatient and ambulatory health services; (2) AIDS Drug Assistance Program treatments defined under 42 USC 300ff-26; (3) AIDS pharmaceutical assistance; (4) oral healthcare; (5) early intervention services described in 42 USC 300ff-51(e); (6) health insurance premium and cost sharing assistance for low-income individuals in accordance with 42 USC 300ff-15; (7) home healthcare; (8) medical nutrition therapy; (9) hospice services; (10) home and community-based health services as

defined under 42 USC 300ff-14(c); (11) mental health services; (12) substance abuse outpatient care; and (13) medical case management, including treatment adherence services (42 USC 300ff-51(b)(1)(A) and 51(c)).

The requirement that the recipient must spend at least 75 percent of the amount remaining after reserving amounts for administration, planning and evaluation, and/or clinical quality management on core medical services is waived for the COVID-19 CARES Act funding. Sections 2604(c), 2612(b), and 2651(c) of the PHS Act.

e. Funds may be used to pay the costs of providing support services that are needed for people with HIV to achieve their medical outcomes. These services include, but are not limited to, outreach services, non-medical case management, medical transportation, translation, and referrals for healthcare and support services. Support services are subject to approval of the secretary of HHS or designee (42 USC 300ff-51(b)(1)(B) and 51(d)).

f. Funds may be used for the establishment of a clinical quality management program to assess the extent to which medical services that are provided to patients are consistent with the most recent Public Health Service guidelines for the treatment of HIV/AIDS and related opportunistic infections, and, as applicable, to develop strategies for ensuring that such services are consistent with the guidelines, and to ensure that improvements in the access to and quality of HIV health services are addressed (42 USC 300ff-64 (g)(5)). Policy Clarification Notice #15-02 https://hab.hrsa.gov/sites/default/files/hab/Global/HAB-PCN-15-02-CQM.pdf.

g. Funds may be used for administrative expenses; no more than 10 percent on administrative expenses (42 USC 300ff-51(b)(1)(C)).

2. *Activities Unallowed*

a. Funds may not be used to make payments for any item or service to the extent that payment has been made or can reasonably be expected to be made for that item or service under any state compensation program, under an insurance policy (except for a program administered by or providing the services of the Indian Health Service), or under any federal or state health benefits program or by an entity that provides health services on a prepaid basis (42 USC 300ff-64(f)(1)).

b. Funds may not be awarded to for-profit entities to carry out required early intervention services unless they are the only available providers of quality HIV care in the area (42 USC 300ff-51(e)(3)(A)).

c. Funds may not be used to fund AIDS programs or to develop materials, designed to promote or encourage, directly, intravenous drug abuse or sexual activity, whether homosexual or heterosexual (42 USC 300ff-84).

d. Funds may not be used to purchase sterile needles or syringes for the hypodermic injection of any illegal drug (Consolidated Appropriations Act, 2016 (Pub. L. No. 114-113), Division H, Title V, Section 520 and subsequent appropriations, as applicable). Other elements of syringe services programs may be allowable if in compliance with applicable HHS and HRSA-specific guidance.

e. Funds received under this grant will not be expended for any purpose other than the purposes for which the grant was awarded (42 USC 300ff-64(g)(1)).

f. Funds may not be used to purchase or improve land or to purchase, construct, or make permanent improvement to any building (42 USC 300ff-64(g)(1).

g. Payments for clinical research.

h. Payments for nursing home care.

i. PrEP or nPEP medications or medical services. As outlined in the June 22, 2016 RWHAP and PrEP program letter, the RWHAP legislation provides grant funds to be used for the care and treatment of PLWH, thus prohibiting the use of RWHAP funds for PrEP medications or related medical services, such as physician visits and laboratory costs. However, RWHAP Part C recipients and subrecipients may provide prevention counseling and information, which should be part of a comprehensive PrEP program.

j. International travel.

k. Funds may not be used to make cash payments to intended recipients of RWHAP services (42 USC 300ff-28(b)(6) and Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Uses of Funds, Policy Clarification Notice #16-02 https://hab.hrsa.gov/sites/default/files/hab/program-grants-management/ServiceCategoryPCN_16-02Final.pdf.

B. Allowable Costs/Cost Principles

Costs charged to federal funds under this program must comply with the cost principles at 45 CFR Part 75, Subpart E, and any other requirements or restrictions on the use of federal funding.

J. Program Income

The Notice of Award provides guidance on the use of program income. The additional method is used for RWHAP Part C EIS. Program income must be used for activities described in III.A.1, "Activities Allowed."

L. Reporting

1. Financial Reporting

a. *SF-270, Request for Advance or Reimbursement* – Not Applicable

b. *SF-271, Outlay Report and Request for Reimbursement for Construction Programs* – Not Applicable

c. *SF-425, Federal Financial Report* – Applicable

2. Performance Reporting

Not Applicable

3. Special Reporting

Not Applicable