93.917 HIV CARE FORMULA GRANTS

State Project/Program: RYAN WHITE PROGRAM

U. S. Department of Health and Human Services
Health Resources and Services Administration

Federal Authorization: Public Health Service Act, Public Law 111-87, October 30, 2009, Ryan White HIV/AIDS Treatment Extension Act of 2009.

State Authorization: North Carolina Administrative Code Title 15A, Section 16A.0900 and 16A.1000

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SFY 2024 audit confirmation reports for payments made to Counties, Local Management Entities (LMEs), Managed Care Organizations (MCOs), Boards of Education, Councils of Government, District Health Departments and DHSR Grant Subrecipients will be available by mid-October at the following web address: https://www.ncdhhs.gov/about/administrative-offices/office-controller/audit-confirmation-reports. At this site, click on the link entitled "Audit Confirmation Reports (State Fiscal Year 2023-2024". Additionally, audit confirmation reports for Nongovernmental entities receiving financial assistance from DHHS are found at the same website except select "Non-Governmental Audit Confirmation Reports."

The auditor should not consider the Supplement to be "safe harbor" for identifying audit procedures to apply in a particular engagement, but the auditor should be prepared to justify departures from the suggested procedures. The auditor can consider the supplement a "safe harbor" for identification of compliance requirements to be tested if the auditor performs reasonable procedures to ensure that the requirements in the Supplement are current.

The grantor agency may elect to review audit working papers to determine that audit tests are adequate.

Auditors may request documentation of monitoring visits by the State Agencies.

This compliance supplement must be used in conjunction with the OMB 2024 Compliance Supplement which will be issued in the summer. This includes "Part 3 - Compliance Requirements," for the types that apply, "Part 6 - Internal Control," and "Part 4 - Agency Program" requirements if the Agency issued guidance for a specific program. The OMB Compliance Supplement is Section A of the State Compliance Supplement.

I. PROGRAM OBJECTIVES

The goal of the Ryan White program is to ensure the provision of outpatient medical and ancillary care services for HIV-positive individuals and their families through:

1 Affording access to HIV medications for low-income individuals who have no other source to provide payment for these medications. This includes ensuring the availability of a formulary of HIV-specific medications, which are consonant with current federal standards of care, and a prescribed procedure for authorizing and ensuring participation in the program.

2 Development and implementation of a network of care and prevention system to ensure planning and delivery of HIV care services consistent with local needs. There are 10 regional Networks of Care and Prevention in North Carolina serving 95 counties. These Networks receive funding based upon a distribution formula, which considers the numbers of infected individuals. Networks are permitted to use up to 10% of allocated funds for administration, up to 5% for planning and evaluation activities and up to 5% for Quality Management activities. In addition, at least 75% of all client services funds must be for the provision of Core Medical Services, as defined by HRSA. Up to 25% of client services funds can be for Support Services, also defined by HRSA. These services can be provided directly or by subcontractors, in response to an RFA, RFP or through another distribution methodology designated by the Network.

3 Planning, development, and implementation of programs to ensure that specialized care services, which are not local in nature, are available to HIV-positive individuals. This is meant to ensure that services which cannot be provided throughout a Network region, or which have a multi-regional or statewide impact, can be funded. Current funding in this area includes a UNC project to provide primary HIV medical care.

I. PROGRAM PROCEDURES

The HIV CARE formula grant program is authorized under Part B of the Ryan White HIV/AIDS Treatment Modernization Act of 2006, which is codified at 42 USC 300ff-21 through 300ff-38, as extended and amended by the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. No. 111-87). The State Legislature has also appropriated funds strictly for the provision of HIV Medications.

Funds are awarded on the basis of a Request for Applications (RFA) or a Request for Proposals (RFP) or may be re-authorized based on a previous competitive process. Funds may additionally be awarded through sole source contracts for projects to meet specific emergent needs. HIV Medications funds - HIV Medication Assistance Program – HMAP (formerly known as the AIDS Drug Assistance Program – ADAP) are administered directly by the State.

III. COMPLIANCE REQUIREMENTS

Noted below in the following matrix are the types of compliance requirements that are applicable to the federal program. These Types are determined by the federal agency, noted as "Y," on the "Matrix of Compliance Requirements" located in Part 2 of the OMB 2024 Compliance Supplement; however, the State Agency may have added the Type and this is noted by "Y." If the State determines that the federal requirement does not apply at the local level or if the State modifies the federal requirements, this is noted in the supplement under the type of compliance requirement. If the federal and/or State agencies have determined that the type is not applicable, it is noted by "N."

If the Matrix indicates "Y," the auditor must determine if a particular type of compliance requirement has a direct and material effect on the federal program for the auditee. For each such compliance requirement subject to the audit, the auditor must use the OMB 2024 Compliance Supplement, Part 3 (which includes generic details about each compliance requirement other than Special Tests and Provisions) and Part 4 (which includes any program-specific requirements) to perform the audit.

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	Y	Y	Y	Y	Y	N	Y	Y

A. Activities Allowed or Unallowed

Funds received under a grant may be used to provide a comprehensive continuum of care to individuals and families with HIV disease; provide home and community-based care services for individuals with HIV disease; provide assistance to assure the continuity of health insurance coverage for individuals with HIV disease; and provide treatments, that have been determined to prolong life or prevent serious deterioration of health, to individuals with HIV disease. A state shall ensure that spending on women, infants, children and youth is commensurate with the demographics of those populations in the state. Funds may not be used to purchase or improve land, or to purchase, construct or make permanent improvement to any building except for minor remodeling. Funds may not be used to make payments to recipients of services. States may use no more than 10 percent of funds for administration and no more than 10 percent of funds for planning and evaluation; however, states may use no more than 15 percent for administration, planning and evaluation. States may use the lesser of 5 percent (5%) of total grant funds or $3 million for the required Clinical Quality Management program. After the first year of grant support, 75 percent of grant funds must be obligated within 120 days of the budget period start date. Subgrantees may use a maximum of 10 percent of their award for

administration. The HIV Care Program further permits Networks to use up to 5 percent of their award for planning and evaluation and up to 5% for Quality Management activities. Subgrantees must spend at least 75% of all client services funds for the provision of core services.

B. Allowable Costs/Cost Principles

All grantees that expend State funds (including federal funds passed through the N. C. Department of Health and Human Services) are required to comply with the cost principles described in the N. C. Administrative Code at 09 NCAC 03M .0201.

C. Cash Management – not applicable at the local level.

E. Eligibility

All public and private non-profit organizations are eligible for Communicable Disease Branch funding. Proof of non-profit status is required.

Individuals and families with HIV disease are eligible to receive services. Federal guidelines suggest that funds be utilized to provide services for those who are most needy; they do not provide a definition of this criteria, therefore, each state has adopted its own qualifiers. For the HIV Medications Program, the State will provide services for those whose net family income is 300 percent or less of the FPL and for those whose income is between 301percent and 500 percent of the FPL who have been grandfathered in and have no lapse in their twice a year eligibility determination (15A NCAC 16A.1004, 15A NCAC 24A.0200). Under certain conditions when a waiting list exists for the program, the eligible income level may be adjusted to a lower percentage of the FPL.

F. Equipment and Real Property Management

Local procedures and guidelines are delineated in the NC Division of Public Health contract with the local agency and should be audited accordingly.

G. Matching, Level of Effort, Earmarking – not applicable at the local level.

H. Period of Performance

Funds are available to the subgrantee for the period delineated by the effective dates of the contract with the Division of Public Health.

I. Procurement and Suspension and Debarment

These are all addressed in the Division of Public Health contract with the local agency and should be audited accordingly.

J. Program Income – not applicable at the local level.

M. Subrecipient Monitoring

The subgrantee shall not subcontract any of the work contemplated under this financial assistance contract without prior written approval from the Division of Public Health. Any approved subcontract shall be subject to all conditions of this contract. Only the subcontractors specified in the contract documents are to be considered approved upon award of the contract. The Division shall not be obligated to pay for any work performed by any unapproved subcontractor. The Contractor shall be responsible for the

performance of all of its subcontractors and will monitor said performance to ensure compliance with performance standards.

N. Special Tests and Provisions

The DHHS Division of Public Health is made up of five major sections: Administrative, Local and Community Support, Chronic Disease and Injury, Epidemiology, Oral Health and Women's and Children's Health Sections. The Division utilizes a single written agreement to manage all funds, that is, State, federal, or private grant funds, that the Division allocates to local health departments across the State. This document, as amended, is called the Consolidated Agreement.

The Consolidated Agreement sets forth the more general requirements of the funding relationship between the State and local public health agencies. The respective requirements are detailed under the headings: Responsibilities of the Department (Local Public Health Unit); Funding Stipulations; Fiscal Control; Responsibilities of the State; and Compliance. More specific information related to program activity is set out in a document called the Agreement Addenda, which detail outcome objectives (which may or may not be negotiable at the beginning of each fiscal year) that each health department must achieve in exchange for the funding. A third part of the system is the Budgetary Authorization which is sent annually from each of the Sections or Branches of the Division to all health departments being allocated funds from specific sources, i.e., State appropriations or other federal grant funds for specific activities. This Estimate indicates the amount of the allocated funds and their respective sources. Each health department should be able to provide an auditor with a copy of the Consolidated Agreement for the particular year being audited, as well as copies of the Budgetary Authorization and any revisions, Agreement Addenda, expenditure reports and any activity reports for each source of money received. If the health department cannot provide these documents, they may contact the State Division of Public Health Budget Office for assistance.

Suggested Audit Procedures – The auditor should review Section B. FUNDING STIPULATIONS of the Consolidated Agreement before beginning an audit. The fourteen items of this Section describe much of the detailed information the auditor may be seeking during a review of these programs.

Conflicts of Interest and Certification Regarding No Overdue Tax Debts

All non-State entities (except those entities subject to the audit and other reporting requirements of the Local Government Commission) that receive, use or expend State funds (including federal funds passed through the N. C. Department of Health and Human Services) are subject to the financial reporting requirements of G. S. 143C-6-23 for fiscal years beginning on or after July 1, 2007. These requirements include the submission of a Conflict-of-Interest Policy (see G. S. 143C-6-23(b)) and a written statement (if applicable) completed by the grantee's board of directors or other governing body that the entity does not have any overdue tax debts as defined by G. S. 105-243.1 at the federal, State or local level (see G. S. 143C-6-23(c)). All non-State entities that provide State funding to a non-State entity (except any non-State entity subject to the audit and other reporting requirements of the Local Government Commission) must hold the subgrantee accountable for the legal and appropriate expenditure of those State grant funds.

Audit Objective – Determine whether the grantee has adopted and has on file a conflict-of-interest policy, before receiving and disbursing State funds.

Suggested Audit Procedures:

1. Ascertain that the grantee has a written conflict of interest policy.
2. Check the policy and verify through board minutes that the policy was adopted before the grantee received and disbursed State funds.

Section 340B Drug Pricing Program

Section 602 of Public Law 102-585, the "Veterans Health Care Act of 1992," enacted section 340B of the Public Health Service Act ("PHS Act"), "Limitation on Prices of Drugs Purchased by Covered Entities." Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally qualified health center look-alikes and qualified hospitals. Drugs purchased from participating drug manufacturers by covered entities through the 340B Program may not be sold or transferred to anyone other than the patients of the covered entities. In addition, drugs purchased through the 340B Program are not entitled to rebates under the Medicaid program because this would result in duplicate discounts.

While an organization is eligible to participate in the program, it must notify the Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs (OPA) of its intention to participate by registering for the 340B Program. Participation in the 340B Program normally begins on the first day of a quarter. It is the entity's responsibility to tell its wholesaler or manufacturer that it is registered for 340B discount prices when it places an order.

All organizations receiving 340B prices are required to maintain records of purchases of covered outpatient drugs and of any claims for reimbursement submitted for such drugs under title XIX of the Social Security Act (Medicaid program, CFDA 93.778). Guidance for the 340B program is found in the following documents available at https://www.hrsa.gov/opa/registration/index.html:

"Guidance Regarding Section 602 of the Veterans Health Care Act of 1992 Limitation on Prices of Drugs Purchased by Covered Entities" 58 FR 27289 (May 7, 1993)

"Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases (58 FR 34058-34059), June 23, 1993.

"Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines" 59 FR 25110 (May 13, 1994).

Additional information is available at https://www.hrsa.gov/opa/index.html.

Compliance Requirements – Organizations participating in the 340B Program must ensure that (1) their organizational information is accurate in the 340B database maintained by OPA; (2) outpatient drugs purchased under the 340 B Program are not being given to individuals who are not eligible patients (diversion); and (3) discounts are not being received from both Medicaid rebates and 340B discounts (duplicate discounts).

Accurate Information

Section 340B of the PHSA requires OPA to maintain accessible data on the identity of participating entities. Covered entities are required to ensure the accuracy of the information in the database by regularly updating (at least annually) their information, including the covered entity's exact name and street address, through submission of change request forms to OPA.

Diversion

Section 340B(a)(5)(B) of the PHSA prohibits covered entities from selling, transferring, or giving covered outpatient drugs to anyone other than patients of the covered entity. The statute does not define the term "patient" in section 340B and in 1996, HRSA issued a guideline regarding the definition of a "patient" under the 340B program. An individual is a ''patient'' of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if: (1) the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; (2) the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that

responsibility for the care provided remains with the covered entity; and (3) the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding is provided. Additional information is available at http://www.hrsa.gov/federalregisternotices/patientandentityeligibility102496.pdf. "Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility."

Duplicate Discounts
Section 340B(a)(5)(A) of the PHSA required the Secretary of HHS to establish a mechanism to ensure that manufacturers did not pay a "duplicate discount" on a drug claim. A "duplicate discount" would occur if an entity received a ***340B discount*** and a ***Medicaid rebate*** were provided on the same drug. The mechanism that the Secretary established to comply with the legislation's mandate to prohibit duplicate discounts is a part of the OPA database called the Medicaid Exclusion File (58 FR 34058 (June 23, 1993) and 59 Fed. Reg. 25110 (May 13, 1994)). Additional information is available at http://www.hrsa.gov/opa/medicaidexclusion.htm. If this program includes a "payer of last resort" provision, a patient's Medicaid eligibility will require the return of rebate funds to manufacturers so as not to incur double recovery.

Audit Objectives – To determine if (1) a grantee's records are correct in the 340B database; (2) drugs were diverted to individuals who are not eligible patients; and (3) if the organization received duplicate discounts.

Suggested Audit Procedures

a. Determine if the grantee is participating in the 340B Program and, if so, continue with the remaining audit procedures.
b. Review the grantee's latest change form submitted to OPA and compare it with the organization's actual physical location and other current information about the entity.
c. Test a sample of drugs purchased for use under the funding program (i.e., CFDA 93.xxx) during the audit period to determine whether 340B drugs were properly identified throughout the procurement process, including (1) payment at the discounted price and (2) proper identification as a 340B drug upon receipt.
d. Test a sample of records of 340B drugs purchased for use under the funding program and released from inventory during the audit period to determine whether required authorizations were received, to whom the drugs were dispensed, and if the grantee determined that such individuals were eligible patients before dispensing the drugs.
e. For eligible patients who received 340B drugs, test a sample of Medicaid reimbursement requests to verify that the grantee did not claim, receive, or retain a duplicate rebate for those drugs under the Medicaid program.