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**TUBERCULOSIS DEMONSTRATION, RESEARCH, PUBLIC
AND PROFESSIONAL EDUCATION**

**State Project/Program: PROJECT GRANTS AND COOPERATIVE AGREEMENTS
FOR TUBERCULOSIS CONTROL PROGRAMS**

**U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION**

Federal Authorization: Public Health Service Act, Section 317(a)317E, 42 U.S.C. 247b-b(a), as amended; Health Services and Centers Amendments of 1978, Public Law 95-626; Omnibus Budget Reconciliation Act of 1981, as amended, Public Law 97-35; Preventive Health Amendments of 1984, Public Law 98-555; Public Health Service Act of 1987, as amended, Public Law 100-177; TB Prevention Amendments Act of 1990, as amended, Public Law 101-368, Subpart A of 42 CFR 51b is applicable, including all regulations incorporated by reference under Section 51b.105. PHS Grants Policy Statement, DHHS Publication No (OASH) 94-50,000, (Rev.) April 1, 1994 is available.

State Authorization: 15A NCAC 19A .0801

**N. C. Department of Health and Human Services
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N. C. DHHS Confirmation Reports:

SFY 2019 audit confirmation reports for payments made to Counties, Local Management Entities (LMEs), Managed Care Organizations (MCO's), 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 2018-2019)". Additionally, audit confirmation reports for Nongovernmental entities receiving financial assistance from the DHHS are found at the same website except select "Non-Governmental Audit Confirmation Reports (State Fiscal Years 2017-2019)".

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.

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I. PROGRAM OBJECTIVES

The goal of the TB Program is to eliminate tuberculosis as a public health problem. The elimination of TB can only be accomplished by aggressively using TB drugs to treat active cases and preventively to treat infected individuals before active disease can develop. Interrupting or preventing transmission of the tubercle bacilli will eventually eliminate death, disability, illness, emotional trauma, family disruption and social stigma caused by TB. State and local program objectives are that by June 30, 2019:

- 85% of cases with initial positive sputum cultures will have documentation of culture status every 2 weeks until microbiologic conversion to negative is achieved.
- 73% of cases with positive sputum culture results will have documented conversion to sputum culture-negative within 60 days entered into the North Carolina Electronic Disease Surveillance System (NC EDSS).
- 96% of cases with positive AFB sputum-smear results will have treatment initiated within 7 days of specimen collection and that information will be entered into NC EDSS.
- 96% of patients who are suspected of having TB will be started on the recommended initial 4-drug regimen and that information will be entered into NC EDSS.
- 100% of cases will receive directly observed therapy (DOT) in accordance with North Carolina TB Control policy and state law for the duration of treatment in North Carolina and that information will be recorded in NC EDSS.
- 99% of patients with newly diagnosed TB and for whom 12 months or less of therapy is indicated will complete treatment within 12 months and that information will be entered into NC EDSS.
- 100% of contact information for all pulmonary and pleural cases will be entered in NC EDSS.
- 100% of all TB patients with positive AFB sputum–smear results will have contacts identified and entered into NC EDSS.
- 94% of contacts to sputum AFB smear-positive TB patients will be fully evaluated and that information will be entered into NC EDSS.
- 71% of contacts to sputum AFB smear-positive TB patients with newly diagnosed latent TB infection (LTBI) will start treatment and that information will be entered into NC EDSS.
- 68% of contacts to sputum AFB smear-positive TB patients who start treatment for newly diagnosed LTBI will complete prescribed treatment and that information will be entered into NC EDSS.
- 65% of all persons (non-contacts) who begin treatment for latent infection will complete treatment.
- 100% of all TB cases alive at diagnosis will have HIV test results recorded in their medical record and in NC EDSS.
- 100% of suspect TB cases will be reported in NC EDSS to the regional TB Nurse Consultant within 7 days of notification.

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- 85% of all surveillance reports (Report of Verified Case of Tuberculosis [RVCT] plus the Follow Up #1 Report) on both laboratory and clinically confirmed cases will be forwarded in NC EDSS to the nurse consultant within 12 weeks of starting treatment.
- 98% of each core RVCT data item will be reported into NC EDSS.
- 95% of all RVCT Follow Up #2 Reports will be reported electronically through NC EDSS to the nurse consultant within 4 weeks of treatment completion.
- Any Public Health Nurse who is responsible for the TB Control program will have attended the Introduction to Tuberculosis Management course or will attend the next date the course is offered.
- 100% of TB case medical records will, at a minimum, contain the following:
 - signed and dated physician orders for the treatment of disease that are consistent with the TB Control Manual policies and procedures;
 - monthly documentation of the PHN's assessment for possible medication side effects;
 - completed TB Epidemiologic Record;
 - interpretation of the initial chest x-ray;
 - a signed TB treatment agreement or isolation order;
 - an end of treatment chest x-ray if pulmonary or pleural TB;
 - baseline lab results and subsequent lab results as indicated;
 - TB Drug Record/DOT record containing current and accurate information; and
 - documentation that the patient was examined by a physician or mid-level provider at the beginning and end of therapy.
- 64% of class B immigrants and refugees will have a medical evaluation initiated within 30 days of arrival.
- 65% of class B immigrants and refugees will have a completed medical evaluation and presumptive diagnosis within 90 days of arrival.
- 52% of class B immigrants and refugees who are diagnosed with LTBI during evaluation in the U. S., will start treatment.
- 66% of class B immigrants and refugees and who are diagnosed with LTBI during evaluation in the U.S. and started on treatment will complete treatment.
- 78% of Class B events in NC EDSS will have all core data items completed.
- 96% of TB cases with a pleural or respiratory site of disease and who are 12 years or older will have a sputum-culture result reported.
- All TB drug invoices will be mailed to the NC DPH Communicable Disease Branch within three (3) business days of the receipt of the drug order.

II. PROGRAM PROCEDURES

The TB Program supports county tuberculosis control endeavors by:

- funding health departments partially to support staff and/or operating costs;
- supplying pharmaceuticals to health departments for TB testing and for TB treatment at no cost to people being treated curatively or preventively;

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- providing medical and nursing consultation and case management assistance;
- providing technical assistance and training for the surveillance system;
- offering health education programs and training; and,
- performing program evaluation, and data quality assurance.

All health departments provide direct TB services involving:

- case management including provision and monitoring of medication;
- epidemiologic evaluations; measures to interrupt and prevent transmission, including provision and monitoring of preventive treatment; and,
- communication, coordination, education and promoting TB awareness among all health care providers in their jurisdiction.

Federal funds provided to local health departments are obtained through a competitive Federal cooperative agreement administered by CDC. The number of counties funded and the amount of funding are approved annually by CDC.

In regard to State funds, the funds are allocated to local health departments based upon a needs-based formula. Additionally, non-formula funds are utilized to support one-time costs such as operating expenses, equipment, etc.

The TB Program is administered by the TB Program, Communicable Disease Branch, Epidemiology Section, Division of Public Health, Department of Health and Human Services, 1200 Front Street, Suite 103, Raleigh, NC 27609, (919) 755-7286.

In addition to federal statutory requirements, the State has the authority to issue rules consistent with State statutes. These rules are incorporated by reference into this compliance supplement. A copy of the rules may be obtained from the TB Control Program or the local provider.

III. COMPLIANCE REQUIREMENTS

In developing the audit procedures to test compliance with the requirements for a federal program, the auditor should look first at Part 2, Matrix of Compliance Requirements, to identify which of the 14 types of compliance requirements described in Part 3 are applicable and then look to Parts 3 and 4 for the details of the requirements.

The Commission for Health Services has the authority to adopt rules consistent with State statutes. Funds are made available to contractors by written service contracts. The contract between the parties should be reviewed prior to beginning the audit. The contractual relationship between the State and local health departments / CBOs is more fully explained below.

A. ACTIVITIES ALLOWED OR UNALLOWED

Local health departments may utilize TB Program funds for the following:

- Diagnostic, evaluation or treatment services for TB patients, suspects, contacts, and reactors;
- Follow-up services for TB patients, suspects, contacts, and reactors;
- Outreach services for TB patients, suspects, contacts, and reactors.

TB funds MAY NOT be used for the following:

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Purchase, construction or permanent improvement of any building or other facility unless such spending is specifically approved in writing by the TB Program;

Purchase of any equipment item unless specifically approved by the TB Program.

Use of TB testing materials purchased by the NC TB Program for any locally mandated pre-employment skin testing programs. TB testing materials (PPD) purchased by the TB Program may only be used to test a person suspected of having Tuberculosis, a close contact of a confirmed TB patient or active case, or high-risk persons as defined in the NC TB Control Policy manual, Chapter II.

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

Funds are granted on a reimbursement basis and no testing is required at the local level.

E. ELIGIBILITY

Local health departments are required by statute to provide diagnostic, treatment, evaluation, and follow-up services for all tuberculosis patients, suspects, contacts and reactors. These services are to be provided at no charge to the client and determining the patient's financial eligibility is not necessary. However, the health department may bill any third party for services rendered. (15A NCAC 19A .0802 - .0803)

F. EQUIPMENT AND REAL PROPERTY MANAGEMENT

Local procedures and guidelines are delineated in the Division of Public Health contract with the local agency.

H. PERIOD OF AVAILABILITY OF FEDERAL FUNDS

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

I. PROCUREMENT AND SUSPENSION AND DEBARMENT

All grantees that expend federal funds (received either directly from a federal agency or passed through the N. C. Department of Health and Human Services) are required to conform to federal agency codifications of the grants management common rule accessible on the Internet at

https://www.ecfr.gov/cgi-bin/text-idx?tpl=/ecfrbrowse/Title02/2cfr200_main_02.tpl.

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 procurement standards described in the North Carolina General Statutes and the North Carolina Administrative Code, which are identified in the North Carolina Procurement Manual accessible on the Internet at http://www.pandc.nc.gov/documents/Procurement_Manual_5_8_2013_interavivte.pdf.

Nongovernmental subrecipients shall maintain written Procurement policies that are followed in procuring the goods and services required to administer the program.

L. REPORTING

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Local health departments can request monthly draws against funds budgeted in each program fund and center as outlined in the Consolidated Agreement between the Department of Health and Human Services and local health departments. Other contracted agencies are required to submit monthly contracted expenditure reports (form DHHS 2481) and statistical reports on a schedule set out in the contract between the parties (refer to specific contracts OR agreement addenda).

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

Health departments can request State TB funds for the provision of diagnostic or evaluation services for certain patients, which requires written approvals of the TB Medical Director and the State Epidemiologist or the CD branch head. The TB Program may request budget revisions to move funds into account 536961 – General Contracted or Purchased Services for the payment of such services. This can be done only to the extent that funds are available. The services for which it may be necessary to obtain outpatient services are those not generally available through local health departments and those which are necessary to the treatment of the patient's active tuberculosis. Two examples are as follows:

1. Diagnostic; such as:
 - Sputum induction and/or bronchoscopy,
 - Tomographic radiography,
 - Pleural biopsy and/or aspiration of pleural fluid,
 - Renal TB evaluations; i.e., IV programs and retrograde pyelography.
2. Evaluations prior to or during therapy because of complications and/or suspected drug toxicity:
 - Ophthalmologic examination,
 - Audiologic examination,
 - Hepatic disease evaluation - acute or chronic.

The health department will pay no more than the allowable Medicaid rate for the service. Information concerning the allowable payment rate and eligibility determination may be obtained from the Purchase of Care Unit, Division of Health Services, Raleigh, North Carolina, telephone number (919) 733-3037. The eligibility determination and the computation of allowable payment to the provider should be carried out in a manner similar to the methods used by the Maternal and Child Health's School Health Fund and Delivery Fund. When a claim is sent to the Purchase of Care Office's Claims Processing Unit, it should include a statement indicating "pricing only - TB Program" and the health department's name should be clearly indicated on the form. The State TB Medical Director must certify that this medical service is necessary. Both the approval of the State TB Medical

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Director and payment for the service, at or below the Medicaid rate, need to be documented in health department records.

Third party fees collected by the health department for provision of TB services must be used to expand, maintain or enhance TB services.

Suggested Audit Procedures: These special services may be tested by: 1) reviewing whether a contract was developed between the health department and the provider of this special service; 2) requesting evidence from the health department of prior written approval from the State TB Medical Director and State Epidemiologist or CD branch head and, 3) requesting and reviewing the required budget amendment which provided the special funds for this service.

Consolidated Contract with Local Health Departments/Districts

The DHHS Division of Public Health is made up of six major sections: Chronic Disease & Injury, Environmental Health, Epidemiology, Women's and Children's Health, Oral Health, and Administrative, Local, and Community Support. The Division utilizes a single written agreement to manage all funds (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 Agreements 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, e.g., 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 NC Division of Public Health Budget Office for assistance.

Suggested Audit Procedures: Section B. FUNDING STIPULATIONS of the Consolidated Agreement should be reviewed by the auditor 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.

Conflict of Interest and Certification Regarding No Overdue Tax Debts

Compliance Requirements: The subrecipient expressly states that he/she presently has no interest and shall not acquire any interest, direct or indirect, which would conflict in any manner or degree with the performance of services required to be performed under this contract. The subrecipient shall not employ any person having such interest during the performance of this contract. The subrecipient further agrees to notify the Division of Public

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Health, Epidemiology Section in writing of any instance that might have the appearance of a conflict of interest.

Nongovernmental Organizations

The 1993 General Assembly enacted legislation (Chapter 321, Section 16, 1993 Session Laws) requiring each private, not-for-profit entity, as a prerequisite to the receipt of funding from the State, formally to adopt a policy which addresses conflicts of interest that might arise involving the entity's management, employees, and/or board members. 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 Notarized Conflict of Interest Policy (see G. S. 143C-6-23(b)) and a written statement (if applicable) 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 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.