

93.268

IMMUNIZATION COOPERATIVE AGREEMENTS

State Project/Program: IMMUNIZATION PROGRAM / AID TO COUNTY FUNDING

**U. S. Department of Health and Human Services
Centers for Disease Control and Prevention**

Federal Authorization: Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)) reauthorized in Section 4204 of the Patient Protection and Affordable Care Act. Prevention and Public Health Fund (PPHF) funding is authorized under sections 301 and 317 of the Public Health Service Act (PHS Act), 42 USC, 241 and 247b as amended and the Patient Protection and Affordable Care Act (PL 111-148). The Vaccines for Children (VFC) program is authorized under Section 1902(a)(62) of the Social Security Act, 42 U.S.C. section 1396a(a)(62). The VFC Program was established under the authority of Section 1928(a) of the Social Security Act, 42 U.S.C. 1396s(a).

State Authorization: N/A

**N. C. Department of Health and Human Services
Division of Public Health**

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SFY 2022 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 DHHS 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 2020-2021)". Additionally, audit confirmation reports for Nongovernmental entities receiving financial assistance from DHHS are found at the same website except "[Non-Governmental Audit Confirmation Reports \(State Fiscal Years 2020-2022\)](#)".

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

This compliance supplement must be used in conjunction with the OMB 2022 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 Immunization Action Plan is to prevent disease, disability, and death from vaccine-preventable disease in children. Immunization Branch programs, services and subrecipients help to reduce the spread of vaccine preventable diseases by assuring that individuals are age appropriately immunized, and by managing outbreaks of vaccine-preventable diseases.

Local health departments will support the North Carolina Immunization Program (NCIP) in reaching that goal by working together to accomplish the following objectives as supported by Healthy People-2030:

1. Increase the age-appropriate immunization levels of two-year old children to 90% or more; and
2. Assure that at least 95% of North Carolina children aged <6 years are represented in the North Carolina Immunization Registry (NCIR).

II. PROGRAM PROCEDURES

As part of the Immunization Action Plan, the North Carolina Department of Health and Human Services—Division of Public Health, Women's and Children's Health Section, Immunization Branch funds local health departments to eliminate barriers that delay or prevent delivery of age-appropriate immunizations, and to assure the safe delivery of vaccines, the Local Health Department shall:

- a. Follow the current CDC and NCIP guidelines for storage of vaccines to ensure proper safeguarding including risks of loss from negligence, theft, expiration, or improper storage temperature;
- b. Maintain current standing orders as part of the Local Health Department's immunization policy and protocol. All standing orders or protocols developed for nurses in support of this program must be written in the North Carolina Board of Nursing format. All local health departments shall have a policy in place that supports nurses working under standing orders. <http://www.ncbon.com/vdownloads/position-statements-decision-trees/standing-orders.pdf>. This immunization policy and protocol, which is reviewed and evaluated by immunization staff during every Local Health Department visit, shall:
 - i. be updated and signed annually by a currently employed physician;
 - ii. provide for age-appropriate immunizations or physician referrals when contraindications exist;
 - iii. contain temporary and permanent contraindications as outlined in the North Carolina Administrative Code (NCAC);

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- iv. comply with the most current immunization schedule recommended by the Advisory Committee on Immunization Practices (ACIP) and the NC Immunization Rules. The immunization schedules can be found at these links:
 - Children: http://www.immunize.nc.gov/family/immnz_children.htm;
 - Adolescents:
http://www.immunize.nc.gov/family/immnz_adolescents.htm; and
 - Adults: http://www.immunize.nc.gov/family/immnz_adults.htm
- v. specifies simultaneous administration of needed vaccines, reviewing vaccines given at each routine visit.
- c. Refer clients being seen for immunization-only services, if indicated, to other services within the Local Health Department or to a private provider;
- d. Follow all conditions outlined in the most recent Vaccines For Children (VFC) Program Provider Agreement and the NCIP Local Health Department Vaccine Agreement;
- e. Ensure that vaccinations are provided for 100% of eligible two-year-old children for the annual statewide immunization assessment. The basis for determining whether the vaccine provision percentage has been achieved will be a report generated from the NCIR;
- f. Ensure that vaccinations are provided for 100% of eligible children ages 0 to 18 years seeking vaccinations. The basis for determining whether the vaccine provision has been achieved will be a report generated from the NCIR;
- g. Follow the most current (ACIP) recommendations for vaccine administration for 100% of clients;
- h. By the close of business each day, completely and accurately enter into the NCIR all information regarding publicly and privately purchased vaccines administered by the Local Health Department;
- i. Vaccinate walk-in patients who are eligible for vaccinations.
- j. Identify groups and subgroups within the priority populations and develop and implement innovative strategies to improve flu vaccine delivery.
- k. Conduct outreach in the community by coordinating off-site vaccine clinics and adapt vaccination procedures to maintain COVID-19 protective measures to ensure the safety of individuals receiving immunization services. Offsite vaccine outreach clinics should target at risk populations, with a focus in certain settings (i.e., healthcare employee worksites, long term care facilities (LTCFs), homeless shelters, migrant farm worksites, essential employee worksites, etc.).

2. Vaccine-Preventable Disease Surveillance To

To ensure that vaccine-preventable diseases are identified, monitored, and managed, the Local Health Department shall:

- a. Identify, upon the receipt of any suspect vaccine-preventable disease or condition, and investigate immediately, the circumstances surrounding the occurrence of the disease or condition to determine the authenticity of the report;
- b. Ensure that all health care providers within their jurisdiction are educated on reporting laws and requirements and are reporting any suspected vaccine-preventable disease to the Local Health Department within 24 hours;

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- c. Notify the Communicable Disease Branch's on-call Epidemiologist immediately by phone (919-733-3419) of any suspected cases of diphtheria, measles, polio, rubella, or congenital rubella syndrome (CRS), and report by phone within 24 hours any suspected cases of mumps or pertussis involving high-risk settings (such as healthcare settings and childcare settings providing care to infants);
- d. Identify 100% of persons for whom control measures are required;
- e. Follow the most current guidelines and recommendations for the prevention and treatment of vaccine-preventable diseases, as outlined in the CDC's *Manual for the Surveillance of Vaccine- Preventable Diseases*, the American Public Health Association's *Control of Communicable Diseases Manual*, and the CDC's *Guidelines for the Control of Pertussis Outbreaks*;
- f. Collect and submit appropriate clinical specimens for testing to assist in the diagnosis of disease and indication of the duration of control measures required, including coordination with private physicians to submit appropriate specimens to the Division of Public Health's State Laboratory of Public Health;
- g. Ensure a minimum of two State Laboratory of Public Health Pertussis PCR and culture test kits with non-expired media are available for immediate use in the Local Health Department at all times;
- h. Determine and ensure control measures have been provided for, and complied with, as directed in 10A NCAC 41A .0201;
- i. Provide or ensure provision of Perinatal Hepatitis B case-management services following current ACIP and these CDC guidelines:
 - i. All pregnant women are tested for HBsAg during each pregnancy;
 - ii. All infants born to HBsAg-positive women and all infants born to women with unknown HBsAg status receive HBIG and a dose of hepatitis B vaccine within 12 hours of birth;
 - iii. All infants born to HBsAg-positive women complete the hepatitis B vaccine series per the most current ACIP recommended schedule; and
 - iv. All infants receive timely post-vaccination serology testing per CDC guidelines.
- j. Follow the reporting requirements in the *Agreement for Local Health Department Participation* in the North Carolina Electronic Disease Surveillance System (NC EDSS);
- k. Implement a comprehensive immunization policy and protocol, as defined by CDC, ACIP and the Hospital Infection Control Practices Advisory Committee (HICPAC) for all Local Health Department health-care personnel who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air, as specified in the most current Immunization of Health Care Personnel.

3. Education and Outreach

The Local Health Department shall:

- a. Partner with or facilitate education and trainings for community stakeholders (private and public healthcare providers, community health centers, federally qualified health centers and/or rural health centers) on immunization-related

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topics, recommendations and requirements annually;

- b. Collaborate with local provider organizations such as Women's Infants and Children (WIC), women's health care physicians, pediatricians and social service agencies to provide educational materials on preventing perinatal hepatitis B transmission for distribution to appropriate clients and outreach activities by incorporating immunization education in prenatal, parenting and other health education curriculum;
- c. Increase community awareness by conducting at least one immunization outreach or education event within the county per fiscal quarter based on available funding. The event should be constructed to help improve immunization awareness in the community and subsequently increase vaccine coverage rates among residents of the county. Educational and outreach interventions will, ultimately, help the NCIP reach its goal of eliminating vaccine-preventable disease in North Carolina. Such events may include but are not limited to: health fairs, after-hour immunization clinics, educational mail-outs, on-site or off-site immunization related trainings, and in-school clinics. (Technical guidance is available from the NCIP about off-site vaccine clinics.)

4. North Carolina Immunization Registry

To assure quality of community-wide immunization service delivery, the Local Health Department shall coordinate countywide immunization monitoring and follow-up, and shall:

- a. Ensure that the Local Health Department uses the NCIR to identify its active clients two years of age residing in the county who are due or past due for immunizations;
- b. Assign at least one staff person to conduct immunization monitoring and follow-up services to:
 - i. track 100% of active Local Health Department clients that are due or past due for immunizations;
 - ii. ensure that all immunizations administered, and the associated historical immunization information, are entered into the NCIR; and
 - iii. ensure that NCIR access and reporting capabilities is assessable to all health care personnel with within the agency;
- c. Identify and target under-immunized areas in the community using the NCIR and conduct at least two interventions to improve the immunization rate in one area of need in the county;
- d. Integrate immunization screening and referral within WIC and other appropriate programs using the NCIR.

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 2022 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."

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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 2022 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	N	Y	N	Y	Y	N	Y	Y	Y

A. Activities Allowed or Unallowed

Contractors, which include local health departments, are to complete activities as noted on their contract addenda/scope of work. See individual contract scopes of work for more information. A general list of allowable and unallowable expenses/purchases are listed here:

Allowed

Local Health Departments may use funding for:

- Salary/Fringe Benefits
- Travel expenses
- Equipment
- Supplies
- General Contractual Services
- Indirect Costs
- Miscellaneous Expenses (Program advertising, communications, data processing, printing, shipping, software licenses, training, etc.)

Unallowed

Local Health Departments may not use funding for:

- Honoraria
- Alcoholic beverages
- Building purchases, construction, capital improvements
- Land purchases
- Legislative/lobbying activities
- Bonding
- Depreciation on use charges

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- h. Fundraising
- i. Non-immunization clinical services
- j. Entertainment
- k. Food
- l. Payment of bad debt
- m. Vehicle Purchase

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

Local Governments and Public Authorities

All local governments and public authorities are required to follow cash procedures for State funds outlined in the State's Budget and Fiscal Control Act (General Statute 159-34) and rules, policies, and procedures established by the Local Government Commission. Additionally, the State-awarding agency may specify their own requirements for the management of State funds and these requirements can be found in Part 10 of this Compliance Section.

Audit Objectives – Determine whether:

1. The recipient/subrecipient followed procedures established by the applicable laws, regulations, statutes, and agency requirements.
2. The pass-through entity implemented procedures to assure that subrecipients conformed substantially to the same requirements that applied to the pass-through entity.

Suggested Audit Procedures

1. Select a sample of advances of State funds and compare to the dates the funds were disbursed and/or when the checks were presented to the banks for payment. Using these data, verify that:
 - a. The timing of disbursements is in compliance with any requirements of the awarding agency or any applicable laws, regulations, or statutes.
 - b. If applicable, procedures were established to minimize the time elapsing between drawdown and disbursement of State funds.
2. Where applicable, select a sample of reimbursement requests and trace to supporting documentation showing that the costs for which reimbursement was requested were paid prior to the date of the reimbursement request.

F. Equipment and Real Property Management

Prior written approval from the Program must be obtained before purchasing equipment valued at over \$5,000.00. Real property cannot be purchased in this program.

Audit Objectives – Determine whether:

1. The grantee maintains proper records for equipment and adequately safeguards and maintains equipment.
2. Disposition or encumbrance of any equipment acquired with State awards is in accordance with the requirements of the awarding agency.

Suggested Audit Procedures

1. Obtain entity's policies and procedures for equipment management and ascertain if they comply with the awarding agency's policies and procedures.
2. Select a sample of equipment transactions and test for compliance with the awarding agency's policies and procedures for management and disposition of equipment.

H. Period of Performance

Contract funds may be used to support costs incurred during the funding period. In the case of local health departments, this period is the same as the State fiscal year and the period covered by the Consolidated Agreement, July 1 through June 30. Unobligated, unexpended funds may not be carried forward. Settle-up and final expenditure submission should occur within forty-five days of the end of the contract period, i.e., June 30. (Consolidated Agreement)

Audit Objective – Determine whether State funds were obligated within the period of availability and obligations were liquidated within the required time period.

Suggested Audit Procedures

1. Review the award documents and regulations pertaining to the program and determine any award-specific requirements related to the period of availability and document the availability period.
2. Test a sample of transactions charged to the State award after the end of the period of availability and verify that the underlying obligations occurred within the period of availability and that the liquidation (payment) was made within the allowed time period.
3. Test a sample of transactions that were recorded during the period of availability and verify that the underlying obligations occurred within the period of availability.
4. Select a sample of adjustments to the State funds and verify that these adjustments were for transactions that occurred during the period of availability.

I. Procurement and Suspension and Debarment

Compliance Requirements

Procurement

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 with federal agency codifications of the grants management common rule accessible on the Internet at <https://www.whitehouse.gov/omb/information-for-agencies/circulars/>.

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 State of North Carolina Procurement Manual accessible on the Internet at http://www.pandc.nc.gov/documents/Procurement_Manual_5_8_2013_interactive.pdf.

Audit Objectives – Determine whether procurements were made in compliance with the provisions of the program requirements and any applicable laws, regulations, statutes or other provisions of the awarding State agency.

Suggested Audit Procedure

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Test a sample of procurements to ascertain if the applicable laws and the awarding agency procedures were followed.

Suspension and Debarment

Does not apply.

L. Reporting

Financial Reporting

At the time an agreement addendum is signed, all local health departments are required to complete a Planned Use of Federal Immunization Program Funds attachment to document anticipated expenditures. This attachment is returned with the signed agreement. Expenditures are reviewed during monitoring visits.

Performance Reporting

Using the North Carolina Immunization Registry (NCIR), Local Health Departments will report:

- The number of eligible two-year old children served with a status of active in the NCIR.
- The number of all eligible individuals vaccinated.

Audit Objective – Determine whether required reports include all activity of the reporting period, are supported by applicable accounting or performance records, and are fairly presented in accordance with program requirements.

Suggested Audit Procedures

1. Perform monthly review of submitted reports to ascertain whether they are properly formatted and completed.
2. Review amounts requested and compare with previous months for outliers or unreasonable expenditures.
3. Compare submitted workload with established objectives for the current fiscal year to track compliance with yearly objectives.

M. Subrecipient Monitoring

Local health departments and other entities frequently contract with other agencies to provide allowable services. Unless services are obtained on other than fee for service contracts, the auditor does not need to audit for this requirement. (Reference Section C(1)(c and d) of the Consolidated Agreement between the local health department and the Division of Public Health).

N. Special Tests and Provisions

Consolidated Agreement System

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, that is, State, Federal, or private grant funds, that the

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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, 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 Notarized 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 procurements were made in compliance with the provisions of the program requirements and any applicable laws, regulations, statutes or other provisions of the awarding State agency.

Suggested Audit Procedures – The auditor should select a sample of non-State entities that received, used, or expended State funds and confirm there is an associated Notarized Conflict of Interest Policy and a written statement