

Division of Public Health

Agreement Addendum

FY 16–17

Master

Local Health Department Legal Name

Epidemiology/Communicable Disease

DPH Section/Branch Name

894 STD Drugs

Activity Number and Description

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DPH Program Contact
 (name, telephone number with area code, and email)

06/01/2016 – 05/31/2017

Service Period

DPH Program Signature **Date**
 (only required for a negotiable agreement addendum)

07/01/2016 – 06/30/2017

Payment Period

- Original Agreement Addendum**
 Agreement Addendum Revision # _____ (Please do not put the Budgetary Estimate revision # here.)

I. Background:

The North Carolina Administrative Code (10A NCAC 41A .0204) requires North Carolina local health departments to provide free treatment for clients diagnosed with sexually transmitted diseases (STDs):

Local health departments shall provide diagnosis, testing, treatment, follow-up, and preventive services for syphilis, gonorrhea, chlamydia, nongonococcal urethritis, mucopurulent cervicitis, chancroid, lymphogranuloma venereum, and granuloma inguinale. These services shall be provided upon request and at no charge to the patient.

The Communicable Disease Branch provides funds to local health departments to assist with the purchase of STD drugs. These funds are to be used exclusively for the treatment of local health department clients who are either diagnosed with or who are sexual partners of someone with a STD.

Local health departments are expected to purchase drugs at the lowest available pricing. The Health Resources and Services Administration’s (HRSA) federal 340B Drug Pricing Program requires drug manufacturers to provide outpatient drugs to eligible health care organizations/covered entities at significantly reduced prices which are generally recognized as the cheapest available. This 340B Program enables covered entities to stretch scarce federal and state resources as far as possible, reaching more eligible patients and providing more comprehensive services. Local health department clinics which diagnose and treat sexually transmitted diseases and receive funding from state and local resources are 340B Program covered entities.

Health Director Signature	(use blue ink)	Date						
<table border="0" style="width: 100%;"> <tr> <td style="width: 35%;">Local Health Department to complete: (If follow-up information is needed by DPH)</td> <td style="width: 65%;">LHD program contact name: _____</td> </tr> <tr> <td></td> <td>Phone number with area code: _____</td> </tr> <tr> <td></td> <td>Email address: _____</td> </tr> </table>			Local Health Department to complete: (If follow-up information is needed by DPH)	LHD program contact name: _____		Phone number with area code: _____		Email address: _____
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Signature on this page signifies you have read and accepted all pages of this document.

An individual is a patient of a 340B covered entity only if:

- the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
- 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
- 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 has been provided to the entity.

II. Purpose:

The goal is to assist Local Health Department staff in meeting the STD service needs for patients by providing state-appropriated funds to purchase STD drugs. These drugs will be used to reduce the morbidity, mortality and spread of STDs in North Carolina.

III. Scope of Work and Deliverables:

The Local Health Department (LHD) shall:

1. Offer onsite STD treatment from appropriately trained staff to any person diagnosed with an STD and sexual partners of a person with an STD who is evaluated by the LHD. Onsite STD treatment is defined as administering approved drug treatment regimens at the time of diagnosis or providing client with a prescription for an approved drug treatment regimen.
2. In addition to the named diseases in 10A NCAC 41A .0204, the Communicable Disease Branch requires that local health departments provide treatment for trichomoniasis, symptomatic bacterial vaginosis, and symptomatic herpes since these conditions may contribute to HIV transmission. Conditions that are likely caused by gonorrhea or chlamydia, such as pelvic inflammatory disease and epididymitis, should also be treated.
3. Maintain an account with Cardinal Health, Inc. in order to purchase and receive STD drugs.
4. Maintain eligibility for the 340B Drug Pricing Program through the HRSA Office of Pharmacy Affairs (OPA).
5. Maintain a minimum of three months' supply of all commonly used STD drugs in the event of shortages.

IV. Performance Measures/Reporting Requirements:

Performance Measure # 1:

The Local Health Department is expected to provide gonorrhea and chlamydia treatment services to no less than 85% of local health department clients (including family planning, maternity, adult health, and STD clinics) within 14 days of the specimen collection date; 95% or more clients should receive appropriate treatment within 30 days of the specimen date.

Numerators:

- a. Number of clients per clinic treated for chlamydia and gonorrhea within 14 days of the date of specimen collection.
- b. Number of clients per clinic treated for chlamydia and gonorrhea within 30 days of the date of specimen collection

Denominator: Total number of clients per clinic diagnosed with chlamydia or gonorrhea.

Reporting Requirements:

Reports must be entered in the NC Electronic Disease Surveillance System (EDSS) within 30 days of the specimen date. The person entering data into NC EDSS should enter both the LHD county name and the clinic name as the ordering provider. For example, *County X STD Clinic, County X FP Clinic, County X MAT Clinic, or County X Adult Health Clinic*. The LHD must include treatment information on all clients with an STD unless the CDB has approved an alternative means of monitoring for drug resistance and compliance with Agreement Addendum requirements.

Performance Measure #2:

The Local Health Department shall ensure program integrity and maintain auditable records which document compliance with all 340B Program requirements as specified at <http://www.hrsa.gov/opa/programrequirements/index.html>. Billing policies and procedures must be in compliance with North Carolina Administrative Code (10A NCAC 41A .0204) and insurance requirements. Medications on the STD Formulary must be charged at the cost of acquisition. The Local Health Department must establish a fee schedule for all billable STD tests and treatments.

Reporting Requirements:

Billing policies and procedures and the published fee schedule for STD services must be electronically available upon request to the Regional CDB Nurse Consultant.

V. Performance Monitoring and Quality Assurance:

NC EDSS events are routinely monitored quarterly by the CDB using the NC EDSS's *Treatment Time Report*. Policies and procedures are reviewed annually. Additionally, the LHD will receive an onsite STD Program monitoring visit by Regional CDB Nurse Consultants at least once every three years.

Should the LHD fall below expectations, the Division of Public Health will negotiate a corrective action plan. Failure to comply with the plan may result in a reduction or loss of current year funding or a loss in future funding.

VI. Funding Guidelines or Restrictions:

1. Requirements for pass-through entities: In compliance with 2 CFR §200.331 – *Requirements for pass-through entities*, the Division provides Federal Award Reporting Supplements to the Local Health Department receiving federally funded Agreement Addenda.
 - a. Definition: A Supplement discloses the required elements of a single federal award. Supplements address elements of federal funding sources only; state funding elements will not be included in the Supplement. Agreement Addenda (AAs) funded by more than one federal award will receive a disclosure Supplement for each federal award.
 - b. Frequency: Supplements will be generated as the Division receives information for federal grants. Supplements will be issued to the Local Health Department throughout the state fiscal year. For federally funded AAs, Supplements will accompany the original AA. If AAs are revised and if the revision affects federal funds, the AA Revisions will include Supplements. Supplements can also be sent to the Local Health Department even if no change is needed to the AA. In those instances, the Supplements will be sent to provide newly received federal grant information for funds already allocated in the existing AA.
2. These funds are to be used exclusively for the treatment of local health department clients who are either diagnosed with or who are sexual partners of someone with a STD.
3. Local health departments may not use these state funds for treatment of scabies infections.

4. The LHD is expected to purchase drugs at the lowest available pricing.
5. Local health departments may use these state funds to provide Expedited Partner Therapy (EPT) provided the local health department has a policy consistent with CDC and DPH guidelines for this practice.
6. Medications available to the Local Health Department on the STD Drug Formulary may be used to treat non-reportable STDs and sexually transmitted infections. In those instances where these drugs are used to treat non-reportable STDs and sexually transmitted infections, the Local Health Department may bill the insurer according to local billing policy. Local Health Departments may charge insurers no more than the cost of acquisition.
7. When billing Medicaid for medications available on the STD Drug Formulary, only the cost of acquisition may be billed if utilizing the Physician Drug Program (PDP). The UD modifier must also be entered on the claim. Medicaid will only reimburse for injectable medications utilizing the PDP. If there is a point of sale (POS) retail pharmacy located within your agency then a Local Health Department may bill Medicaid for prescription non-injectable medications only. The Medicaid dispensing fee may be included and again, the UD modifier must be added. No dispensing fee may be billed to Medicaid for treatment of vulvovaginal candidiasis because it is not a sexually transmitted infection.