

Division of Public Health Agreement Addendum FY 18-19

Durham County Health Department
Local Health Department Legal Name

584 Viral Hepatitis Prevention
Activity Number and Description

01/01/2019 – 05/31/2019
Service Period

02/01/2019 – 06/30/2019
Payment Period

Original Agreement Addendum
 Agreement Addendum Revision # _____

Epidemiology / Communicable Disease Branch
DPH Section / Branch Name

Dianne D. Brewer RN, 919-546-1694
dianne.brewer@dhhs.nc.gov
DPH Program Contact
(name, phone number, and email)

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

I. Background:

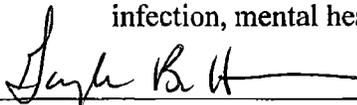
The primary mission of the Communicable Disease Branch (CDB) is to reduce morbidity and mortality resulting from communicable diseases that are a significant threat to the public through detection, tracking, investigation, control, treatment, and providing educational and care activities to improve the health of people in North Carolina.

An estimated 3.5 to 5.3 million Americans are chronically infected with hepatitis B (HBV) or hepatitis C (HCV) and deaths attributed to viral hepatitis infections far exceed those attributed to HIV/AIDS.

North Carolina's acute HCV rate increased greater than 900% from 2007 to 2016. Since 2008, North Carolina's acute HCV cases have continued to exceed that of the U.S. rate. As of 2017, it is estimated that 110,000 to 150,000 North Carolinians are now living with chronic HCV infection. Injection drug use (IDU) is by far the greatest risk factor for HCV acquisition. Since 2013, North Carolina has seen a steady increase in HCV among those with IDU as a risk factor.

Despite the significant public health impact of viral hepatitis infections, the public, at-risk populations, and health care professionals remain largely unaware of this silent epidemic. The North Carolina Communicable Disease Branch seeks to:

- a. Provide HCV prevention messages through client education
- b. Test high-risk populations for viral hepatitis, HIV, and other sexually transmitted infections
- c. Provide lists of resources and information to clients interested in pursuing medical care for HCV infection, mental health and substance abuse disorder treatment


Health Director Signature (use blue ink)

2/21/19
Date

Local Health Department to complete: (If follow-up information is needed by DPH)	LHD program contact name: <u>Dianne Brewer, IDU</u>
	Phone number with area code: <u>(919) 546-1694</u>
	Email address: <u>Dianne.Brewer@dhhs.nc.gov</u>

- d. Prevent viral hepatitis transmission
- e. Strengthen viral prevention capacity and infrastructure
- f. Vaccinate high-risk populations against Hepatitis A/B

Viral hepatitis and HIV/STDs contribute greatly to health care disparities in North Carolina. Many individuals infected with HCV have comorbidities with mental health and/or substance abuse disease. Local health departments are a valuable resource and are a pivotal touch point to building strong network partnerships, facilitating community engagement, and increasing linkage to care.

II. Purpose:

This Agreement Addendum provides funding to the Local Health Department to cover the costs associated with venipuncture, sample handling fees, and baseline laboratory studies necessary to evaluate persons infected with hepatitis C virus (HCV) for treatment. Baseline laboratory studies are required to assess liver fibrosis and determine appropriate treatment course.

While there are many barriers to procuring affordable treatment, a pivotal step following screening and identification of infection is the ability to successfully complete the baseline laboratory studies before HCV treatment can be initiated. Without baseline studies, patients cannot be prescribed treatment and will not be cured of their HCV infection.

Currently, the Local Health Department is screening for HCV and many sites are launching hepatitis C clinics. The Local Health Department is becoming a treatment site for patients diagnosed with HCV and is helping to expand access to affordable treatment. By allocating funds to cover costs associated with diagnostic studies, the Local Health Department will provide a critical step in the HCV Curative Cascade and ensure patients have access to curative treatments.

III. Scope of Work and Deliverables:

The Local Health Department shall:

1. Utilize the services of the Durham County Department of Public Health laboratory for HCV baseline laboratory studies for viral hepatitis screening and diagnostic assessment, including laboratory fees for tests outlined in Paragraph 3 below. The Local Health Department will be responsible for facilitating and coordinating all laboratory studies.
2. Generate a unique billing code to identify the work ordered in this Agreement Addendum.
3. Ensure baseline studies are ordered for each patient selected for the HCV baseline laboratory pilot. Baseline laboratory studies should follow HCV treatment guidelines outlined by American Association for the Study of Liver Disease (AASLD), which can be found at <https://www.aasld.org/>. HCV baseline laboratory studies are limited to laboratory studies outlined in this Paragraph 3. Baseline laboratory studies are defined as studies completed at during the patient's first or second diagnostic appointment with their hepatitis C treatment-prescribing provider. Baseline laboratory studies include the following:
 - a. Complete Blood Count (CBC) with Differential
 - b. Prothrombin time (PT)/ International normalized ratio (INR)
 - c. Serum Creatinine (sCr)
 - d. Liver function tests: ALT, AST, ALP, albumin, and bilirubin
 - e. Iron
 - f. HCV Genotype Test

- g. Quantitative HCV RNA
 - h. Hep A IgG
 - i. Hep B surface antigen
 - j. Hep B core antibody
 - k. NS5A Resistance testing. (NS5A Resistance testing is not mandated for every patient. NS5A is necessary for patients with genotype 1a and when elbasvir/grazoprevir is considered for treatment).
4. Provide price sheets to the DPH Program Contact by January 1, 2019 for the following fees:
 - a. For each baseline laboratory test listed in Paragraph 3 above.
 - b. For venipuncture and for handling fees associated with items listed in Paragraph 3 above.
 - c. For secondary tests listed in Paragraph 5 below.
 - d. For venipuncture and for procedure and handling fees listed in Paragraph 5 below.
 5. Upon review of baseline test results, obtain secondary studies as deemed to be medically necessary by ordering provider. Secondary diagnostic tests are necessary for certain patients and part of a patient's evaluation for HCV treatment. Secondary diagnostic tests included in this activity are:
 - a. Ferritin
 - b. % Transferrin Saturation
 - c. Urine Drug Screen (UDS)
 - d. Fibroscan
 6. Establish patient eligibility criteria for the pilot. Eligibility criteria must address the patient's ability to pay for HCV staging labs, financial obstacles, and hardships that block a patient's assessment for HCV treatment. The pilot is intended for patients who cannot afford staging diagnostic labs and who would otherwise be unable to proceed with treatment evaluation.
 7. Record patients enrolled in the pilot program. Documentation must include case and the total number of tests ordered in Paragraphs 3 and 5.
 8. Provide a quarterly report that includes the total number of patients diagnosed with HCV that have financial means to pay for baseline staging laboratory tests and the total number of patients enrolled in the baseline laboratory pilot program. The quarterly reports are due to the DPH Program contact after the completion of each quarter, by the 15th day of the following month.
 9. Decide on an aggregable regional approach to incorporate counties and clinical sites to reach patients who can benefit from services outlined in this activity. The aggregable approach needs to consider funding to support negotiated fees for baseline laboratory staging and secondary tests outlined in Paragraphs 3 and 5.

IV. Performance Measures/Reporting Requirements:

Performance Measure #1: The Local Health Department will generate a unique billing code by January 1, 2019 to identify the work ordered in this Agreement Addendum with its laboratory to process diagnostic tests necessary to oversee treatment of viral hepatitis infections.

Reporting Requirements: The Local Health Department will notify the DPH Program Contact by January 15, 2019 that a unique billing code has been established within its laboratory and will provide a copy of the unique billing code to the DPH Program Contact by January 30, 2019.

Performance Measure #2: The Local Health Department will provide quarterly performance reports to the Hepatitis C Nurse Consultant for work outlined in Section III.

Reporting Requirements: The Local Health Department will provide quarterly performance reports by the 15th of the month following each quarter.

V. Performance Monitoring and Quality Assurance:

The Hepatitis C Nurse Consultant will review the quarterly performance reports and conduct at least one telephone consultation during the Service Period of this Agreement Addendum with the medical director or program point of contact at the Local Health Department to discuss work accomplishments facilitated by the Agreement Addendum. The intent of this Activity is to remove a barrier to treatment for patients unable to afford staging laboratory tests for hepatitis C.

If the Local Health Department is deemed out of compliance, the Viral Hepatitis Program Staff will assist as needed. Funds may be withheld until the Local Health Department is compliant with deliverables. If technical assistance does not prove beneficial, the Agreement Addendum may then be terminated.

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.

FY19 Activity: 584 Viral Hepatitis Prevention

Supplement 2

Supplement reason: In AA+BE or AA+BE Rev -OR- -

CFDA #: 93.270 Federal awd date: 10/30/18 Is award R&D? no FAIN: NUS1PS005096 Total amount of fed awd: \$ 176,000

CFDA name: Adult Viral Hepatitis Prevention and Control	Fed award project description: Improving Hepatitis B and C Care Cascades; Focus on Increased Testing and Diagnosis
	Fed awarding agency: DHHS, Centers for Disease Control and Prevention Federal award indirect cost rate: n/a %

Subrecipient	Subrecipient DUNS	Fed funds for this Supplement	Total All fed funds for this Activity	Subrecipient	Subrecipient DUNS	Fed funds for this Supplement	Total All fed funds for this Activity
Alamance	965194483	=	=	Jackson	019728518	0	67,643
Albemarle	130537822	=	=	Johnston	097599104	=	=
Alexander	030495105	=	=	Jones	095116935	=	=
Anson	847163029	=	=	Lee	067439703	=	=
Appalachian	780131541	=	=	Lenoir	042789748	=	=
Beaufort	091567776	=	=	Lincoln	086869336	=	=
Bladen	084171628	=	=	Macon	070626825	=	=
Brunswick	091571349	=	=	Madison	831052873	=	=
Buncombe	879203560	=	=	MTW	087204173	=	=
Burke	883321205	=	=	Mecklenburg	074498353	=	=
Cabarrus	143408289	=	=	Montgomery	025384603	=	=
Caldwell	948113402	=	=	Moore	050988146	=	=
Carteret	058735804	5,000	5,000	Nash	050425677	=	=
Caswell	077846053	=	=	New Hanover	040029563	=	=
Catawba	083677138	=	=	Northampton	097594477	=	=
Chatham	131356607	=	=	Onslow	172663270	=	=
Cherokee	130705072	5,000	5,000	Orange	139209659	=	=
Clay	145058231	=	=	Pamlico	097600456	=	=
Cleveland	879924850	=	=	Pender	100955413	=	=
Columbus	040040016	=	=	Person	091563718	=	=
Craven	091564294	=	=	Pitt	080889694	5,000	5,000
Cumberland	123914376	=	=	Randolph	027873132	=	=
Dare	082358631	=	=	Richmond	070621339	=	=
Davidson	077839744	=	=	Robeson	082367871	=	=
Davie	076526651	=	=	Rockingham	077847143	=	=
Duplin	095124798	=	=	Rowan	074494014	=	=
Durham	088564075	=	=	RPM	782359004	=	=
Edgecombe	093125375	=	=	Sampson	825573975	=	=
Forsyth	105316439	=	=	Scotland	091564146	=	=
Franklin	084168632	=	=	Stanly	131060829	=	=
Gaston	071062186	=	=	Stokes	085442705	=	=
Graham	020952383	=	=	Surry	077821858	=	=
Granville-Vance	063347626	=	=	Swain	146437553	=	=
Greene	091564591	=	=	Toe River	113345201	=	=
Guilford	071563613	=	=	Transylvania	030494215	=	=
Halifax	014305957	=	=	Union	079051637	=	=
Harnett	091565986	=	=	Wake	019625961	=	=
Haywood	070620232	=	=	Warren	030239953	=	=
Henderson	085021470	=	=	Wayne	040036170	=	=
Hertford	627320971	=	=	Wilkes	067439950	=	=
Hoke	091563643	=	=	Wilson	075585695	=	=
Hyde	832526243	=	=	Yadkin	089910624	=	=
Iredell	074504507	=	=				

Activity 584	AA	1175 2681 FE	1311 720C HP	1311 9809 00	1311 981A HV	1311 981B HV	Proposed Total	New Total
Service Period		01/01-05/31	01/01-05/31	06/01-05/31	06/01-12/31	01/01-05/31		
Payment Period		02/01-06/30	02/01-06/30	07/01-06/30	07/01-01/31	02/01-06/30		
01 Alamance		0	0	0	0	0	0	0
D1 Albemarle		0	0	0	0	0	0	0
02 Alexander		0	0	0	0	0	0	0
04 Anson		0	0	0	0	0	0	0
D2 Appalachian		0	0	0	0	0	0	0
07 Beaufort		0	0	0	0	0	0	0
09 Bladen		0	0	0	0	0	0	0
10 Brunswick		0	0	0	0	0	0	0
11 Buncombe		0	0	0	0	0	0	80,000
12 Burke		0	0	0	0	0	0	0
13 Cabarrus		0	0	0	0	0	0	0
14 Caldwell		0	0	0	0	0	0	0
16 Carteret	* 0	0	5,000	0	0	0	5,000	5,000
17 Caswell		0	0	0	0	0	0	0
18 Catawba	* 0	11,250	0	0	0	0	11,250	11,250
19 Chatham		0	0	0	0	0	0	0
20 Cherokee	* 0	0	5,000	0	0	0	5,000	5,000
22 Clay		0	0	0	0	0	0	0
23 Cleveland		0	0	0	0	0	0	0
24 Columbus		0	0	0	0	0	0	0
25 Craven		0	0	0	0	0	0	0
26 Cumberland		0	0	0	0	0	0	0
28 Dare		0	0	0	0	0	0	0
29 Davidson		0	0	0	0	0	0	0
30 Davie		0	0	0	0	0	0	0
31 Duplin		0	0	0	0	0	0	0
32 Durham	* 0	0	5,000	0	0	0	5,000	5,000
33 Edgecombe		0	0	0	0	0	0	0
34 Forsyth		0	0	0	0	0	0	0
35 Franklin		0	0	0	0	0	0	0
36 Gaston		0	0	0	0	0	0	0
38 Graham		0	0	0	0	0	0	0
D3 Gran-Vance		0	0	0	0	0	0	0
40 Greene		0	0	0	0	0	0	0
41 Gullford		0	0	0	0	0	0	0
42 Halifax		0	0	0	0	0	0	0
43 Harnett		0	0	0	0	0	0	0
44 Haywood		0	0	0	0	0	0	0
45 Henderson		0	0	0	0	0	0	0
46 Hertford		0	0	0	0	0	0	0
47 Hoke		0	0	0	0	0	0	0
48 Hyde		0	0	0	0	0	0	0
49 Iredell		0	0	0	0	0	0	0
50 Jackson		0	0	0	0	0	0	67,643
51 Johnston		0	0	0	0	0	0	0
52 Jones		0	0	0	0	0	0	0
53 Lee		0	0	0	0	0	0	0
54 Lenoir		0	0	0	0	0	0	0
55 Lincoln		0	0	0	0	0	0	0
56 Macon		0	0	0	0	0	0	0
57 Madison		0	0	0	0	0	0	0
D4 M-T-W		0	0	0	0	0	0	0
60 Mecklenburg		0	0	0	0	0	0	0
62 Montgomery		0	0	0	0	0	0	0
63 Moore		0	0	0	0	0	0	0
64 Nash		0	0	0	0	0	0	0
65 New Hanover	* 1	0	5,000	0	0	0	5,000	85,000
66 Northampton		0	0	0	0	0	0	0
67 Onslow		0	0	0	0	0	0	0
68 Orange		0	0	0	0	0	0	0

