Ending the Hepatitis C Epidemic in New York

Hepatitis C virus (HCV) infection is the leading cause of serious liver disease in the United States. Untreated HCV can lead to cirrhosis, liver cancer or liver transplantation. It also increases the risk for heart disease, bone loss and difficulties with memory and concentration. Although the most serious consequences of HCV may take decades to manifest, earlier-stage liver disease may cause chronic pain, fatigue, and other symptoms that impact individuals’ quality of life.\(^1\)

Well over 200,000 New Yorkers have chronic HCV infection, with an estimated 50% unaware of their status.\(^2\) Among those who have been diagnosed, many lack consistent care or access to curative treatment, a fact that drives increasing HCV-related mortality. End-stage liver disease from HCV is a leading cause of death among people living with HIV (PLHIV).\(^3\) Recent research from NYC has shown that on average people with HCV die 20 years earlier than uninfected people, and people who are co-infected with HCV and HIV die more than 25 years earlier.\(^4\)

Injection drug use is the leading risk factor for HCV. New local outbreaks among young people who inject drugs have been identified alongside an increase in heroin use both across New York\(^5\) and nationally.\(^6\) Transmission among young injectors is a particular concern, with studies showing incidence of 10-35% per year.\(^7\) Also of concern are the alarming racial/ethnic disparities in HCV infections—although NYS does not currently require reporting on race/ethnicity for HCV surveillance, a recent NYC Department of Health and Mental Hygiene report shows that approximately 65% of persons with a newly reported positive HCV antibody or viral RNA were black or Hispanic.\(^8\) The sharp rise in HCV infection among HIV-positive men who have sex with men (MSM) and transgender women is another area for serious concern; in the year 2000, 7% of HCV reports among people with HIV were MSM and transgender women, while this percentage had tripled to 24% by the year 2010.\(^9\) As many as 30% of all PLHIV in New York are HCV co-infected.\(^10\)

Nationally, at least 3.5 million people are living with chronic HCV, and additional sources of potential underestimation suggest that true prevalence could well be higher.\(^11\) Hepatitis C now kills more people in the United States each year than AIDS,\(^12\) and both in New York and the rest of the country, HCV-related mortality has risen steadily during the past decade.\(^13\) According to the U.S. Centers for Disease Control and Prevention (CDC), chronic liver disease is the 6\(^{th}\) leading cause of death among Latinos, much of this as a consequence of hepatitis; this does not happen with any other racial group.\(^14\)

With the recent U.S. Food and Drug Association (FDA) approval of a game-changing new generation of all-oral, 90% to 100% effective, and easy to tolerate HCV curative treatment, we are finally at a moment where the epidemic can be controlled – and eventually eradicated –
with the tools we have available. However, New York’s investment in HCV control has historically been limited, depriving communities of the prevention, testing, care, and curative treatment resources they need. Needless legislative and other barriers also hinder access to prevention and testing services in particular.

New York has nonetheless made important progress in responding to the epidemic. In 2013, the State passed the nation’s first birth cohort-based HCV testing law for people born between 1945-1965, a strategy that CDC scientists have found identifies five times as many cases as previously used strategies. The Department of Health’s innovative Hepatitis C Care and Treatment Initiative and the NYC Department of Health and Mental Hygiene’s Project Inspire are building HCV clinical capacity. New York’s more than twenty-year history of support for syringe exchange and related harm reduction services, and its role in originating and expanding opioid agonist therapy for the treatment of opioid dependence, have influenced HIV, hepatitis, and drug services worldwide. Meanwhile, alongside the largest state-level HCV epidemic, New York has some of the most skilled medical providers, prevention specialists, researchers, and public health officials in the nation.

But more can and must be done to lower the cost of hepatitis C treatment and end current restrictions on coverage to fully leverage the therapeutic advances against HCV, and reduce transmission, morbidity, and mortality. The Coalition demands that the State, Medicaid Managed Care Organizations (MCOs), private insurers and pharmaceutical companies negotiate an arrangement to ensure that every person living with hepatitis C in New York State has access to life-saving treatment, in compliance with American Association for the Study of Liver Disease (AASLD) guidelines and the November 5, 2015 Centers for Medicare and Medicaid Services (CMS) letter to State Medicaid programs.

The NYS Hepatitis C Coalition recommends that Governor Andrew Cuomo and the New York State Legislature fund the following budget proposals as an initial step to combat the State’s hepatitis C (HCV) epidemic while the Department of Health (NYSDOH) and community partners formulate a comprehensive plan to eliminate the State’s HCV epidemic.

**Hepatitis C Budget Proposals, FY 2016-2017**

1. **Increase funding for NYSDOH viral hepatitis programs to increase statewide HCV surveillance, youth HCV prevention, and patient navigation programs.**

NYSDOH AIDS Institute viral hepatitis programs have been flat-funded at less than $2 million/year for several years, while the epidemic continues to grow. We recommend an additional $6 million in new funding to fill three pressing gaps:

- **Statewide Surveillance:** Municipal and county health departments currently lack resources to monitor the HCV epidemic, investigate new outbreaks, and utilize epidemiological data, including race/ethnicity, risk factors and country of origin, to
efficiently guide public health resources. New York should provide $2,000,000 in funding to county health departments and the NYS Department of health to bolster statewide HCV and hepatitis B surveillance.

- **Youth HCV Prevention:** The statewide increase in prescription opioid and heroin injecting, especially among young people, has put a new generation at risk of HCV infection. Because of currently limited prevention resources, many young people are becoming infected before they engage with services. We propose $1,000,000 of new funding to support youth-targeted HCV prevention programs including education, harm reduction services, and linkage to drug treatment.

- **Linkage to Care and Patient Navigation:** Peer HCV patient navigation services modeled on programs developed to combat the HIV epidemic have been vital to engaging and retaining people in care and treatment. The NYC Council’s Viral Hepatitis Initiative, created in 2014, included seed funding for innovative patient navigation services that have significantly exceeded targets. New York should invest $1,000,000 to replicate that program statewide and fill coverage gaps in NYC.

- **Hepatitis C Public Awareness and Anti-Stigma Campaign:** An estimated 50% of New Yorkers living with chronic HCV are unaware of their status. We recommend a public social messaging anti-stigma campaign to increase hep C screening and awareness, to be focused in areas with high HCV prevalence: Estimated cost $1,000,000.

- **Prevention and Screening Services for Populations that Experience High HCV Incidence and Prevalence:** New York HCV surveillance shows sharp increase in new HCV infections among MSM and transgender people over the past decade. We recommend expanded prevention and screening services for MSM and transgender individuals, and other populations that experience high HCV incidence and prevalence. Estimated cost $1,000,000.

Total Proposed FY17 Budget: $6,000,000

### Hepatitis C Items From Ending the Epidemic Budget Proposals, FY 2016-2017

The NYS Hepatitis C Coalition strongly supports the Governor’s plan to end the HIV/AIDS epidemic in New York State and sees the Governor’s Ending the Epidemic (ETE) initiative and Task Force process as a model. The NYS Hep C Coalition supports the hepatitis C related budget proposals from the End AIDS NY 2020 Community Coalition’s NYS budget ask for 2016-17, since these budget proposals are crucial to near-term HCV control.

2. **Support for NYSDOH oversight of HIV/HCV testing and treatment in correctional facilities.**

Ending the HIV/AIDS Epidemic Blueprint recommendation #BP9 calls for providing enhanced services for people with HIV within correctional and other institutions and for specific programming for patients returning home from corrections or other institutional settings. Identifying these populations of people with HIV and HCV, getting them into treatment, and
retaining them in care once they are released is crucial to ending New York’s HIV and HCV epidemics.

*Proposed FY17 Budget: $2,000,000*

3. **Support for program development, outreach, linkage and retention in care for HIV and HCV co-infected persons.**

As Ending the HIV/AIDS Epidemic recommendation #BP26 explains, approximately 15% to 30% of people in the United States with HIV are estimated to be co-infected with HCV. The reduction and treatment of HCV transmission is a key priority for ensuring one devastating epidemic is not ended while another, which impacts many in the same populations, continues. HCV detection and treatment directly relates to individual health outcomes and overall quality of care.

*Proposed FY17 Budget: $3,000,000*

4. **Expanded access to syringe exchange and other effective harm reduction programs statewide.**

Ending the HIV/AIDS Epidemic recommendation #BP15 calls for increased momentum in promoting the health of people who use drugs and recognizes harm reduction approaches like syringe exchange as being the most successful way to meet the needs of this population. BP15 calls for expanded statewide access to clean syringes for injection drug users and increased access to drug treatment.

*Proposed FY17 Budget: $2,000,000*

5. **Establish grant program to train pharmacists on drug treatment referral, hepatitis C education, nPEP and PrEP education.**

NYS should establish and fund a grant program to expand the number of qualified pharmacists trained to provide counseling and referral for drug treatment, hepatitis C education, and HIV prevention education. Qualifying pharmacies could apply to the grant program to be reimbursed for the cost of sending pharmacy assistants to be trained by the AIDS Institute or an AI grantee on providing counseling on drug treatment referral, hiv c education, and nPEP and PrEP education. The relevant training curriculum already exists and costs associated would be aimed at educating pharmacy providers on the program and training for relevant staff. Investment in this program should reviewed during the 2016-17 fiscal year based on the number of grants applied for/funded to determine a continuing investment in the program.

*Proposed FY17 Budget: $2,000,000*
6. Create a pilot program to develop Supervised Injection Facilities (SIFs) in locations experiencing high levels of HIV or HCV transmission or drug overdose.

Among the Blueprint Getting to Zero (GTZ) recommendations, GTZ3 recommends establishing SIFs as one way of improving drug user health, improving public safety, and ending AIDS as part of a larger effort to shift New York’s criminal justice drug use policy to a public health approach. In use in approximately 100 locations worldwide, numerous scientific studies have found that SIFs reduce HIV and HCV transmission, prevent fatal drug overdoses, increase access to drug treatment and other healthcare, and reduce public disorder including improperly discarded syringes. We propose the NYSDOH be funded to support the integration of supervised injection services with existing drug services programs, such as syringe exchanges, and/or the establishment of specialized SIFs where need and local community support is identified.

Proposed FY17 Budget: $2,000,000

Legislative Proposals

A. Decriminalize syringe possession and reform the Expanded Syringe Access Program. (A.5471-Gottfried / S.4099-Rivera)

NYS bills A.5471 and S.4099 will repeal the criminal law on syringe possession and amend NY Public Health Law, §§ 3381 to allow pharmacies and healthcare agencies registered under the Expanded Syringe Access Program (ESAP) to remove the limit on the sale of hypodermic syringes and needles per transaction and remove the ban on program advertising, allowing consumers to access more than 10 syringes at one time and for pharmacies to advertise the availability of syringes to the public. In addition, the bills should be amended to include authorization of a grant program to be administered by the AIDS Institute to train ESAP pharmacy staff members to provide substance use treatment referrals, hepatitis C education, and nPEP and PrEP education. Qualifying pharmacies would be eligible to apply through the grant program for reimbursement of the costs of sending pharmacy staff members for training by the AIDS Institute or an AI grantee.

Importance to ending the hep C epidemic: Harm reduction programs, including syringe exchange programs and wraparound services, are effective HIV and hepatitis B and C prevention tools, and the first meaningful point of contact with the healthcare system for many persons who use illegal drugs. Strengthening these programs supports the ETE Blueprint goal of decreasing new HIV infections (BP15, Increase momentum in promoting the health of people who use drugs, and GTZ3, Enact reforms to improve drug user health).

Status of Legislation: During 2015 session, referred to Codes Committee in both chambers. No vote was scheduled in Senate or Assembly. Language to enact the ESAP reform provisions of the bill was included in Gov. Cuomo’s executive budget Article VII legislation but not adopted in the final state budget.
B. Authorize pharmacists to administer HCV rapid screening tests and offer referrals for HCV viral load testing and linkage to care.

The federal government regulates all laboratory testing, except research, performed on humans through the Clinical Laboratory Improvement Amendments (CLIA). A CLIA waiver was created as an exception to performing a select number of tests with minimal levels of complexity outside of traditional laboratory settings, such as at a pharmacy. As of July 1, 2015 there were 5,398 community pharmacies in NYS. It is estimated that each pharmacy is visited an average of 3,700 to 4,000 times per week. Like influenza, the hepatitis C test is one of over 120 tests eligible for a pharmacist to conduct with a valid CLIA waiver. However, NYS pharmacists are currently prohibited from performing rapid testing of any kind due to Title V of the New York State Public Health Law, which requires that a limited service laboratory must be overseen by a qualified “laboratory director” to administer CLIA-waived rapid tests. Pharmacists are not included under the definition of a qualified laboratory director.

We propose including pharmacists in the definition of qualified individuals who can be laboratory directors; add pharmacists to the list of practitioners who can administer CLIA-waived tests as an adjunct to treatment of their patients; and strongly recommend a program aimed at raising patients’ awareness of this new avenue toward access to HCV care and treatment.

Rapid antibody testing identifies people who have been infected with hepatitis C virus, but a viral load test is needed to confirm current HCV infection. Expanding the pool of providers who are qualified to conduct HCV antibody testing increases opportunities for linkage to HCV care and treatment.

Importance to ending the hep C epidemic: Testing individuals at risk for HCV infection, identifying cases, and linking people with the virus to care and treatment is a core strategy for preventing forward transmission and reducing morbidity and mortality. Although New York’s 2013 HCV testing law has resulted in an increase in tests being administered, there are currently far too few testing locations given the estimated scale of the epidemic. Every person who learns their status is a person who may take steps to prevent transmitting the virus to others and to protect their own health to avoid disease progression and costly medical care.

Status of Legislation: No bill introduced to date.

C. Authorize the Department of Corrections and Community Supervision and the Department of Health to establish HCV prevention programs in every state prison. (A.4256-Gottfried / S.1017-Montgomery)

New York State prisoners have extremely high HCV prevalence, with more than 6,000 (11% of all prisoners) estimated to be living with the virus in 2013. Correctional facilities are a potentially high risk environment for transmission of HCV and other blood-borne diseases, but
also afford unique opportunities for prevention, testing, and linkage to care and treatment. The Department of Corrections and Community Supervision should collaborate with the Department of Health to establish programs that include education, counseling, and other prevention efforts, including the distribution of condoms in every correctional facility to prevent the spread of HCV, HIV, and other blood-borne and sexually transmitted infections. We urge lawmakers to pass legislation to this effect by supporting A4256 (Gottfried) / S1017 (Montgomery).

*Importance to ending the hep C epidemic:* A significant proportion of prisoners with HCV do not know their status or are not in care, and prison environments lacking prevention resources allow the virus to spread further. Dedicated anti-HCV programs in DOCCS facilities are a key opportunity for interrupting the epidemic in a high-prevalence population.

*Status of Legislation:* During the 2015 session, referred to Assembly Committee on Correction and Senate Committee on Crime Victims, Crime, and Correction. No vote was scheduled in either chamber.

### Organizations Endorsing the Platform

ACT UP/New York  
American Run for the End of AIDS, Inc. (AREA)  
Coalition On Positive Health Empowerment (COPE)  
End AIDS Now  
Harm Reduction Coalition  
Hepatitis C Mentor and Support Group (HCMSG)  
Hispanic Health Network  
Housing Works  
Latino Commission on AIDS  
NATAP  
OASIS-Latino LGBT Wellness Center  
Treatment Action Group  
VOCAL New York
Citations: