New York State Drug Utilization Review Board
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RE: New York State Drug Utilization Review Board Hepatitis C Virus Clinical Criteria Review

To Whom It May Concern:

The undersigned organizations, medical providers, and people at risk for and living with the hepatitis C virus (HCV), are gravely concerned about the proposed clinical criteria for HCV treatment in New York's Medicaid program. Our concerns are outlined below:

1. **This proposed policy undermines the public health imperative to identify, treat, and cure people living with hepatitis C and will result in preventable infections.** With an estimated 200,000-400,000 New Yorkers living with HCV and HCV the primary cause of hepatocellular carcinoma, which is the fastest growing cancer in the nation, now is the time to act aggressively against HCV. This policy is too restrictive given the health crisis caused by HCV in New York State and the tremendous opportunity HCV treatments provide to improve health, save lives, reduce health care costs, and eradicate HCV in the vulnerable Medicaid population by curing the majority of people living with HCV. Limiting treatment to only people with advanced liver disease ensures that New York State is committing to treating hepatitis C for many years to come. Patients who develop advanced cirrhosis and other complications will require ongoing medical treatment, even after they are cured. Early treatment prevents liver damage and liver cancer, improves quality of life, and stems the tide of onward transmission of the virus. In fact, identifying and treating everyone with hepatitis C in the United States will net a $1.4 trillion in benefit to society over time.[1]

2. **The proposed policy, based on cost containment concerns and not evidence, will result in rationing of care and will require doctors to practice two standards of care, one for Medicaid patients and one for everyone else**. Requiring patients to have advanced liver disease (i.e., METAVIR F3-4 or equivalent) to receive treatment authorization means patients have to be seriously sick from a chronic, infectious, life-threatening disease before they can be offered the cure. Treatment should be available to all patients who are highly motivated to get cured of the virus (i.e., patients likely to adhere to the treatment regimen) and who are identified by their physicians as appropriate treatment candidates. Provider and patient discretion should be the standard on which to base treatment decisions. Data presented by Dr. Philip Coffin at

[1] Dana Goldman, Economist, University of Southern California. Presentation to Brookings Institute, "Are New Breakthrough Treatments Worth Their Price? Assessing the Social Costs and Benefits of Biomedical Innovation," during event *The Cost and Value of Biomedical Innovation: Implications for Health Policy*,October 1, 2014. Webcast accessed October 3, 2014 at http://www.brookings.edu/events/2014/10/01-cost-and-value-biomedical-innnovation-hep-c

CDC's Public Health Grand Rounds on the occasion of the 25th anniversary of the discovery of HCV demonstrated that more than 200,000 people with hepatitis C will die needless preventable deaths if treatment is restricted to patients with advanced disease.[2] Moreover, instituting complex prior authorization guidelines places an undue burden on providers who are forced to spend hours filling out forms instead of treating their patients. It also discourages physicians and patients who might qualify for treatment from even attempting to obtain approval (or even seeking care or even testing).

3. **The policy flies in the face of the letter and the spirit of the New York State legislation passed just a year ago and signed into law by the Governor requiring all primary care physicians to offer hepatitis C testing to all New Yorkers born during 1945-1965.** These provisions would now mean that doctors will be required to test thousands of asymptomatic patients and then inform those testing positive that New York State will not allow them to be treated because they are indigent.

4. **Restricting access to treatment in this way will have the effect of discouraging individuals from getting tested, resulting in a missed opportunity not only to identify and treat those who have advanced liver disease, but to prevent or mitigate further liver damage in individuals who may not yet have reached that point of deterioration.** Despite its high prevalence in the United States, nationally, it is estimated that 50-75% of individuals do not even know they are infected. Analysis of death records between 1992 and 2009 by the Massachusetts Department of Public Health for example, found that of those who died of HCV related causes in Massachusetts, 73% died within five years of diagnoses.[3] These findings underscore the emergent need to diagnose infected individuals and get them into treatment. Further, individuals living with chronic hepatitis C can take specific steps to try to both mitigate potential liver damage and ensure they do not inadvertently spread the virus to others.

5. **This policy undermines our ability to address health inequities and disparities, particularly among communities of color, which have disproportionally higher HCV prevalence.** The Centers for Disease Control and Prevention have found that African American "Baby Boomers" (those born between 1945 through 1965) are twice as likely to have HCV as Baby Boomers in general.[4] Latinos experience some of the highest rates

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[2] Coffin P. Steps toward ending hepatitis C in the US. CDC Public Health Grand Rounds, 25th Anniversary of the Discovery of the Hepatitis C Virus, Atlanta, Ga., June 17, 2014. Available at http://www.cdc.gov/cdcgrandrounds/archives/2014/june2014.htm. [accessed 3 October 2014].

[3] V. Lijewski, et a., Division of Epidemiology and Immunization, Bureau of Infectious Disease, Massachusetts Department of Public Health, "Mortality trends Among People Diagnosed with Hepatitis C Virus Infection: Massachusetts 1992-2009." Abstract Submitted to the Council of State and Territorial Epidemiologists, fall 2012.

[4] http://blog.aids.gov/2014/02/fighting-hepatitis-c-among-african-americans.html

of hepatitis C infection in the U.S., with an estimated overall prevalence rate of 2.6%, and incidence appears to be rising.[5]

6. **The proposed policy that patients have advanced liver disease (i.e., METAVIR F3-4 or equivalent) to receive treatment authorization is arbitrary, as results are +/- 1 fibrosis stage – even liver biopsy cannot conclusively differentiate between stage 2 and stage 3 disease.** Limiting access in this way will therefore inevitably miss some individuals who are suffering from advanced liver disease and who are urgently in need of treatment.

7. **The policy prevents women of childbearing age (15 to 44 years of age) the opportunity to avoid vertical transmission.** By rationing treatment to only individuals with a METAVIR F3-4 or equivalent, women of childbearing age who do not meet that criteria are denied the ability to eradicate the virus, ensuring that preventable perinatally transmitted HCV will continue to infect future children in New York.

8. **While we commend that the proposed policy supports HCV treatment access for HIV coinfected individuals, limiting access to only those with undetectable HIV viral load is inappropriate.** Although guidelines now suggest that everyone who is diagnosed with HIV initiate antiretroviral therapy, some people with HIV develop hepatotoxicity with HIV medications and need to initiate anti-HCV treatment before they can tolerate HIV medications. Others may have high CD4 counts and choose to treat their HCV infection first. Clinicians should have the opportunity to determine an HIV patient's suitability for anti-HCV treatment.

9. **The policy's requirement that people show "no signs of high-risk behavior" is overly broad, has no clinical basis, and is discriminatory.** "High-risk behavior" is an overly broad, non-clinical term and offers no actual guidance to providers. Moreover, such a term could be used to discriminate against many different groups of individuals, and particularly those with substance use disorders. Denying or discontinuing treatment because of alcohol or illicit drug use is unnecessary, offensive to patients, and a waste of time and money. Treating people who inject drugs (PWID) is critical to curbing HCV in New York, as they comprise the group with the most new HCV infections. Active injection drug use in and of itself is not an evidence-based reason to exclude patients from therapy, per the 2002 National Institutes of Health Consensus Development Conference statement on the management of HCV.[6] Indeed, it was New York State's own AIDS Advisory Council who wrote a letter to NIH in 2000 objecting to the prior guideline that unjustly restricted treatment of drug users and urging that it be changed.[7]

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[5] http://blog.aids.gov/2013/05/latino-community-rallies-to-generate-awareness-of-viral-hepatitis.html, accessed October 3, 2014

[6] National Institutes of Health. *National Institutes of Health Consensus Development Conference statement: management of hepatitis C: 2002. Final statement, 12 September. 2002.* Available at http://consensus.nih.gov/2002/2002hepatitisc2002116html.htm [accessed 20 May 2014].

[7] Letter to National Institutes of Health from Allan Rosenfield, MD, Dean, Mailman School of Public Health, Columbia University, and Chairman, New York State AIDS Advisory Council, 2000.

Now New York State is proposing to institute this odious policy itself. Hepatitis C treatment can be successful in patients who do not abstain from drugs. In fact, there is abundant evidence that PWID can be successfully treated for hepatitis C.[8] Similar to the NIH statement, guidelines developed by the American Association for the Study of Liver Diseases[9], European Association for the Study of the Liver[10], or World Health Organization[11] guidelines make no distinctions with respect to treating people who use drugs. The Veterans Administration (VA) guidelines state that PWID should be referred to an addiction medicine specialist, but do not require any period of abstinence. As noted in the VA guidelines for treatment: "[t]here are no published data supporting a minimum length of abstinence as an inclusion criterion for HCV antiviral treatment. Patients with active substance- or alcohol-use disorders should be considered for therapy on a case-by-case basis and care should be coordinated with substance-use treatment specialists."[12] Indeed, alcoholics are in especially urgent need of antiviral treatment because HCV can synergistically accelerate the progression of liver disease. New York should follow the standard of care outlined by these nationally recognized experts and ensure people who use drugs and those with substance use disorders are not uniformly excluded from treatment.

10. **The requirement for HCV RNA test results in order to continue therapy is in direct contradiction to AASLD/IDSA guidance on this matter.** AASLD/IDSA guidelines specifically state, **"**Quantitative HCV viral load monitoring at 4 weeks is recommended, but discontinuation of treatment because this test result is missing is NOT recommended."[13] There are many reasons why a test result might be missing (including lab error) and denying patients who have already embarked on treatment the opportunity to complete it because of a missed lab test result would be particularly egregious since it would waste the resources already invested in treatment and revoke the opportunity for a cure from adherent patients for no good medical reason.

11. **New York is facing a new wave of HCV transmission in association with the epidemic of opioid use among young people.** Increased transmission of HCV among young adults has been reported in at least 30 states,[14] New York prominently among them.[15]

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[8] Bruggmann P, Litwin AH. Models of care for the management of hepatitis C virus among people who inject drugs: one size does not fit all. Clin Infect Dis 2013;57(suppl 2):S56-61.
[9] http://www.hcvguidelines.org/, accessed October 3, 2014
[10] http://www.easl.eu/_newsroom/latest-news/easl-recommendations-on-treatment-of-hepatitis-c-2014, accessed October 3, 2014
[11] http://www.who.int/hiv/pub/hepatitis/hepatitis-c-guidelines/en/, accessed October 3, 2014.
[12] http://www.hepatitis.va.gov/provider/guidelines/2014hcv/special-groups.asp
[13] http://www.hcvguidelines.org/, accessed October 3, 2014
[14] Suryaprasad AG, White JZ, Xu F, Eichler BA, Hamilton J, Patel A, Hamdounia SB, Church DR, Barton K, Fisher C, Macomber K, Stanley M, Guilfoyle SM, Sweet K, Liu S, Iqbal K, Tohme R, Sharapov U, Kupronis BA, Ward JW, Holmberg SD. Emerging Epidemic of Hepatitis C Virus Infections Among Young Nonurban Persons Who Inject Drugs in the United States, 2006-2012. Clin Infect Dis 2014. PMID: 25114031.
[15] Zibbell JE, Hart-Malloy R, Barry J, Fan L, Flanigan C. Risk Factors for HCV Infection Among Young Adults in Rural New York Who Inject Prescription Opioid Analgesics. Am J Public Health 2014:e1-e7. PMID: 25211717.

Prevention measures must urgently be implemented, among them antiviral treatment which can uniquely stop transmission by curing the infection. The proposed restrictions will deny public health workers struggling to stop this new epidemic effective tools to achieve success.

12. **These extensive restrictions clearly represent solely an attempt to reduce NYS Medicaid expenditures and have no foundation in science, evidence, or clinical or public health considerations.** New York is facing a large and growing hepatitis C epidemic. New antiviral agents now place the opportunity to stem the tide of morbidity and mortality within our grasp. Restricting access to these medications will snuff out this opportunity just as it is appearing. Moreover, cost projections have been fictitiously inflated. Most Medicaid patients with hepatitis C do not know they have it, and despite last year's legislation most with undetected infections have not been tested and diagnosed. Many suffer additional barriers to healthcare access due to patient, provider, and systemic factors that will prevent their accessing treatment in the near term. Furthermore, hepatitis C treatment is a one-time expense, and it accrues savings many years into the future. The need to reduce expenditures should be addressed by negotiating pricing with the manufacturer of drugs, not by denying effective and medically indicated treatment to indigent New Yorkers. Denying Medicaid patients such care is an abdication of the State's responsibility to provide appropriate and effective medical care to indigent patients, and a decision to knowingly exacerbate health inequities in the state of New York.

13. **Policies, like this one, that deny access to new, highly effective hepatitis C treatment to certain populations and limit treatment only to the sickest patients may violate federal Medicaid laws that ban discrimination against specific patient populations.** Federal Medicaid law mandates that states that offer a prescription drug benefit must cover all drugs that are approved by the Federal Food and Drug Administration (FDA) and whose manufacturer participates in the Medicaid drug rebate program, as is the case with Sovaldi. "A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling … the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary."[16] Contrary to New York's proposed policy, there no such distinction with respect to meaningful therapeutic advantage in patient populations with particular degrees of liver damage or past or current substance use disorders based on the FDA's label.

    Further, a "Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition."[17] This proposed policy for instance, would

[16] 42 USC §1396r-8(d)(4)(C)
[17] 42 CFR § 440.230(c)

arbitrarily exclude individuals with substance use disorders from accessing medically necessary treatment on the basis of their illness.

14. **Decisions to deny care based on economic considerations should be made rationally and systematically.** Economic analyses have demonstrated that sofosbuvir-based regimens are highly cost-effective even at the wholesale acquisition cost (which Medicaid does not pay).[18] Restricting cost-effective care — especially safe, quick, easy, nontoxic treatment for a life-threatening communicable infection — is not a rational approach to reducing expenditures.

We appreciate the opportunity to provide input into this process. Unfortunately, the five-day period provided for public comment on this proposed policy is inadequate to get meaningful public comment, particularly since the criteria that the public is supposed to respond to are not actually posted online as far as we can determine. We only received a copy of the criteria because a health department employee provided us with one. In addition, the hearing on the 18th and the announcement of the five-day public comment period were not widely publicized and, we only knew of them because of a stakeholder who happened to attend the hearing. We recommend that the DURB provide a longer period for comment (e.g., two weeks or 30 days), post the proposed criteria in an easily accessible place online, and make a good faith effort to ensure the announcement of the hearing and the announcement of the proposed policy are widely circulated to all stakeholders, especially medical providers and patient advocacy groups.

We concur with hepatitis C advocates, providers, and consumers around the country who ask that any utilization management or prior authorization requirements that might be put in place by public or private payers be developed through a transparent process that:

a. *Is in accordance with clinical factors and not just cost considerations;*
b. *Involves consultation with recognized hepatitis C medical experts;*
c. *Includes meaningful input from the hepatitis C patient and advocate community; and*
d. *Includes an exceptions process for any individual to appeal a denial of access based on their specific individual circumstances.*[19]

We demand nothing less of the New York State Drug Utilization Review Board with regard to Medicaid patients living with hepatitis C. Any and all barriers to access, of which there are many without payers erecting new ones, will slow progress toward reducing the increasing toll hepatitis C on New Yorkers in morbidity and mortality.

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[18] Saab S, Gordon SC, Park H, Sulkowski M, Ahmed A, Younossi Z. Cost-effectiveness analysis of sofosbuvir plus peginterferon/ribavirin in the treatment of chronic hepatitis C virus genotype 1 infection. Aliment Pharmacol Ther 2014;40(6):657-75. PMID: 25065960.

[19] National Viral Hepatitis Roundtable, et al. National hepatitis C treatment access sign-on letter, dated July 24, 2014.

Please contact us if you have questions or require additional information. We look forward to your response to our concerns.

Sincerely,

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Organizations
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National Viral Hepatitis Roundtable (national)
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Individuals