



NEW YORK CITY DEPARTMENT OF  
HEALTH AND MENTAL HYGIENE  
Mary T. Bassett, MD, MPH  
*Commissioner*

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November 10, 2015

Ms. Jean Osterholt  
Bureau of Program Implementation and Administration  
Office of Health Insurance Programs  
NYS Department of Health  
Corning Tower, Mail Stop OCP-720  
Empire State Plaza  
Albany, NY 12237

Dear Ms. Osterholt:

I am writing to you as Commissioner of the New York City (NYC) Department of Health and Mental Hygiene (DOHMH), and on behalf of viral hepatitis health care providers and all New Yorkers infected with hepatitis C (HCV). Since the Medicaid Drug Utilization Review Board (DURB) approved the first drugs for HCV infection in 2014 and issued its prescriber guidelines restricting the use of these lifesaving medications to HCV infected patients only when they become very sick, we have observed firsthand the impact of these restrictive guidelines on the number of patients denied a cure for HCV infection. In addition, New York State (NYS) Medicaid has selected a drug as preferred on its formulary that has more limited uses than others, and most providers prefer to prescribe other drugs, as shown in data from our direct service programs.

Deaths due to HCV are continuing to rise in NYC, and the death rate (7.3 deaths per 100,000 in 2013<sup>1</sup>) is almost as high as for HIV. We are seeing increases in rates of hepatocellular carcinoma and health care costs due the consequences of HCV infection. Thus, now is the time to act aggressively against this disease both to reduce morbidity and mortality and prevent further transmission.

It has been shown that "identifying and treating everyone with hepatitis C in the United States has been estimated to net a \$1.4 trillion benefit to society over time."<sup>2</sup> Several recent cost analyses have demonstrated that the new regimens are cost-effective. However, by limiting treatment in the various ways set forth by the DURB, thousands of individuals with HCV infection face continued progression to advanced liver disease.

<sup>1</sup> DOHMH unpublished surveillance data. Hepatitis B and C Annual Report. Revised Oct. 22, 2015.

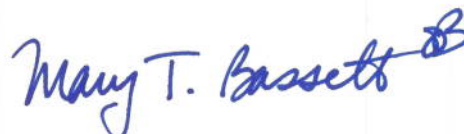
<sup>2</sup> Dana Goldman, Economist, University of Southern California. Presentation to Brookings Institute, "Are New Breakthrough Treatments Worth Their Price? Assessing the Social Costs and Benefits of Biomedical Innovation," during event The Cost and Value of Biomedical Innovation: Implications for Health Policy, October 1, 2014. <http://www.brookings.edu/events/2014/10/01-cost-and-value-biomedical-innovation-hep-c>

The most current American Association for the Study of Liver Disease (AASLD) treatment guideline update makes it very clear that the available evidence supports treatment for all HCV-infected persons, except those with limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions, and that the most immediate benefits of treatment will be realized by populations at highest risk for liver-related complications. In addition, the guidelines indicate that treatment delays may decrease the benefit of a cure, therefore the current DURB policy restricting treatment to those with Metavir fibrosis stage F3 or higher would decrease mortality from hepatocellular carcinoma (HCC) and cirrhosis.<sup>3</sup> Likewise, in a letter to State Medicaid programs, the Centers for Medicare and Medicaid Services (CMS) expresses concern that many states “are restricting access to DAA HCV drugs contrary to the statutory requirements in section 1927 of the Act by imposing conditions for coverage that may unreasonably restrict access to these drugs.”<sup>4</sup> CMS advises that use of such limitations, similar to those that exist in NYS, “should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infections.” Because we hear directly from clinicians and patients in our own linkage-to-care interventions that patients are being denied coverage of certain HCV treatment medications, we ask that you lift these restrictions.

I emphatically ask the Board to reconsider the current restrictions on prescriptions of HCV infection medications in the New York State Medicaid program and to follow current AASLD guidelines and newly published recommendations from the Centers for Medicare and Medicaid Services. In addition, since most NYS residents with Medicaid now are insured under a Medicaid Managed Care Organization (MCO) plan, I urge the Board and NYS Department of Health to further work with these MCOs to review their drug utilization guidance and ensure that they also follow AASLD guidelines and CMS recommendations. Because the NYS Medicaid MCOs are contractually obligated to provide a standard of care for determining medical necessity that is not more restrictive than that is used by the NYS Fee-For-Service plan, I further ask that your office monitor denials of HCV treatment prescriptions by contracted MCOs to ensure that their actions are not contradictory to their legal obligations to the NYS Medicaid program and their patients, as recommended in the letter from CMS.

Lastly, we welcome the formation of a panel of public health professionals, legal experts, clinicians, and patient advocates to work with the NYS DOH and the Office of Health Insurance Programs to review the DURB guidelines for medical necessity and legal soundness and eventually propose revisions.

Sincerely,

A handwritten signature in blue ink that reads "Mary T. Bassett" followed by a stylized monogram "MB".

Mary T. Bassett, MD, MPH  
Commissioner

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<sup>3</sup> AASLD. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. 2015.

<sup>4</sup> Department of Health and Human Services, Centers for Medicare & Medicaid Services. MEDICAID DRUG REBATE PROGRAM NOTICE Release No. 172 For State Technical Contacts. Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs. Nov. 5, 2015