



February 19, 2015

Roderick Bremby  
Commissioner  
Department of Social Services  
55 Farmington Avenue  
Hartford, CT 06106

**Re: Access to Hepatitis C Virus Cure**

Dear Commissioner Bremby:

The undersigned organizations, which serve or advocate for individuals living with the hepatitis C virus (HCV), or individuals with other chronic medical problems, are very concerned about the new clinical criteria for HCV treatment under Connecticut's Medicaid program, as announced in the department's bulletin issued to providers on November 24, 2014, entitled "New Hepatitis C Prior Authorization Criteria - Sovaldi™", both in and of themselves and as a dangerous precedent potentially restricting access to any kind of expensive drug. This bulletin, which went into effect on December 10, 2014, and which was somewhat modified in January 2015, bars treating providers from even **requesting** prior authorization for Sovaldi if narrow substantive criteria are not met.

The severe restrictions in Sovaldi (sofosbuvir) violate state and federal law and are unwise public health policy. They will significantly restrict access to this new curative drug, which will dramatically improve, and in some cases save, the lives of individuals living with HCV, and can also save tens of thousands of dollars (or more) in future treatment costs, as well as substantially slow transmission of this life-threatening disease. While we recognize the high cost of some of the newer HCV treatments, and in fact some of us are involved with the Fair Pricing Coalition which is working to address this problem right now, in the meantime, Connecticut may not respond to this cost issue through the denial of access to medically necessary medications.

**A. Rationing Solvadi for Medicaid Enrollees Harms Public Health, Exacerbates Health Disparities, and Generates Higher Costs for the Medicaid Program**

HCV is a transmissible disease which, if untreated, has a high likelihood of resulting in very expensive medical complications, including the development of cirrhosis, hepatocellular carcinoma, the need for liver transplantation and death. Below are some of the reasons why the newly-announced policies are unwise and bad medicine, and will ultimately cost the taxpayers more, as vulnerable individuals with this disease who could be cured of it are forced to go untreated.

**1. The new policy will inappropriately restrict access to medically necessary treatment through Sovaldi in at least the following ways:**

- Requiring a Metavir score of 3 or 4<sup>1</sup> will mean that only people with advanced liver disease can get this curative drug, blocking access to treatments which might **prevent** expensive, life-threatening conditions from developing and even provide cure and avoid transmission
- Authorizing only five specific kinds of specialists to provide a written consult as a prerequisite for approval of Sovaldi will severely restrict access because Medicaid enrollees have extreme difficulty securing timely consults with specialists<sup>2</sup>
- Forcing patients with Genotype 1 hepatitis C to use interferon instead of Sovaldi if they are "interferon-eligible" even though this is no longer the standard of care<sup>3</sup>
- Excluding individuals with any malignancy, whether or not the malignancy is related to HCV status, Sovaldi will have any effect on treatment for the malignancy or the cancer treatment will impair effectiveness of the Sovaldi treatment
- Barring pregnant women or women who might become pregnant from access to Sovaldi, based on purported FDA restrictions, when the FDA contraindication for pregnancy applies not to Sovaldi itself but to adjuncts (ribavirin or peginterferon alfa/ribavirin), which adjuncts are only (previously) recommended to be taken with Sovaldi and can be replaced with another drug for a particular patient
- Barring patients from access if they previously had a full or "incomplete" course of treatment, when some patients will need more than one course and the failure to complete a course may not have been the patient's fault (such as becoming otherwise ill or losing their Medicaid coverage mid-treatment)
- Limiting access to the medication even after it has been approved by DSS, by prohibiting the patient from getting more than a 14 day supply at a time and categorically prohibiting early refills (before 85% of a 14 day supply used up) even through special request, causing patients to be non-compliant with their approved regimens because of inability to timely obtain a refill.

**2. This new policy undermines the public health imperative to identify, treat, and cure people living with hepatitis C, and will result in preventable infections.**

Increased transmission of HCV among young adults has been reported in at least 30 states.<sup>4</sup> With thousands of Connecticut residents living with HCV and HCV the primary cause of

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<sup>1</sup> While we appreciate the Department expanding PA eligibility from only F4 to F3 and F4, F3 is still a very high standard, requiring organ damage to receive treatment.

<sup>2</sup> We understand that HIV specialists are an additional kind of specialist allowed to provide prescriptions for Sovaldi, in addition to the four kinds specified in the bulletin.

<sup>3</sup> There appears to be an error in the bulletin, even as intended, in that the FDA label for Sovaldi, which this criteria presumably is based on, refers to individuals with Genotype 1 being appropriate for just Sovaldi and ribavirin, instead of these two in combination with interferon, as would historically be prescribed for Genotype 1 if the person is "interferon ineligible." Nothing in the label even suggests that in order to be prescribed Sovaldi the person must be "interferon ineligible." And there appears to be an erroneous word "not" in this criteria in the bulletin. In addition, as discussed below, since the Sovaldi label was approved by the FDA, interferon is no longer the standard of care even for Genotype 1.

hepatocellular carcinoma, the fastest growing cancer in the nation, now is the time to act aggressively against HCV—**not** to slow down the fight. This new policy is far too restrictive given the health crisis caused by HCV and the tremendous opportunity HCV treatments provide to improve health and save lives, by curing the majority of people living with HCV and reducing transmission. Patients who develop advanced cirrhosis and other complications due to lack of early treatment will require ongoing medical treatment, even after they are cured, whereas early treatment **prevents** liver damage and liver cancer and improves quality of life, while stemming the tide of onward transmission of the virus. Without treatment, women of childbearing age who do not meet the strict F3/F4 criteria in the new policy will be unable to avoid perinatal transmission to their future children. Limiting treatment with Sovaldi in the various ways set forth in the bulletin ensures that Connecticut is committing unnecessarily to treating thousands of individuals with hepatitis C for many years to come.

### **3. The new policy ignores the economic benefits of providing Sovaldi early on.**

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>5</sup> Economic analyses have demonstrated that sofosbuvir-based regimens specifically are highly cost-effective even at the wholesale acquisition cost (which Medicaid does not pay).<sup>6</sup> In fact, the cost of a treatment regimen with interferon and ribavirin and with one of the older direct acting agents (which were toxic and caused a lot of complications) was comparable to current treatment costs with Sovaldi. Depending on the duration of treatment, dual therapy with pegylated interferon alfa and ribavirin can vary between \$18,000 and \$36,000. Adding telaprevir or boceprevir (Victrelis) (these were the older generation of direct acting agents before Sovaldi) to the other two drugs more than doubles the cost of therapy to a range of \$48,000 to \$85,000. This does not factor in the much lower cure rate (less than 60% even for those able to tolerate interferon's severe side effects, vs. the Sovaldi cure rate of 95%), such that there are inevitably additional costs for treating the half of individuals unable to be cured with the expensive interferon regime. Hepatitis C treatment with Sovaldi is in the vast majority of cases a one-time expense, and it accrues savings many years into the future.

The need to reduce expenditures further should be addressed by negotiating pricing with the manufacturer of drugs, not by denying effective and medically indicated treatment to indigent low-income individuals. Restricting cost-effective care — especially safe, quick, easy, nontoxic treatment for a life-threatening communicable infection — is not a rational approach to reducing expenditures.

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<sup>4</sup>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.

<sup>5</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. Webcast accessed October 3, 2014 at <http://www.brookings.edu/events/2014/10/01-cost-and-value-biomedical-innovation-hep-c>

<sup>6</sup>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.

#### **4. The new policy will result in inappropriate rationing of care for Medicaid patients.**

The Department's restrictive policies regarding Sovaldi apply only to Medicaid enrollees. But Medicaid enrollees already suffer barriers to healthcare access due to patient, provider, and systemic factors that restrict their ability to access treatment relative to the general population, particularly in terms of accessing specialists. These new policies will severely exacerbate these barriers. Whatever justifications might be set forth for rationing of life-sustaining health care generally, rationing such health care for vulnerable low-income Medicaid patients, who already have serious health care access problems, is particularly inappropriate.

#### **5. The policy undermines our ability to address health inequities and disparities, particularly among communities of color, which have disproportionately 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.<sup>7</sup> Latinos experience some of the highest rates of hepatitis C infection in the U.S., with an estimated overall prevalence rate of 2.6%, and incidence appears to be rising.<sup>8</sup> Since people of color are disproportionately represented within the Medicaid program, this policy will stifle efforts to achieve health equity and could increase the disparate outcomes for HCV in communities of color.

#### **6. The New Policy Undermines the HCV Public Health Legislation Enacted in 2014.**

The department's Sovaldi policy undermines the important public health legislation passed by the General Assembly last year requiring all primary care physicians to offer hepatitis C testing to all Connecticut residents capable of consent (except in an emergency situation). Public Act No. 14-203. The testing mandated in this new law underscores the urgent need to diagnose infected individuals and get them into early treatment. These provisions, which just went into effect on October 1, 2014, mean that health care providers are now required to test thousands of asymptomatic patients born between 1945 and 1965. But, under the bulletin, those same providers would then have to inform those testing positive that Connecticut will not allow them to be **treated** for this serious and potentially life-threatening medical condition because they are on the Medicaid program unless they already have suffered organ damage from the disease.

Indeed, it would be cruel not to encourage people to be tested for a life-threatening and curable disease, but, if they test positive for it, they should be entitled to treatment. It would be far crueler to deny them the available treatment. The legislative history makes clear that this was clearly not the legislature's intent. *See* Public Health Committee, Joint Favorable Report on SB 257, *available at* <http://www.cga.ct.gov/2014/JFR/S/2014SB-00257-R00PH-JFR.htm> (summarizing testimony). *See also* Statement of Sen. Olsten from Joint Favorable Report ("I am in favor of SB 257...I am emphasizing that this test will ultimately save the Connecticut's

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<sup>7</sup> <http://blog.aids.gov/2014/02/fighting-hepatitis-c-among-african-americans.html>

<sup>8</sup> <http://blog.aids.gov/2013/05/latino-community-rallies-to-generate-awareness-of-viral-hepatitis.html>, accessed October 3, 2014

healthcare system many millions of dollars by providing *early diagnosis and treatment.*)(emphasis added).

**7. The supply limitations in the bulletin will needlessly restrict access even where the need for treatment is confirmed, threatening ineffectiveness of the Sovaldi regime.**

The bulletin provides extreme limitations on access to Sovaldi even after it has been **approved** by DSS, by prohibiting the patient from getting more than a 14 day supply at a time (versus 30 days for all other drugs with a course of 30 days or more) and categorically prohibiting early refills (before 85% of a 14 day supply is used up, allowing a fixed two-day window), even through special request. These two limitations, uniquely applicable to Sovaldi, will cause treatments to be missed within already approved regimens, because it is far more difficult for Medicaid enrollees than others to get to the pharmacy to obtain a supply of a medication due to transportation and other barriers. Medicaid rules allow a 30 day supply in part because of this reality. Requiring a return to the pharmacy every 14 days increases the chances that treatments will be missed, threatening the efficacy of the entire regimen and causing state expenditures to have been wasted when they could have effectuated a total cure.

Similarly, not allowing a Medicaid enrollee even to **request** an exception to the 85% early refill bar, as allowed for all other medications, increases the chances that critical treatments will be missed if the individual is unable to make it to the pharmacy, due to illness, a family obligation or otherwise, during the very short (two day) window for picking up refills allowed under the highly restrictive new policy. Both of these policies undermine access to treatments already found by the department to be medically necessary for the individual.

**B. The Policies Set Forth in the Bulletin Are Illegal.**

Under federal Medicaid law, notwithstanding the cost, states must cover Sovaldi under their Medicaid programs and do not have the discretion to deny or delay anyone Solvaldi where this drug is prescribed by a treating provider for an individual with Hepatitis C and there is a specific medical need for it, as defined in our state’s statutory definition of medical necessity, Conn. Gen. Stat. § 17b-259b(a). This state law also declares that “[c]linical policies, medical policies, clinical criteria or any other generally accepted clinical practice guidelines used to assist in evaluating the medical necessity of a requested health service shall be used solely as guidelines and *shall not be the basis for a final determination of medical necessity.*” C.G.S. § 17b-259b(b)(emphasis added). DSS may use more restrictive criteria such as those specified in its new bulletin, but only if DSS makes clear to all providers that treatment requests for individuals who do **not** meet those criteria will be individually assessed based on the statutory definition of medical necessity, and so long as no one is **denied** any requests for Sovaldi under those more-restrictive criteria.

DSS’s bulletin violates these requirements, as well as federal coverage, timely access and due process requirements. The bulletin states unequivocally that the criteria specified in the bulletin must be met and reinforces that point by requiring any provider requesting prior authorization to sign the PA form and “certify that use of Sovaldi™ for this patient is consistent with the above criteria/guidelines,” blocking all providers from even **requesting** prior authorization if the guidelines are not met. All of the criteria in the new Sovaldi bulletin are

therefore illegal unless changed to being **recommended** criteria for quick review and approval. This, and the many other violations of state and federal law contained in the bulletin, are discussed in detail in the February 3, 2014 letter to you from legal advocates (three Connecticut legal services programs and the Global Health Justice Partnership of the Yale Law School and the Yale School of Public Health).

### **C. Conclusion**

We respectfully request that your agency immediately remove these harmful and illegal barriers to access to appropriate treatment for Medicaid patients living with hepatitis C. Our immediate suggestion for doing so is to issue a corrective bulletin (1) stating that the November bulletin and January PA Form are only “guidelines” and that all requests for prior authorization for Sovaldi will hereinafter be individually assessed for medical need pursuant to C.G.S. § 17b-259b (and removing the requirement of certifying on the PA request form that the narrow criteria are met), and (2) changing the 14 day supply to a 30 day supply (up to the end of the course of treatment) and allowing requests for PA for early refills, while the Department begins a process to engage the advocacy, patient and provider communities in the collaborative development of replacement **recommended** guidelines.

We welcome the opportunity to engage with your agency in developing a replacement policy of recommended guidelines, through a cooperative process involving all stakeholders. We also welcome the opportunity to join forces with your agency and other state Medicaid agencies to address the high cost of the various new HCV drugs directly with manufacturers. We share your goal of reducing the per treatment costs of these drugs and believe that, through education of providers, we can put downward price pressure on the manufacturers.

Please contact us if you have questions or require additional information. We look forward to your response to our concerns and to working with you in the manner outlined above.

Thank you for your attention to this matter of critical importance to the individuals we serve.

Respectfully yours,



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cc: Honorable Dannel P. Malloy  
OPM Secretary Benjamin Barnes  
Kate McEvoy, Medicaid Director  
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