



August 25, 2014

Toby Douglas
California Department of Health Care Services
SENT VIA EMAIL: Toby.Douglas@dhcs.ca.gov

RE: “California Department of Health Care Services Utilization and Treatment Policy for Simeprevir and Sofosbuvir in the Management of Hepatitis C”

Dear Mr. Douglas,

Project Inform, the National Viral Hepatitis Roundtable, and the undersigned organizations, medical providers, and lay health and social service providers, who represent constituents at risk for and living with the hepatitis C virus (HCV), are gravely concerned about the final “California Department of Health Care Services Utilization and Treatment Policy for Simeprevir and Sofosbuvir in the Management of Hepatitis C”, dated June, 30, 2014. Numerous organizations and experts provided feedback regarding draft versions of this policy and received no response from DHCS to our concerns. In developing the policy, DHCS disregarded expert and community input. Many of these stakeholders’ concerns are outlined below.

- 1. This policy undermines the public health imperative to identify, treat, and cure people living with hepatitis C and will result in preventable infections.** The policy is too restrictive given the health crisis caused by HCV in California and the tremendous opportunity simeprevir and sofosbuvir provide to improve health, save lives, considerably reduce health care costs, and eradicate HCV in the vulnerable Medi-Cal population by curing the majority of people living with HCV. Early treatment prevents liver damage and liver cancer, improves quality of life, and stems the tide of onward transmission of the virus. With an estimated 750,000 Californians living with HCV¹ 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. The policy also undermines our ability to address health inequities and disparities, particularly among communities of color, which have disproportionately higher HCV prevalence.

¹ California Department of Public Health. *Chronic Hepatitis B and Hepatitis C Infections in California: Cases Newly Reported through 2011*. 2013, November 13. Available at <http://www.cdph.ca.gov/programs/Documents/ChronicHepBandHepCinCalifornia,2011.final.pdf> [accessed 20 May 2014]

2. **The 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 Medi-Cal 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. In addition, 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. Provider and patient discretion should be the standard on which to base treatment decisions.
3. **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, putting potential future children at risk of contracting HCV.
4. **The policy facilitates rapid progression of HCV in HIV/HCV co-infected individuals and onward sexual transmission among co-infected individuals who have condomless sex.** With 25% of people living with HIV co-infected with HCV, the rapid progression of HCV in co-infected individuals, and the well-documented sexual transmission of HCV among HIV-positive individuals, failing to treat HCV in co-infected individuals poses a serious threat to their health and the health of their sexual partners.
5. **The policy's prohibition on treating people who actively use drugs is based on non-medical, discriminatory thinking.** Requiring urine toxicology for all patients considered for treatment with simeprevir or sofosbuvir is unnecessary, offensive to patients, and a waste of time and money. Treating people who inject drugs (PWID) is critical to curbing HCV in California, 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.² Hepatitis C treatment can be successful in patients who do not abstain from drugs. Requiring referral to substance use disorder treatment and active participation in treatment for the disorder or six months abstinence from drugs prior to the initiation of HCV treatment is not an evidence-based standard and flies in the face of

² 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].

science and common sense. These requirements are not mentioned in American Association for the Study of Liver Diseases, European Association for the Study of the Liver, or World Health Organization guidelines. The VA guidelines state that PWID should be referred to an addiction medicine specialist, but do not indicate the length of time of abstinence necessary to initiate treatment. Indeed, the VA guidelines, like the NIH Consensus Statement, note that the decision to treat active substance users should be made on a case-by-case basis.

6. **The criteria for reauthorization/continuation of therapy are onerous for patients and providers.** We encourage DHCS to allow for a one-time replacement of lost medications to ensure that patients do not have to discontinue effective treatment and lose the opportunity to be cured of HCV in the event of a one-time loss of medication. In addition, we encourage DHCS to have supportive policies regarding missed medical and lab appointments in cases where the physician feels the patient is adhering to and responding well to treatment and the patient has worked with the physician to reschedule missed appointments or created a plan for closer adherence support. Discontinuing treatment due to a missed lab wastes the resources already invested in treatment for no good medical reason.
7. **The 14-day supply limit is burdensome for physicians and patients.** To ease the burden, the refill process should follow the timeline of laboratory monitoring, meaning refills should be made at weeks 4, 8, and 12, as appropriate to the treatment regimen.

While the Affordable Care Act recently helped millions of Americans gain access to health coverage, many for the first time, its mandate that no individual be denied insurance based on a pre-existing condition is meaningless if that coverage restricts access to the treatment needed to cure that condition. **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 violate laws that now ban discrimination against specific patient populations.**

Hepatitis C advocates around the country are putting out a call to all payers that:

Any utilization management or prior authorization requirements that might be put in place by public or private payers must not be tolerated except when it can be demonstrated that such restrictions are developed through a transparent process that:

- a. Is in accordance with clinical factors and not just cost effectiveness;*
- 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.³*

³ National Viral Hepatitis Roundtable, et al. National hepatitis C treatment access sign-on letter, dated July 24, 2014.

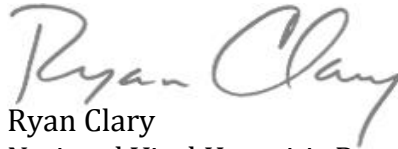
We demand nothing less of DHCS with regard to Medi-Cal patients living with hepatitis C.

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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Signatures (as of 8/25/14):

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AIDS Project Los Angeles
Asian Pacific Liver Center at St. Vincent Medical Center (*Los Angeles*)
Black AIDS Institute (*Los Angeles*)
California Hepatitis Alliance (*San Francisco*)
Christie's Place (*San Diego*)
C.O.R.E. Medical Clinic (*Sacramento*)
Drug Policy Alliance (*San Francisco*)
Glide Foundation (*San Francisco*)
Harm Reduction Coalition (*Oakland*)
Harm Reduction Services (*Sacramento*)
Hep B Free, Los Angeles
Hepatitis C Support Project / HCV Advocate (*Sacramento*)
Hepatitis C Task Force for Los Angeles County (*Los Angeles*)
hepatitisCmeditations project (*San Francisco*)
LA Community Health Project (*Los Angeles*)
Los Angeles LGBT Center
Mendocino County AIDS/Viral Hepatitis Network (*Ukiah*)
San Francisco AIDS Foundation
San Francisco Hepatitis C Task Force
San Luis Obispo County AIDS Support Network (*San Luis Obispo*)
SF Hep B Free (*San Francisco*)
SLO Hep C Project (*San Luis Obispo*)
S.T.O.P. Hepatitis Task Force (*Sacramento*)

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