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SENT VIA ELECTRONIC MAIL: sue.birch@state.co.us

Susan Birch, Executive Director
Colorado Department of Health Care & Policy Financing
1570 Grant St.
Denver, CO 80203

Dear Director Birch:

We write on behalf of Colorado Medicaid beneficiaries with Hepatitis C who, as a result of Health Care Policy and Financing (“HCPF”) prescription drug policies, are unable to access medically necessary treatment.

The HCPF’s Prior Authorization Criteria for Hepatitis C Virus (“HCV”) treatments unreasonably restrict access to curative treatment, in violation of federal Medicaid law. These unreasonable restrictions on access to HCV treatment include: (1) requiring that beneficiaries have a Metavir Fibrosis Score¹ of F3 or F4 before they can access curative medical treatments; (2) requiring that beneficiaries receive a prescription for the treatment from a liver specialist; and (3) requiring that beneficiaries abstain from drugs and alcohol for six months prior to treatment. We urge HCPF to take immediate steps to eliminate these unreasonable (and illegal) restrictions.

I. BACKGROUND

Hepatitis C is a blood-borne infectious disease which, when left untreated, can cause liver damage, liver failure, liver cancer, and death. Even in the initial stages of the disease, individuals with HCV can experience serious symptoms, including fatigue, joint pain, depression, sore muscles, arthritis, mental changes, heart attacks, diabetes, nerve damage, jaundice, and various cancers. The Center for Disease Control and Prevention estimates that nearly 20,000 deaths were associated with HCV in 2014, making it the most deadly infectious disease in the United States.² Approximately 70,000 Coloradans suffer HCV infections.³ HCPF recently estimated that at least 9,000 Colorado Medicaid beneficiaries have HCV.

¹ The severity of liver damage due to HCV is measured by a scoring system. Liver disease is graded according to the level of liver scarring and assigned a Metavir Fibrosis Score (“fibrosis score”). A fibrosis score of F0 or F1 indicates no or minimal scarring; F2 is an intermediate stage of fibrosis; a score of F3 indicates severe fibrosis; F4 indicates cirrhosis. HCV is a chronic inflammatory condition. Lack of liver damage does not suggest that the individual does not have the disease (which can be confirmed by blood tests) or that the individual is not suffering other, extrahepatic symptoms of the disease. All the F score measures is liver damage, which is only one of multiple effects of the disease. *See generally*, Gill, Ghazinian, Manch, Gish, *Hepatitis C virus as a systemic disease: reaching beyond the liver*, HEPATOLOGY INTERNATIONAL, Vol. 9, No. 4 (2015).

² Center for Disease Control and Prevention, *Hepatitis C Kills More Americans than Any Other Infectious Disease*, <http://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html>.

³ *See* David Olinger, *Ninety Percent of Colorado Residents with Hepatitis C Going Untreated*, DENVER POST (May 18, 2016 8:22 AM), <http://www.denverpost.com/2016/05/18/ninetypercentofcoloradoreidentswithhepatitiscgoinguntreated/>.

Until recently, the standard therapy for HCV consisted of a three-drug treatment regimen consisting of boceprevir, interferon, and ribavirin. At best, this course of treatment cured HCV in only 70% of patients, and it was often accompanied by significant adverse side effects such as bone pain, muscle pain, joint pain, anemia, insomnia, memory loss, anxiety, depression, nausea, liver failure, and death. In addition, this treatment regimen was lengthy, often requiring almost one year to complete. Because of the side effects and length of treatment, this HCV drug therapy was generally provided only to individuals with severe liver damage, as measured by a fibrosis score of F3 or F4.

Fortunately, in the past five years HCV treatments have advanced significantly. Beginning in 2011, the Food and Drug Administration (“FDA”) began approving new direct-acting antiviral (“DAA”) medications which, unlike the earlier HCV drugs, are capable of curing the disease via a short course of once-daily pills over the course of 8-12 weeks. These DAAs carry minimal side effects and are markedly more effective than the previous drugs, curing over 90% of patients. The FDA has designated DAAs as “breakthrough therapies,” a classification reserved for drugs that provide substantial improvement over existing therapies in treating serious or life-threatening conditions.

According to evidence-based, expert-developed guidelines published by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (“AASLD/IDSA Guidelines”), DAAs are now “recommended for *all* patients with chronic HCV infection,” with the narrow exception of patients “with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy.”⁴ These guidelines specifically urge early treatment of HCV, as in patients with fibrosis scores of F0, F1, and F2. In other words, the guidelines explicitly refute the idea that DAA drugs should be prescribed only to patients with severe liver damage, instead recommending that virtually all HCV patients receive DAA treatments regardless of their fibrosis score. The AASLD/IDSA Guidelines represent the professionally-accepted clinical standard of care for treatment of HCV.

As a result of this consensus, the Centers for Medicare and Medicaid Services (“CMS”)—the federal agency responsible for administering Medicaid—issued Guidance on November 5, 2015, advising state Medicaid agencies that the new DAAs must be included in coverage of outpatient prescription drugs.⁵ CMS was clear as to the animating purpose of the Guidance: “CMS is concerned that some 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 drug.”⁶ Further, CMS warned states that any restrictions on access to DAAs “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.” Specifically, CMS identified three conditions which unreasonably restrict access to DAAs: (1) limiting treatment to beneficiaries with fibrosis scores of F3 and F4; (2) conditioning access to treatment on a period of abstinence from drug or alcohol abuse; and (3) requiring that DAAs be prescribed by, or in consultation with, specialists such as infectious disease specialists, gastroenterologists, or hepatologists. More than six months after receiving this Notice from CMS, Colorado Medicaid continues to enforce each of these three unreasonable restrictions on access to DAA medications.

II. HCPF’S PRIOR AUTHORIZATION CRITERIA FOR HCV TREATMENTS

Contrary to the AASLD/IDSA Guidelines and the CMS Notice, HCPF’s Prior Authorization Criteria for HCV treatments strictly—and illegally—restrict beneficiaries’ access to medically necessary care, namely DAA drugs. There are three restrictions that HCPF must rescind.

First, HCPF prevents Colorado Medicaid beneficiaries from obtaining curative HCV treatment

⁴ American Association for the Study of Liver Diseases & Infectious Diseases Society of America, *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C*, <http://www.hcvguidelines.org/> (emphasis added).

⁵ Centers for Medicare and Medicaid Services, *Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Release No. 172)*, Nov. 5, 2015.

⁶ *Id.*

unless they have severe liver damage, as measured by a fibrosis score of F3 or F4. This restriction flatly contradicts the AASLD/IDSA Guidelines, which advise that virtually all chronic HCV patients, regardless of their fibrosis score, receive DAA treatment upon diagnosis. The HCPF policy has the bizarre effect of requiring eligible beneficiaries—who could be treated immediately with few to no adverse side effects—to wait until their disease causes irreparable liver damage before they can access curative treatment. While DAAs are extremely effective in curing HCV, the drugs cannot reverse liver scarring; thus, requiring beneficiaries to wait until their disease progresses results in serious, preventable, and permanent organ damage. Moreover, because HCV is communicable, delaying treatment not only harms the individual beneficiary’s health, but also endangers the health of their family and the general public. By requiring HCV patients to go without treatment, perhaps for years, Colorado Medicaid increases the risk that the disease will be transmitted to others.

Second, curative HCV treatment is denied under Colorado’s criteria if the beneficiary’s prescription is not issued by, or in conjunction with, an infectious disease specialist, gastroenterologist, or hepatologist. Because access to specialist care is limited, particularly in rural areas of Colorado, this requirement places an onerous burden on Medicaid beneficiaries. The AASLD/IDSA Guidelines label lack of access to specialists “a primary barrier to hepatitis C care.” Because DAAs require only a short course of treatment and involve few serious adverse side effects, the AASLD/IDSA Guidelines recommend relying on and expanding the role of primary care physicians in managing and treating HCV.

Third, HCPF’s Prior Authorization Criteria deny curative treatment to beneficiaries who have used alcohol, marijuana, or other drugs in any amount at any time during the six months prior to treatment. There is simply no medical justification for this policy. Drug and alcohol use has not been proven to decrease efficacy of DAA treatment for HCV. Further, the AASLD/IDSA Guidelines note that injection drug users have demonstrated adherence to DAA treatment regimens at rates comparable to individuals who do not use injection drugs, as well as low rates of reinfection. In fact, because HCV can be transmitted through injection drug use, the AASLD/IDSA Guidelines recommend treating individuals who use injection drugs to curb the spread of the disease. Not only is this restrictive policy unsupported by medical evidence, it also creates perverse public health outcomes. As the AASLD/IDSA Guidelines conclude, “there are no data to support the utility of pretreatment screening for illicit drug or alcohol use in identifying a population more likely to successfully complete HCV therapy. These requirements should be abandoned, because they create barriers to treatment, add unnecessary cost and effort, and potentially exclude populations that are likely to obtain substantial benefit from therapy.”

These three restrictive policies deny medically necessary HCV treatment to Medicaid beneficiaries, and thereby violate federal Medicaid law. Similar restrictions have been successfully challenged in Washington, where a federal district court recently enjoined the state Medicaid agency from enforcing its HCV treatment policy and ordered that HCV prescription drugs be provided to beneficiaries without regards to fibrosis score.⁷ Similar litigation is pending in Indiana. Medicaid agencies in a number of states, including Delaware, Florida, Massachusetts, and New York, have recently responded to legal and policy advocacy by rescinding their overly restrictive policies regarding access to HCV medications. Colorado must do the same.

Lifting the restrictions is the right thing to do, not only because it is legally required, but because this efficacious and curative treatment is indisputably medically necessary for the affected Colorado Medicaid enrollees. Moreover, providing full access to HCV treatments is the fiscally sound decision for Colorado Medicaid, because early treatment precludes expenses that would otherwise be incurred as a result of the disease’s progression.⁸ And, finally, lifting the restrictions avoids the need to resort to the courts. It would be better for all if HCPF did the right thing on its own initiative, and rescinded these unjustifiable

⁷ See Order Granting Plaintiffs’ Motion for Preliminary Injunction, *B.E. v. Teeter*, No. C16-227-JCC (W.D. Wash. May 27, 2016), 2016 U.S. Dist. Lexis 70021 (W.D. Wash. May 27, 2016).

⁸ See, e.g., Alexis P. Chidi et al., *Economic and Public Health Impacts of Policies Restricting Access to Hepatitis C Treatment for Medicaid Patients*, 19 *VALUE IN HEALTH* 326 (2016) (concluding that expanding access to DAAs resulted in long-term cost savings ranging from \$5,369 to \$11,960 per patient).

restrictions that impede access to medically necessary treatment, rather than have a federal court order it to do so.

Sincerely,



Mark Silverstein
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