

For Immediate Release

Contact:

Kevin Costello, Director of Litigation
Center for Health Law and Policy Innovation
kcostello@law.harvard.edu
617.390.2578

Anna Haac
Tycko & Zavareei LLP
ahaac@tzlegal.com
202.973.0900 x 105

Laura J. Waterland, Esq., Supervising Attorney
Community Legal Aid Society, Inc.
lwaterland@declasi.org
302-575-0660 ext. 231

IN FACE OF CLASS ACTION LAWSUIT, DELAWARE MEDICAID REMOVES UNLAWFUL RESTRICTIONS TO THE CURE FOR THE HEPATITIS C VIRUS

(Wilmington, DE – June 07, 2016) After weeks of negotiation arising from a formal threat of litigation, officials at the Delaware Department of Health and Human Services and its Division of Medicaid and Medical Assistance (DMMA) have changed their policy on rationing coverage of life-saving drugs to cure Hepatitis C virus (HCV). On March 28, 2016, attorneys from Community Legal Aid Society, Inc. of Delaware, in conjunction with Tycko & Zavareei LLP, and the Center for Health Law and Policy Innovation at Harvard Law School sent a formal demand letter to Delaware officials on behalf of their client, Valerie Green, a Delaware Medicaid recipient. The demand letter notified DMMA officials that unless it immediately agreed to remove categorical coverage exclusions of HCV cures from its Medicaid policy, Delaware would face a federal class action lawsuit. On Friday, June 3, 2016, DMMA officials issued a policy revoking these categorical exclusions, effective immediately.

The state's concession represents a substantial win for Delaware's Medicaid population. "DMMA's new approach is a sea-change in policy that will directly improve the lives of many of our clients—some of Delaware's most vulnerable citizens. To the extent that DMMA is now focusing on the individual health circumstances of each person whose doctor has prescribed these medications, Delaware's approach will now be consistent with the law and with many other states around the country," said Laura Waterland of CLASI. Valerie Green adds "the weight of the world has been lifted off my shoulders. Now I'm excited about my future. I know that everyone else who's in my position feels the same way. It's like getting a new lease on life."

HCV is a communicable disease that causes chronic inflammation throughout the body and can lead to serious liver damage and infections, liver cancer, and death. At least 20,000 people in

the United States die each year due to liver disease caused by HCV, making it the most deadly communicable disease in the United States. Even before the advanced state of the disease, individuals with HCV can suffer from diabetes, lymphoma, fatigue, joint pain, depression, myalgias, arthritis and jaundice.

In 2011, the United States Food and Drug Administration (FDA) began approving Direct Acting Antiviral (DAAs) drugs to treat HCV, and in 2014 the FDA approved ledipasvir-sofosbuvir to effectively cure the disease. Treatment guidelines approved by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America confirm that DAAs should be available for “all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy.” See <http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy> (last visited 6/6/16). For its part, the federal Centers for Medicare and Medicaid Services issued guidance in November 2015 warning states that exclusions and limitations on public insurance coverage of DAAs may violate federal law.

Prior to last week’s change, DMMA restricted Medicaid coverage for the HCV cure only to those whose disease had progressed to the point of significant liver damage or cirrhosis. This was flatly inconsistent with the clinical standard of care noted above.

Anna Haac of the law firm Tycko & Zavareei LLP says, “it is unimaginable that an insurance provider would tell someone with cancer ‘We need to wait until you get really sick before we treat you.’ But that’s what patients in Delaware with HCV were being told, and what patients in other states are still being told. It’s unconscionable. Lawyers and advocates have been waiting for Delaware to live up to its promise to Medicaid patients. It is unfortunate that it took the threat of a federal class action suit, but ultimately I’m glad to see that Medicaid enrollees will no longer be barred from needed medicines.”

By making this policy change voluntarily, Delaware joins a rapidly growing list of states that have come into compliance with federal medical necessity requirements for Medicaid. On May 17, 2016, Pennsylvania’s Pharmacy & Therapeutics Committee voted to recommend the removal of all disease severity restrictions for Hepatitis C treatment from the state’s Medicaid policy. Florida Medicaid took a similar step last week. And on May 27, 2016, a federal judge ordered the state of Washington to strike its Medicaid policy imposing similar coverage exclusions. “Delaware has taken an important first step here,” said Kevin Costello, Director of Litigation at the Center for Health Law and Policy Innovation at Harvard Law School. “But enforcement remains key to make sure that the policy is made meaningful. This change is not only the right thing to do from a public health and legal point of view, but it also been proven that this policy will be cost-effective for the state in the long run. And it goes without saying that the real potential of this cure is the eradication of HCV altogether, a goal that is furthered by early treatment of Medicaid beneficiaries that makes, in their case, further transmission of the virus impossible.”

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