



THE AIDS INSTITUTE

October 19, 2017

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

Re: Medicaid Restrictions on Hepatitis C Curative Medications

Dear Administrator Verma:

The AIDS Institute, a national, non-partisan, non-profit organization dedicated to supporting and protecting health care access for people living with HIV/AIDS, viral hepatitis, and other chronic and serious health conditions, looks forward to working with you and the Centers for Medicare and Medicaid Services (CMS) to increase access to hepatitis C (HCV) curative treatments within state Medicaid programs. Given the numerous legal and medical reasons for removing access restrictions on these curative medications, we believe this is an effort you should support in the interest of public health.

Background on HCV

HCV is a deadly infectious disease. Left untreated, it can cause liver damage and cirrhosis and is a leading cause of liver cancer. Each year, nearly 20,000 people in the United States die from HCV and its complications, and HCV-associated deaths now exceed the number of deaths from 60 other nationally notifiable diseases combined, including HIV.¹ Of the estimated 3.5 million people living with HCV in the United States, more than one third are expected to die from HCV-related complications that could be averted by a simple treatment administered over a matter of weeks.^{2 3} Since more than half of all people living with HCV are unaware of their infection,

¹ Centers for Disease Control and Prevention, *Viral Hepatitis - Hepatitis C Information*, Updated May 2016, <http://www.cdc.gov/hepatitis/hcv/statisticshcv.htm>

² Public Health Reports – Surgeon General’s Perspective, *Testing Baby Boomers for Hepatitis C Virus Infection*, Published 2014, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3982548/>

³ Centers for Disease Control and Prevention, *Viral Hepatitis Surveillance United States 2015*, Published June 2017, <https://www.cdc.gov/hepatitis/statistics/2015surveillance/pdfs/2015HepSurveillanceRpt.pdf>

the actual number of people living with the disease is likely much higher. Fueled largely by the current opioid epidemic, the number of new HCV cases has tripled since 2010. We must take action now to address HCV.

State Medicaid Restrictions

Fortunately, HCV can be cured, thanks to the investment by life science companies into medical research and development. Following years of treatments that were difficult to administer and tolerate and had low cure rates, the new drugs are easy to take, have little to no side-effects, and almost always lead to a cure. However, across the country, hundreds of thousands of people living with HCV are unable to access this cure because their state Medicaid programs refuse to pay for their treatment. Claiming high costs, many states restrict access to only those with severe liver damage, who abstain from substance use, or limit prescribers to certain specialists. **This practice of instituting unnecessary hurdles forces people to become sicker and violates current Medicaid law. As Medicaid is largely a federally-funded program, we ask CMS to direct the states to end this practice.**

There have been differing estimates on the number of Medicaid enrollees living with HCV. A September 2015 Milliman study concluded that of the 2.67 million people living with HCV, approximately 457,000 (or 17 percent) are on Medicaid.⁴ The Senate Wyden-Grassley Report released in December 2015 indicates that there are approximately 698,000 enrollees in Medicaid with HCV.⁵ Given the recent increase in new cases of HCV, the actual number likely surpasses reported totals.

Currently, 31 states plus the District of Columbia are restricting access to the HCV cure to patients with a Fibrosis Score of F2 or higher, and 13 of those states require a score of F3 or above.⁶ A score of F2 is associated with moderate liver scarring, while F3 indicates severe fibrosis. Additionally, 38 states require patients to attest to or be tested for sobriety from drugs and/or alcohol, or to be assessed or enrolled in a substance use treatment program, before HCV treatment can begin. As of October 2016, 36 states have known prescriber requirements, meaning patients can only receive their prescription from or in consultation with a certain type of specialist, which can delay the start of treatment and is simply unobtainable for patients in some areas of the country.

⁴ Milliman, *An Actuarial Approach to the Incremental Cost of Hepatitis C in the Absence of Curative Treatments*, Published September 2015, http://www.milliman.com/uploadedFiles/insight/2015/20150915_Incremental-Cost-of-HCV-White-Paper.pdf

⁵ United States Senate Committee on Finance, *The Price of Sovaldi and its Impact on the US Health Care System*, Published December 2015, [https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20\(Full%20Report\).pdf](https://www.finance.senate.gov/imo/media/doc/1%20The%20Price%20of%20Sovaldi%20and%20Its%20Impact%20on%20the%20U.S.%20Health%20Care%20System%20(Full%20Report).pdf)

⁶ States that restrict access to beneficiaries who have a F2: AL, AZ, CA, CO, DC, DE, KY, ID, IN, MD, ME, NC, NJ, OH, OK, TN, VT, WI, WV;

States that restrict access to beneficiaries who have a F3 or higher: AR, IA, IL, KS, LA, MN, MO, MT, NE, OR, RI, SD, TX;

CMS Response

In reaction to the state Medicaid restrictions, CMS sent a State Notice in November 2015 warning states that they cannot restrict access to approved HCV drugs for non-medical reasons and that they must cover every prescription drug by every manufacturer that participates in the Medicaid rebate program.⁷

In the Notice, CMS wrote:

“When establishing formularies, states must ensure compliance with the requirements in section 1927(d)(4), including the requirements of section 1927(d)(4)(C) of the Act. Under this provision, a covered outpatient drug may only be excluded with respect to the treatment of a specific disease or condition for an identified population if, based on the drug’s labeling, or in the case of a drug the prescribed use of which is not approved under the FFDCFA, but is a medically accepted indication based on information from the appropriate compendia described in section 1927(k)(6), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

Accordingly, to the extent that states provide coverage of prescription drugs, they are required to provide coverage for those covered outpatient drugs of manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Act, when such drugs are prescribed for medically accepted indications, including the new DAA HCV drugs.”

CMS continued by stating it was 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 drugs. For example, several state Medicaid programs are limiting treatment to those beneficiaries whose extent of liver damage has progressed to metavir fibrosis score F3, while a number of states are requiring metavir fibrosis scores of F4. Certain states are also requiring a period of abstinence from drug and alcohol abuse as a condition for payment for DAA HCV drugs. In addition, several states are requiring that prescriptions for DAA HCV drugs must be prescribed by, or in consultation with specific provider types, like gastroenterologists, hepatologists, liver transplant specialists, or infectious disease specialists in order for payments to be provided for the drug.”

⁷ Centers for Medicare and Medicaid Services, *Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs*, Published November 2015, <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf>

Unfortunately, since CMS issued that Notice nearly two years ago, we have seen little action by the federal government in enforcing it and requiring states to increase access to HCV curative medications.

Litigation

Since the Notice, some states have expanded access to the medications, but this has mostly come about as a result of litigation, which is a long, arduous, and costly process, or through patient advocacy, including the threat of litigation.

In response to a class-action lawsuit filed in the U.S. District Court for the Western District of Washington in February 2016 on behalf of the nearly 28,000 Medicaid enrollees living with HCV in the state, a federal judge ordered Washington's state Medicaid program to extend treatment to all Medicaid enrollees living with HCV, regardless of fibrosis score.⁸ The plaintiffs in the case accused the state's Medicaid program of "excluding qualified Medicaid recipients from 'medically necessary' treatment as required by law, discriminating among similarly situated Medicaid recipients in violation of the law, and failing to provide medically necessary treatment with 'reasonable promptness.'"

In ruling in favor of the plaintiffs, the judge agreed that the state's Hepatitis C Treatment Policy "deprives Medicaid enrollees from access to a life-saving drug in situations where it is 'medically necessary,'" therefore the agency's policy of restricting access based on fibrosis score was not consistent with Medicaid requirements that drugs be dispensed based on medical need. The judge also agreed the "plaintiffs have introduced compelling evidence that they will suffer irreparable harm" should they have continued to be denied treatment with DAAs.

Similar class-action lawsuits have been filed against state Medicaid programs in Colorado, Indiana, and Missouri, and are still being heard by the courts.^{9 10 11} In each of these cases, plaintiffs contend that state Medicaid programs are legally required to provide and pay for treatment that is deemed "medically necessary." Additionally, the plaintiffs argue that state Medicaid programs participating in Medicaid's Prescription Drug Benefit Program are required to provide and pay for any outpatient drug for its indicated use once the drug manufacturer enters into a rebate agreement and the medicine is approved by the FDA and prescribed by a provider. By restricting access to HCV treatment, which is an FDA-approved drug, and by using a fScore to create an arbitrary cut-off when treatment can begin that is not based on medical need, plaintiffs argue the state Medicaid programs are violating the law.

Ryan v. Birch was filed in the U.S. District Court of Colorado in April of this year. The state recently tried to have the case dismissed, but the judge denied the motion and ruled in favor of

⁸ [WA: B.E. et al v. Teeter; case number: 2:16-cv-00227](#)

⁹ [CO: Ryan v. Birch; case number: 1:17-cv-00904](#)

¹⁰ [IN: Jackson v. Secretary of the Indiana Family and Social Services Administration; case number: 1:15-cv-01874](#)

¹¹ [MO: J.E.M. et al v. Kinkade et al; case number: 2:16-cv-04273](#)

the plaintiffs' complaint by agreeing that the state did not apply a reasonable standard for determining treatment eligibility and the case was legally sufficient to continue. The trial is now in the discovery phase.

To date, state Medicaid programs have not prevailed in the courts in limiting access to HCV drugs.

Some state Medicaid programs have expanded access to the curative treatments after intense pressure from patient advocates, including demand letters threatening litigation. In April 2016, New York's Medicaid program expanded access in its fee-for-service plans following demonstrations by patient advocates at a meeting of the states' Drug Utilization Review Board.¹² Florida's Medicaid program expanded access in June 2016 after patient advocates sent a demand letter, and now treats any Medicaid enrollee living with HCV, regardless of fibrosis score.¹³ Delaware's Medicaid program also expanded treatment access in June 2016 to Medicaid recipients experiencing specific symptoms after receiving a similar demand letter from patient advocates, and announced it would expand treatment access to all Medicaid recipients regardless of fibrosis score by January 2018.¹⁴

The AIDS Institute trusts you, as CMS Administrator, will enforce Medicaid law and ensure that all states are complying with the law. Patients should not have to rely on state-by-state litigation to receive access to FDA approved drugs that can cure them of a life-threatening infectious disease.

Restricting Access to HCV Cures are Contrary to Treatment Guidelines

The restrictions put in place by state Medicaid programs also are contrary to the American Association for the Study of Liver Diseases' treatment guidelines, which encourage treatment of nearly all patients diagnosed with HCV—regardless of Fibrosis Score or abstinence length.

Additionally, the National Academies of Science, Engineering, and Medicine recently recommended that health plans, including Medicaid, “remove restrictions that are not medically indicated and offer direct-acting antivirals to all chronic hepatitis C patients” in order to make eliminating viral hepatitis as a public health threat in the United States a possibility.

In April 2016, a group of eight specialty provider organizations, including The American Association of Family Physicians and the American Gastroenterological Association, sent a [letter](#) to CMS explaining why patients with HCV should have access to all physicians that have the

¹² <http://www.politico.com/states/new-york/albany/story/2016/04/state-removes-bars-for-hepatitis-c-patients-needing-expensive-cures-100835>

¹³ <http://www.healthlaw.org/news/press-releases/498-fla-health-officials-to-correct-criteria-on-hepatitis-c-treatment>

¹⁴ <http://www.delawareonline.com/story/news/health/2016/06/07/state-changes-hep-c-medication-guidelines-avoids-lawsuit/85554396/>

expertise to treat them.¹⁵ Withholding treatment until a patient has severe liver damage, has reached a certain length of abstinence, or has been able to unnecessarily see a specialist causes undue harm and constructs an excessive barrier to accessing curative treatments.

Misconceptions on the Price of the Medications

Though some states continue to claim that high list prices of \$80,000-\$100,000 make it impossible to treat those who need the cure, prices have actually dropped tremendously over the past few years. Several new treatments with lower list prices have been approved, creating a very competitive market in which states and other purchasers are able to receive substantial discounts and rebates. The latest treatment recently approved by the FDA has a list price of only \$26,400 for an 8-week course of treatment. Given the automatic 23 percent rebate from a drug's list price, the cost of curing a Medicaid patient would be \$20,328 at most. Even before this newest drug was approved by the FDA, with substantial discounts provided by pharmaceutical companies, reported prices already have been even lower than that.

Louisiana, a Medicaid expansion state, estimated that the state share to cure a beneficiary would only be \$8,000 per patient. Based on data from the Department of Veterans Affairs, which was released prior to approval of the most recent drug, The AIDS Institute calculates that the VA paid about \$24,000 per patient.¹⁶

Despite these lower prices, Louisiana is considering asking the federal government to take emergency action and force patent laws to be broken in order to obtain the drug at even lower costs. In determining the impact on their State budget, Louisiana assumes that all treatment costs will be borne in a single year. Since only approximately half of all people living with HCV are aware of their HCV status and not all people with HCV seek treatment immediately, not all of the estimated 20,000 Medicaid recipients in Louisiana living with HCV will receive treatment in the first year of increased access. This has been demonstrated in states that have loosened access restrictions; each have seen gradual uptake over time.

States' continued false statements about the price of the cure and its impact on their budgets inject untruths into the debate on drug pricing, while distracting from the fact that people who need treatment are being kept from it. If state Medicaid programs want to save money, increasing restrictions is not the answer. **Numerous studies have found that it is cost-effective to treat HCV early because, if left untreated, HCV can lead to health outcomes that require long-term care at even higher costs.**¹⁷

¹⁵ American Academy of Family Physicians, Published April 2016, <http://www.aafp.org/dam/AAFP/documents/advocacy/workforce/scope/LT-CMS-Hepatitis.pdf>

¹⁶ Department of Veterans Affairs, *FY2018 Funding and FY2019 Advance Appropriations*, Page 147-149, Published May 2017, <https://www.va.gov/budget/docs/summary/fy2018VAbudgetVolumeIImedicalProgramsAndInformationTechnology.pdf>

¹⁷ *Annals of Internal Medicine, Cost-Effectiveness and Budget Impact of Hepatitis C Virus Treatment*, Published March 2015, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4435698/>

We fail to understand why states are singling out and only restricting HCV treatment. In 2015, prescription drug spending accounted on average for less than 10 percent of total Medicaid spending across all states. Spending on the three most commonly prescribed HCV curative treatments was less than 3.5 percent of total national Medicaid drug spending (net of rebates) and less than 0.2 percent of overall Medicaid spending for the year.¹⁸ When considering states' overall Medicaid expenditures, HCV treatment is not a significant cost. **We believe it is unfair for Medicaid programs to present to policy makers that states must make a choice between other funding needs and HCV curative medications.** These arguments are not made for any other class of drugs.

While The AIDS Institute would never suggest a reduction in Medicaid spending for other medications to treat chronic conditions, including other infectious disease, we note that state Medicaid programs spend considerable amounts on these long term treatments. In contrast HCV treatment costs are for a short, several month duration until a patient is cured.

Restricting Access to HCV Medications is Against the Public Health

Restricting access to HCV curative treatments also negatively impacts public health and efforts to eliminate viral hepatitis in the United States.

Given the recent increases in the rate of new cases, and the high number of HCV-associated deaths, HCV poses a serious public health threat in the United States. This makes treatment more important than ever. Someone cured of their HCV can no longer infect others, cutting off a route of transmission and helping reduce the overall number of HCV cases. This “treatment as prevention” strategy is especially important among people who inject drugs, as 65 percent of new HCV cases in 2014 were due to intravenous drug use.

According to the Infectious Diseases Society of America, several health models have shown that even modest increases in successful treatment of HCV infection among persons who inject drugs can decrease prevalence and incidence. Successful treatment of those at greatest risk for transmission represents a formidable tool to help stop HCV transmission in those who continue to engage in high-risk behaviors.¹⁹ **By delaying HCV treatment through access restrictions, states are inadvertently fueling new HCV cases and hurting the nation’s ability to eliminate the disease.**

Eliminating viral hepatitis in the United States is entirely possible. Recent reports by several leading national and international health organizations have outlined how elimination can happen. In March 2016, the Division of Viral Hepatitis at CDC released their report “Strategic Plan, 2016–2020: Bringing Together Science and Public-Health Practice for the Elimination of Viral Hepatitis.”²⁰ In it, the CDC outlines steps the United States can take over the next five

¹⁸ <http://phrma-docs.phrma.org/files/dmfile/RealityofDrugSpending.pdf>

¹⁹ <http://www.hcvguidelines.org/evaluate/when-whom>

²⁰ Centers for Disease Control and Prevention, Division of Viral Hepatitis, *Strategic Plan, 2016–2020: Bringing Together Science and Public-Health Practice for the Elimination of Viral Hepatitis*, Published March 2016, <http://www.cdc.gov/hepatitis/pdfs/dvh-strategicplan2016-2020.pdf>

years to begin eliminating viral hepatitis. The National Academies of Science, Engineering, and Medicine released their report “Eliminating The Public Health Problem of Hepatitis B and C in The United States,” which demonstrates the feasibility of eliminating HBV and HCV from the United States.²¹ In May 2016, the World Health Organization (WHO) released their report “Combating Hepatitis B and C to Reach Elimination by 2030,” which lays out how to eliminate HBV and HCV globally.²² Additionally, the Department of Health and Human Services (HHS) released its “Updated National Viral Hepatitis Action Plan,” which describes goals, strategies, and efforts to reduce viral hepatitis from 2017 to 2020. **Curing HCV is a key goal in each of these plans and is crucial in eliminating viral hepatitis in the United States.**

Conclusion

Modern medicine has given us a way to cure a widespread and deadly infectious disease. State Medicaid programs spend just a fraction of their money on prescription drugs and an even smaller amount on HCV. It is critical that individuals receive access to these HCV curative treatments. We urge CMS to enforce the State Notice and prevent State Medicaid programs from restricting access to approved HCV drugs for non-medical reasons. In so doing, you can help end this infectious disease.

We thank you for your time and attention and would be pleased to meet with you and/or your staff to further discuss these important matters. If you wish to follow up, please contact me at cschmid@theaidsinstitute.org.

Sincerely,



Carl E. Schmid II
Deputy Executive Director

cc: Brian Neale, Center for Medicaid Services
Dr. Don Wright, Acting Assistant Secretary of Health
John Brooks, Counselor to the Secretary
Mary Sumpter Lapinski, Counselor to the Secretary

²¹ National Academies of Sciences, *Eliminating The Public Health Problem of Hepatitis B and C in The United States*, Published April 2016, <https://www.nationalacademies.org/hmd/Reports/2016/Eliminating-the-Public-Health-Problem-of-Hepatitis-B-and-C-in-the-US.aspx>

²² World Health Organization, *Combating Hepatitis B and C to Reach Elimination by 2030*, Published May 2016, <http://www.who.int/hepatitis/publications/hep-elimination-by-2030-brief/en/>