Dr. John J. Wernert, Secretary
Indiana Family and Social Services Administration
402 W. Washington Street P.O. Box 7083
Indianapolis, IN 46207-7083

Dear Secretary Wernert,

The undersigned organizations represent various members of Indiana’s community committed to advocating for clients who are at risk for, or living with, the hepatitis C virus (HCV). We are extremely concerned about Indiana’s Medicaid requirements for the use of the most effective HCV treatments because the requirements restrict timely access to vitally necessary medical treatment, contrary to federal Medicaid law and sound public policy. Adjusting Indiana’s policy would not only save lives, but it would also save taxpayer resources and it is good public health policy. Medical care should be provided early and by the physician of the patient’s medical home. Below please find a review of the facts and the law that apply to this crisis situation.

Indiana’s HCV Crisis. The HCV crisis in Indiana has received international attention. Between 2010 and 2013, the number of people in Indiana infected with HCV has increased by 150 percent.¹ According to the American Liver Foundation, if the virus is left unchecked, the cost of HCV management and treatment will rise nationally to $85 billion in the next 10 to 20 years.²

This virus poses a significant public health risk, especially when left untreated. HCV is spread more easily than HIV and can be deadly. When treatment is denied for HCV-positive Hoosiers who present to their physicians, that denial causes direct harm to both patients and the broader community; Patients who are denied treatment are placed at greater risk for hepatocellular carcinoma, and because HCV- positive patients are left untreated, the virus is allowed to spread further.

² Peter Oyakhire, Healing Hepatitis & Liver Disease Naturally 36 (2010).
The Opportunity to Address this Crisis. As you know, new HCV therapies have shown great promise for dramatically improving the symptoms of HCV and for curing the virus in many patients. Of critical importance is the timing of and setting for HCV treatment. Current research supports the conclusion that new therapies better address the epidemic of HCV when patients are treated immediately, and studies also show that the drugs combat HCV at all stages of the disease. For example, in individuals who are mono-infected with HCV and have no cirrhosis, the recommended treatment period for the use of Harvoni has now been reduced from 12 weeks to eight weeks, significantly lowering the cost of Harvoni. HCV genotype 1 patients who have not yet developed complications can be successfully treated for 8 weeks with Harvoni at cure rates between 93% and 95%. Accordingly, established standards of care for HCV involve treating the disease immediately and with the recognition that delivery by specialty care is not required.

Indiana Medicaid Restrictions on HCV Treatment. Indiana’s current Medicaid restrictions leave the state especially vulnerable to the spread of HCV. Indiana’s Medicaid requirements, released October 1, 2015 in the Indiana Medicaid Preferred Drug List, heavily restrict patient access to the necessary drugs. A similar set of restrictions apply to all six of the new HCV treatments: Harvoni, Olysio, Sovaldi, Vieckira Pak, Technivie, and Daklinza. These treatments are unique because they do not require the use of ribavirin, a component of earlier treatments which has extensive side effects, and they have much higher cure rates. The restrictions applied to these drugs are not connected to the current standard of care for patients and should be removed. The negative effects of Indiana’s Medicaid restrictions are illustrated in this letter through the examples of Havroni and Sovaldi.

Currently, Indiana places many restrictions on Medicaid patient access to Harvoni, including:

- Patients must be at least 18.
- Patients must not be pregnant.
- Patients must receive a prescription from or in consultation with an infectious disease or gastrointestinal specialist.

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6 Id.

7 Id.
Patients must have a diagnosis of chronic hepatitis C genotype 1 with
- Greater than stage 2 fibrosis, or
- Co-infection with HIV or AIDS, or
- Post liver transplant.
- A patient may receive one 12 week approval only for treatment naive members or up to 24 weeks for treatment experienced members.
- Reapprovals must confirm compliance on Harvoni therapy.
- Dosage approved will be from 90-400 mg daily.\textsuperscript{8}

Additionally, Indiana places many restrictions on Medicaid patient access to Sovaldi, including:
- Patients must be at least 18.
- Patients must not be pregnant.
- Patients must receive a prescription from or in consultation with an infectious disease or gastrointestinal specialist.
- Patients must have a diagnosis of chronic hepatitis C with compensated liver disease (cirrhosis) with
  - Greater than stage 3 fibrosis in genotype 1, or
  - Greater than stage 2 fibrosis in genotypes 2-4, or
  - Co-infection with HIV or AIDS, or
  - Post liver transplant, or
  - Hepatocellular carcinoma that meets the criteria for a liver transplant.
- Patients must continue peginterferon alfa and ribavirin, ribavirin therapy, or Olysio therapy concurrently with Sovaldi.
- For re-approvals, providers must confirm compliance or Sovaldi and ribavirin combination therapy.
- Dosage approval will be for 400mg a day.
- Patients may receive up to 12 weeks of therapy for triple therapy with Sovaldi, ribavirin, and peginterferon alfa or dual therapy with Sovaldi and Olysio; up to 24 weeks for dual therapy with Sovaldi and ribavirin, or up to 48 weeks with Sovaldi and ribavirin for members with hepatocellular carcinoma that meet criteria for liver transplant.\textsuperscript{9}

**The Impact of Indiana’s HCV Medicaid Treatment Barriers.** Indiana’s restrictions severely limit patient access to Harvoni and Sovaldi. Requiring that patients have a certain stage of HCV or certain complications significantly reduces the number of people who can access the treatment. The human cost of that policy is significant.

According to the University of Bern’s Institute of Social and Preventive Medicine, treating patients when they have stage four fibrosis as opposed to treating patients when they have stage one fibrosis results in patients being contagious for four times longer and extends the length of

\textsuperscript{8} Id. 
\textsuperscript{9} Id.
the infection by as many as 21 years. Additionally, the study concluded that “delaying treatment until 1 year after diagnosis or until F2, F3 or F4 [stage 2, 3, or 4 Fibrosis] led to 14, 43, 142 and 418 additional cases of liver-related deaths per 1000 HCV infections as compared with treating all patients one month after diagnosis.” Patients also face a 5% rate of developing decompensation, a 20% rate of developing liver cancer, and a 25% rate of liver related death if treated after the development of stage 2 Fibrosis compared to a 1% rate of developing decompensation, a 2% rate of developing liver cancer, and a 3% rate of liver related death if treated soon after their diagnosis. As this study demonstrates, barriers to the access of Harvoni and Sovaldi leave Indiana communities vulnerable to high infection rates and higher Medicaid costs.

Similarly, studies also show that Sovaldi and Harvoni are effective regardless of the absence of secondary complications. Sovaldi’s cure rates are higher across all genotypes when patients do not have cirrhosis, and Harvoni’s cure rates remain about the same in patients with and without cirrhosis. In patients who have received a liver transplant, Sovaldi’s cure rate is at 64% across all genotypes while Harvoni’s cure rate is relatively unchanged. Additionally, studies have found that co-infection with HIV decreases Sovaldi’s cure rates from the mid-90 range across all genotypes to a range of 76% to 92%, depending on the genotype. Again, HCV patients co-infected with HIV taking Harvoni face similar cure rates as monoinfected patients. No medical benefit is achieved by requiring patients develop certain complications before authorizing treatment. The restrictions placed on Sovaldi and Harvoni uncealy limit the number of people who can receive effective treatment.

Limiting the types of physicians who can prescribe Harvoni and Sovaldi also creates a barrier to access of the treatment, as specialists are expensive and difficult to access. There is no evidence that physicians whose qualifications are not in those listed specialties are unable to craft an appropriate treatment plan for HCV patients. In sum, Indiana’s restrictions significantly affect

11 Id.
15 Id.
17 Id.
the number of patients who can qualify to receive Harvoni or Sovaldi. HCV-positive Hoosiers are harmed by these restrictions, as are the communities where they live.

A similar set of harmful restrictions apply to all of the new HCV treatments covered under Indiana’s Medicaid. Just as the restrictions on Harvoni and Sovaldi limit patients’ ability to achieve full recovery and open the community to the spread of HCV, the restrictions on the other four HCV treatments also cause similar issues. The restrictions on Harvoni, Olysio, Sovaldi, Viekira Pak, Technivie, and Daklinza should be removed.19

Legal Obligations for Indiana’s Medicaid Program Not to Restrict Medically Necessary Treatment. According to the federal Medicaid requirements, states must design their Medicaid programs within certain parameters. 42 CFR 440.230 dictates that “the agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures.”20 (emphasis added). According to the federal requirements, as confirmed in 2012 by the U.S. Seventh Circuit Court of Appeals in Bontrager v. Indiana Family and Social Services Administration, Indiana must provide Medicaid patients with treatments which are deemed medical necessities.21 Indiana law mirrors the federal statute. Indiana Code §12-15-21-3 states that limitations must be “consistent with medical necessity concerning the amount, scope, and duration of the services and supplies to be provided.”22 (emphasis added). Treatments deemed a medical necessity must be granted to patients with “reasonable promptness” in accordance with federal Medicaid law.23

The Indiana Court of Appeals held in Davis v. Schrader that “if the individual proves that the equipment or treatment is medically necessary according to the State definition, the regulatory exclusion is invalid and the State Medicaid program must cover the equipment or treatment.”24 Based on Indiana’s current definition of a medical necessity, the new HCV treatments should be provided to patients without restriction. The Indiana Court of Appeals notes in Thie v. Davis that “the responsibility for defining medical necessity is left to the states.”25 Indiana has elected to define medical necessity as a treatment that “is required for the care or well-being of the patient and is provided in accordance with generally accepted standards of medical or professional practice.”26 Additionally, Indiana law holds that medical necessity will be determined by examining the “generally accepted standards of medical or professional practice.”27

In this instance, it is clear that new HCV treatments should qualify as medical necessities under Indiana Law. Before the new HCV treatments were approved by the FDA, the standard

19 Id.
20 42 CFR 440.230
21 Bontrager v. Ind. Family & Soc. Servs. Admin., 697 F.3d 604, 606 (7th Cir. Ind. 2012)
23 42 U.S.C 1396a(a)(8)
24 Id.
26 405 IAC 5-2-17
27 Id.
treatment for HCV included a regimen of interferon and ribavirin. The treatment was often decried by patients as worse than the disease because of the extensive list of side effects: “nausea, diarrhea, itchy skin rashes, insomnia and severe depression.” In addition, the cure rate for the treatment is 50% or lower. In comparison, new HCV treatments boast a cure rate of 90% or higher, depending on the virus’s stage, and Harvoni minimizes drastically the side effects expected by patients. For these reasons, the new HCV treatments are “required for the care or well-being of the patient” and are provided in accordance with “generally accepted standards of medical or professional practice.” Therefore, these treatments are medical necessities and should be provided without restrictions to Indiana patients.

While federal law requires that states provide medically necessary treatments under their Medicaid programs, states are granted some limited ability to restrict patient access. At any time, a state may require prior authorization for a treatment, which Indiana has made contingent upon a patient meeting the previously stated requirements. States may also restrict the coverage of a drug in two instances: if a drug is not a medically accepted indication or if a drug falls into one of the categories listed in 42 U.S. Code § 1396r–8(d)(2). Neither exception applies to Indiana’s treatment of new HCV treatments.

Just last week, the U.S. Department of Health and Human Services’ Center for Medicaid and CHIP Services addressed this very issue in a notice issued to your agency and other state

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29 Id.
30 Id.
33 42 U.S. Code § 1396r–8 (d)(1)(a)
34 42 U.S. Code § 1396r–8 (d)(1)
35 According to 42 U.S. Code § 1396r–8 k(6), a medically accepted indication is defined as “any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act.” On October 10, 2014, the Food and Drug Administration, the agency authorized under the Federal Food, Drug, and Cosmetic Act, approved Harvoni for use against HCV. Because Harvoni has been approved for use in treating HCV, Indiana cannot restrict patient access to the drug for failure to meet the requirement of being a medically accepted indication.

Similarly, Harvoni does not qualify for restriction because it is not one of the kinds of treatments outlined in 42 U.S. Code § 1396r–8(d)(2). 42 U.S. Code § 1396r–8(d)(2) excludes:
agents when used for anorexia, weight loss, or weight gain; agents when used to promote fertility;
agents when used for cosmetic purposes or hair growth; agents when used for the symptomatic relief of cough and colds; agents when used to promote smoking cessation; prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; Nonprescription drugs;
covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee; Barbiturates; Benzodiazepines; agents when used for the treatment of sexual or erectile dysfunction.
Medicaid agencies. Specifically, that notice stated, "CMS is concerned that some states are restricting access to DAA HCV drugs (direct-acting antiviral drugs, including Harvoni and Sovaldi) contrary to statutory requirements...the effect of such limitations should not result in the denial of access to effective, clinically appropriate, and medically necessary treatments."

**Public Policy Considerations for HCV Treatment in Indiana's Medicaid Program.**
In addition to the fact that Indiana's restrictions to access of new HCV treatments are in violation of federal and state Medicaid law, the restrictions are also in direct opposition to sound public policy. According to the U.S. Centers for Disease Control, there are an estimated 2.7 million people infected with HCV in the United States, and the virus caused 15,106 deaths in 2007. As you well know, Indiana is no exception to the expanding problem of HCV. The recent outbreak of HIV and HCV in Scott County, Indiana, illustrates the need for an intervention in the spread of HCV in Indiana's communities. In 2014, the Indiana State Department of Health reported that significant numbers of citizens were living with HCV in thirty-five counties in Indiana.

Physicians treating the outbreak in Indiana are concerned for the long term consequences of Indiana’s Medicaid policy on HCV treatment. Due to the limitations on a patient’s ability to receive meaningful medical treatment, many Indiana residents with HCV are currently untreated. Public health experts outside of Indiana are concerned as well. When speaking about Indiana’s restrictions and the recent outbreak, Dr. David Thomas, head of the Division of Infectious Diseases at John Hopkins Medicine, stated, “You’ve got a structural problem there. That’s something that needs to change quickly.”

Although the new HCV treatments like Harvoni and Sovaldi are expensive, with a full regimen costing as much as $94,000 and $84,000 respectively, without the support of Indiana’s Medicaid program, HCV will be left unchecked. Importantly, state Medicaid programs pay a

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reduced rate for drugs and can negotiate even lower prices. Moreover, studies have even indicated that early treatment is the most cost effective option for HCV treatment. Relegating patients to drugs which have much lower cure rates and more side effects leaves open the possibility that HCV will continue to be a growing problem for the state. Spending money now to address the problem and actually cure patients can stop the spread of HCV and ensure that the state will not be forced to spend more money in the future to confront a broader outbreak. From a public policy standpoint, Indiana should act now to fix the systemic problem.

**Conclusion.** We respectfully request that your agency immediately remove the current Indiana Medicaid restrictions to Harvoni, Olysio, Sovaldi, Viekira Pak, Technivie, and Daklinza. The restrictions run counter to the recommended course of treatment for this dangerous infectious disease, are in violation of federal and state Medicaid law, and run counter to sound public policy. Immediately lifting the restrictions will bring the state into compliance with the law and will greatly benefit Indiana’s communities.

Sincerely,

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