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By E-mail and U.S. Mail

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RE: Access to Hepatitis C Virus Treatment for Rhode Island Medicaid Patients

Dear Secretary Beane & Ms. George:

We represent at least one Rhode Island Medicaid patient who has been denied curative treatment for Hepatitis C Virus (HCV). This treatment is medically necessary for all chronically infected HCV patients, including our client(s). However, for solely budgetary reasons, the Rhode Island Executive Office of Health & Human Services (OHHS) has implemented an illegal rationing scheme, allowing only the sickest Medicaid patients to receive coverage for treatment.

Rhode Island's policy flies in the face of the Medicaid Act. Not only have such policies been struck down in other jurisdictions, but CMS has explicitly proscribed them. Moreover, the Rhode Island Superior Court's recent decision in *Strese v. R.I. Exec. Office of H.H.S* confirms that the OHHS policy violates federal law. If OHHS does not agree to remove disease severity restrictions on HCV treatment coverage by June 15, 2018, it is our intent to challenge the policy in court.

I. The Disease

According to the Centers for Disease Control, more Americans now die as a result of HCV than the next 60 infectious diseases *combined.* Yet, recent pharmaceutical developments have transformed HCV from a lifelong disease to a curable infection. The impact of these advancements on the lives of HCV patients cannot be overstated. Left untreated, HCV is a devastating illness. As HCV infection progresses, the virus can result in irreversible liver damage, as well as a wide range of life-disrupting health conditions, including diabetes, lymphoma, fatigue, joint pain, depression, myalgia, arthritis and jaundice. HCV patients are at significantly greater risk of developing liver cancer. In the worst cases, HCV infection results in death. Unfortunately, for many years the only available treatments were just partially effective, and they often caused intolerable side effects.

The prognosis for HCV patients changed in 2011, when the Food and Drug Administration approved a new class of drugs for treating HCV. These drugs, called direct-acting antiviral medications (DAAs), are a *de facto* cure of the virus, clearing the infection from a patient's system in over 95% of cases. DAAs also come with few of the side effects of prior classes of medication. The invention of DAAs means that HCV patients now have a chance at a life free from the uncertainty, stigma, and debilitating symptoms of infection.

DAAs are the prevailing standard of care for HCV in Rhode Island and nationwide. The American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) have jointly endorsed DAA treatment 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."[1] On a website containing HCV treatment information for medical professionals, the Rhode Island Department of Health (DOH) refers providers directly to the AASLD/IDSA Guidelines.[2]

The AASLD/IDSA Guidelines also note that early treatment of chronic HCV results in better outcomes for patients. By receiving treatment early, patients may avoid irreversible organ damage and a host of other symptoms altogether. Moreover, patients who are cured of HCV are no longer able to transmit the disease to others. In a 2016 report on HCV in Rhode Island, DOH affirmed the individual and public health benefits of treating HCV patients in the early stages of chronic infection, stating that "early diagnosis and treatment can help prevent HCV transmission and reduce HCV-related morbidity and mortality."[3]

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[1] *See* AM. ASS'N FOR THE STUDY OF LIVER DISEASES & INFECTIOUS DISEASES SOC. OF AM., ***HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C*** **1 (2018),** ***available at*** http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy.

[2] *See Hepatitis Publications*, R.I. Dept. of Health, http://www.health.ri.gov/publications/bytopic.php?parm=Hepatitis#Healthcare%20Providers.

[3] See R.I. DEPT. OF HEALTH, *Epidemiological Profile: the Hepatitis C Epidemic in Rhode Island* 4 (2016), *available at* http://www.health.ri.gov/publications/reports/2016HepatitisCEpidemiologicalProfile.pdf.

The HCV treatment policies of a wide range of public and private insurers affirm that the AASLD/IDSA Guidelines represent the universal standard of care. Medicare and the Veteran's Administration do not restrict care based on disease severity. Numerous states, including Alaska, Colorado, Connecticut, Delaware, Florida, Maine, Massachusetts, New Hampshire, New York, Pennsylvania, Vermont, Virginia, Washington, and Wisconsin, have removed disease severity restrictions from their Medicaid coverage criteria.

Moreover, most private insurers in Rhode Island have dropped similar restrictions from their policies, making Rhode Island Medicaid a hold-out for comprehensive DAA coverage in the state. United HealthCare, for instance, reached a national class-action settlement in 2016 under which it agreed to remove severity restrictions from its commercial plans.[4] However, the company continues to require Rhode Island Medicaid patients to provide evidence of severe organ damage in order to receive treatment under its MCO plan. Rhode Island Medicaid thus allows special limitations on the healthcare of the state's neediest patients.

II. OHHS's Exclusionary HCV Prior Authorization Criteria

Although DOH endorses treating patients in the early stages of chronic infection, under OHHS policy, the providers who care for Rhode Island's HCV-infected Medicaid patients cannot comply with these recommendations.

Under prior-authorization criteria implemented on September 9, 2014 and still in effect (January 22, 2018 Pre-Authorization Guidelines attached at **Exhibit A**), Rhode Island Medicaid began systematically denying coverage for DAAs on the basis of a patient's "fibrosis score," a measure of liver damage caused by chronic HCV infection.[5] With narrow exceptions, patients with a fibrosis score of less than F3—a grade indicating significant scarring of the liver—are excluded from coverage for DAAs. These patients must wait until their liver damage progresses to F3 or greater in order to receive coverage for curative treatment. Some patients will experience irreversible organ damage while waiting for their disease to progress. Others who seek DAAs and are denied coverage may become lost to care, putting them at risk of never receiving treatment. *See, e.g.*, *B.E. v. Teeter*, No. C16-227- JCC, 2016 WL 3033500, at *3-4 (W.D. Wash. May 27, 2016). As a matter of sound public health policy, furthermore, treatment prevents the further transmission of the virus to others.

The effects of this policy are acute for Rhode Island Medicaid patients. In a 2015 survey by DOH, Rhode Island providers indicated that 350 Medicaid patients had been denied curative treatment for HCV on the basis of their fibrosis score.[6] And the reasons for this rationing policy

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[4] *See generally Jones, et al. v. United HealthCare Services Inc., et al.*, No. 0:15-cv-61144, (S.D. Fla. Feb. 2, 2017).
[5] *See* Gill, Ghazinian, Manch, Gish, Hepatitis C Virus as a Systemic: Reaching Beyond the Liver, HEPATOLOGY INTERNATIONAL, Vol. 9, No. 4 (2015).
[6] See R.I. DEPT. OF HEALTH, *Epidemiological Profile: the Hepatitis C Epidemic in Rhode Island* 45 (2016), *available at* http://www.health.ri.gov/publications/reports/2016HepatitisCEpidemiologicalProfile.pdf.

are purely budgetary. In its 2016 report on HCV, DOH notes that "high prices of medications have strained state budgets and prompted some health plans to restrict access to drugs for treatment for some patients."[7] However, such restrictions hold only harms—and no conceivable benefits—for patients. There is a case to be made that this approach is not even valid from a budgetary perspective. The costs of treatment for patients with the more severe liver damage caused by the current Medicaid fibrosis score requirements are far more after additional, often irreversible damage is done. Further, the risks of knowingly prolonging the period during which an infected patient is denied treatment, and thus preventably exposing additional Rhode Islanders to the disease, are budgetarily unsound and contrary to accepted public health practice.[8]

III. Fibrosis Restrictions Do Not Hold Up in Court

In November 2015, the Centers for Medicare and Medicaid Services (CMS) issued Guidance warning State Medicaid Directors against the very type of restrictions that Rhode Island Medicaid has enacted. The Guidance conveys that policies that exclude treatment based on Fibrosis Score cannot be used to deny "access to effective, clinically appropriate and medically necessary treatments using DAA drugs for beneficiaries with chronic HCV infections."[9] CMS has thus resolved any questions about whether fibrosis restrictions are in line with federal Medicaid policy. DAA rationing schemes directly contravene states' obligations under the Medicaid Act.

Where states have proven recalcitrant in removing restrictions, attorneys – including one of the undersigned counsel -- have had great success in litigation. In *B.E. v. Teeter*, a court enjoined a Washington Medicaid HCV coverage policy on the grounds that it improperly excluded enrollees from medically necessary care. *Teeter,* No. C16-227-JCC, 2016 WL 3033500, at *2 (W.D. Wash. May 27, 2016). In *Ryan v. Birch*, a federal district court certified a class of Medicaid beneficiaries in a similar challenge, resulting in a pending settlement to remove fibrosis restrictions from Colorado Medicaid criteria. *Birch*, No. 17-CV-00904-KLM, 2017 WL 3896440 (D. Colo. Sept. 5, 2017) (denying Defendant's motion to dismiss). In these cases, the state defendants end up not only paying for the underlying treatment costs but also

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[7] See R.I. DEPT. OF HEALTH, *Epidemiological Profile: the Hepatitis C Epidemic in Rhode Island* 5 (2016), *available at* http://www.health.ri.gov/publications/reports/2016HepatitisCEpidemiologicalProfile.pdf.

[8] Indeed, in one meta-study, health economics researchers found iterations of this treatment to be not just cost-effective (below the routine cost threshold for improved health outcomes) but actually cost-saving (improving health outcomes while simultaneously decreasing costs). J. Chhatwal, T. He, C. Hur, M.A. Lopez-Olivo, "Direct-Acting Antiviral Agents for Patients With Hepatitis C Virus Genotype 1 Infection Are Cost-Saving," *Clinical Gastroenterology and Hepatology* (2017) *available at* https://www.cghjournal.org/article/S1542-3565(16)30673-5/fulltext

[9] *See* CENTERS FOR MEDICARE AND MEDICAID SERVICES, "Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs," State Release 172, *available at* https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf

incur litigation costs, including, in some instances, substantial attorney fees to the plaintiff attorneys. The signatories to this letter have no interest in causing this added element of expense to the Rhode Island taxpayer. We are contacting you in advance of filing a complaint with the express purpose of reaching a resolution that provides medically necessary treatment to patients while avoiding needless litigation costs.

The OHHS policy at issue has already been found to violate federal law. In *Strese v. R.I. Exec. Office of H.H.S.*, Rhode Island Medicaid's fibrosis restrictions were successfully challenged on the basis of the Medicaid Act. No. PC-2017-1282, at *4 (R.I Super. Ct., Feb. 15, 2018). The court in *Strese* found that the OHHS criteria "fail[ed] to respond in any meaningful way to an individual Medicaid recipient's medical need for Harvoni or other direct-action antivirals." *Strese v. R.I. Exec. Office of H.H.S.*, No. PC-2017-1282, at *14 (R.I Super. Ct., Feb. 15, 2018). As the court in *Strese* has made clear, OHHS policy does not meet the requirements of the Medicaid Act.

IV. The OHHS HCV Treatment Policy Violates the Medicaid Act

Rhode Island's policy violates the Medicaid Act in three separate ways. *First*, Rhode Island Medicaid has failed to provide comparable coverage to similarly situated beneficiaries, as required by the Medicaid Act. 42 U.S.C. § 1396a(a)(10)(B) *See Rolland v. Cellucci*, 52 F. Supp. 2d 231, 238 (D. Mass. 1999). All chronically infected HCV patients require DAA treatment in order to be cured of HCV, but Rhode Island Medicaid policy covers treatment for only a fraction of patients. The comparability provision of the Medicaid Act expressly prohibits this type of discrimination.

Second, Rhode Island Medicaid has abrogated its legal obligation to provide coverage for treatment with "reasonable promptness." Section 1396a(a)(8) of the Medicaid Act states that "[a] State plan for medical assistance must ... provide that ... [medical] assistance shall be furnished with reasonable promptness to all eligible individuals." 42 U.S.C. § 1396a(a)(8).42 U.S.C. § 1396a(a)(8). *See also Bryson v. Shumway*, 308 F.3d 79, 89 (1st Cir. 2002), *Boulet v. Cellucci*, 107 F. Supp. 2d 61, 73 (D. Mass. 2000). By denying coverage for DAAs to eligible individuals, Rhode Island Medicaid causes unreasonable delay between diagnosis of chronic HCV and coverage for care.

Third, Rhode Island has evaded its duty under the Medicaid Act to provide necessary medical assistance to qualified medical enrollees. 42 U.S.C. §§ 1396a(a)(10)(A). Courts have regularly interpreted the Medicaid Act to require that state programs provide coverage for medically necessary care. *See B.E. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500, at *2 (W.D. Wash. May 27, 2016); *Ryan v. Birch*, No. 17-CV-00904-KLM, 2017 WL 3896440 at *3 (D. Colo. Sept. 5, 2017). The consensus standard, as embodied in the AASLD-IDSA Guidelines and DOH's statements, is that DAAs are medically necessary for nearly all chronically infected patients. The Medicaid statute details the limited ways in which prescription drug coverage can

be restricted, and none of these narrow exceptions are present in this case. See 42 U.S.C. § 1396r-8(d)(1). Moreover, Rhode Island Medicaid cannot claim that denying Medicaid enrollees access to a cure of their chronic disease is "in the best interests" of Medicaid beneficiaries. *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003).

V. Cost-Effectiveness

OHHS's rationing policy is not only illegal, it is also counterproductive. HCV is a costly disease, with an estimated lifetime cost of $64,490 per individual.[10] Studies of the global costs and benefits of DAAs have found the drugs to be cost-effective, even more so as new formulations have reduced the average cost of regimens.[11] Indeed, DOH heralded the cost-effectiveness of DAAs in its 2016 report on HCV.[12] DAAs do not merely represent a breakthrough treatment for patients; they also offer benefits to the health system as a whole.

There is also no equally cost-effective treatment alternative to DAAs. The drug regimen used prior to the advent of DAAs is more expensive than the available DAA regimens, and it is significantly less effective. A "watch-and-wait" approach cannot be deemed equally effective under any understanding of the term. See *B.E. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500, at *3-*4 (W.D. Wash. May 27, 2016). As such, DAAs remain the standard of care not merely for their efficacy, but also for their cost-effectiveness.

VI. Conclusion

For the foregoing reasons, federal law requires Rhode Island Medicaid to provide coverage for DAA treatment to chronically infected HCV patients, regardless of fibrosis score. While we are prepared to litigate against OHHS, we are certainly open to resolving this issue through a pre-complaint settlement. If you would like to meet with us to discuss the potential for reaching a mutual resolution, please contact Jennifer at (401) 491-1101 ext. 801. She will coordinate with plaintiff co-counsel.

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[10] Homie Razavi, et al., *Chronic Hepatitis C Virus (HCV) Disease Burden and Cost in the United States* 57 HEPATOLOGY 2164 (2013).

[11] *See, e.g.,* T. He, et al., *Systematic Review: Cost-Effectiveness of Direct-Acting Antivirals for Treatment of Hepatitis C Genotypes 2-6*, 46 ALIMENTARY PHARMACOLOGY & THERAPEUTICS 711 (2017); Jagpreet Chhatwal, et al., *Direct Acting-Acting Antiviral Agents for Patients With Hepatitis C Virus Genotype 1 Infection Are Cost-Saving*, 15 CLINICAL GASTROENTEROLOGY AND HEPATOLOGY 827 (2017); Harinder S. Chahal, et al., *Cost-effectiveness of Early Treatment of Hepatitis C Virus Genotype 1 by Stage of Liver Fibrosis in a US Treatment-Naïve Population*, JAMA INTERN. MED. 176(1) (2016); *see* Max Nisen, "AbbVie Wages HCV Drug-Price War on Gilead," Bloomberg (Aug. 7, 2017) *available at* https://www.bloomberg.com/gadfly/articles/2017-08-07/abbvie-mavyret-price-threatens-gilead-hepatitis-dominance.

[12] See R.I. DEPT. OF HEALTH, *Epidemiological Profile: the Hepatitis C Epidemic in Rhode Island* 5 (2016), *available at* http://www.health.ri.gov/publications/reports/2016HepatitisCEpidemiologicalProfile.pdf.

We hope to meet with you quickly to explore whether we can find common ground. We are also aware however that there are R.I. Medicaid patients who have been waiting for these life-saving treatments for some time so we must request that you respond within 30 days or we will be obligated to proceed with filing a lawsuit to challenge the disease severity restrictions in the R.I. Medicaid DAA prior-authorization criteria.

Thank you for giving this issue your attention.

Very Truly Yours,

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Enclosure

EXHIBIT

A

Medications for Treatment of Hepatitis C

Pre-Authorization Guidelines

Effective Date: January 22, 2018

Introduction:

Hepatitis C has been identified as a significant etiology of chronic liver disease, associated co-morbidities, need for liver transplant and death. These guidelines are specific for the use of medications on the Rhode Island Medicaid Preferred Drug List (PDL). Additional medications or drug classes subsequently receiving FDA approval will require separate review. On October 4, 2016 the U.S. Food and Drug Administration (FDA) began requiring a *Boxed Warning* about the risk of Hepatitis B Virus (HBV) reactivation to be added to the labels of direct acting antiviral (DAA) agents. Detailed information is available at http://www.fda.gov/Drugs/DrugSafety/ucm522932.htm.

Modifications to these guidelines will be issued as needed.

General Approval Criteria:

1. Prescribers
    a. Requesting physician must be a gastroenterologist, hepatologist or infectious disease trained clinician. Interested physicians must submit the Preferred Provider application available on the EOHHS website and await approval before submitting medication pre-authorization requests.
    b. Physician Assistants and Nurse Practitioners employed by and co-located with a physician on the Preferred Provider List may request preferred Provider status.
2. Documentation
    The following information must be included in the pre-authorization request:
    a. Summary of current clinical status including hepatic function data and as appropriate determination of compensated/non-compensated cirrhosis. Patients with decompensated cirrhosis must be referred to a physician with experience in managing such disease – ideally at a center with liver transplant capabilities.
    b. History of prior Hepatitis C therapy if relevant.
    c. Hepatitis C genotype, quantitative viral load and date of testing. Testing must be within 90 days of request.
    d. Treatment plan including:
        i. Medication name, dose and duration
        ii. Method and frequency of patient monitoring
        iii. Planned post treatment follow up
        iv. Agreement to submit post treatment viral load data
    e. Documentation of stage 3 or 4 hepatic fibrosis or cirrhosis. Documentation may be by any of the following:
        i. AST to Platelet Ratio (APRI) greater than or equal to 1.0
        ii. Current liver biopsy is not required, however prior biopsy indicating METAVIR score of 3 or 4 may be used.
        iii. Fibroscan score greater than or equal to 9.5kPa
        iv. Fibrotest score greater than or equal to 0.58
        v. Imaging study consistent with cirrhosis.
    f. Patients with HIV co-infection are eligible for treatment with stage 2 disease as documented by any one of the tests listed below:

i. APRI greater than or equal to 0.5 to 1.0
ii. Current liver biopsy is not required, however prior biopsy indicating METAVIR score of 2 disease
iii. Fibroscan score greater than or equal to 7.0kPa
iv. Fibrotest score greater than or equal to 0.32
v. Imaging study consistent with Cirrhosis.

3. Patient Responsibility
    a. Patient must indicate a willingness to comply with treatment and monitoring plans as documented by having a signed "Patient Contract" (sample is available on EOHHS website).
    b. Contract does not have to be submitted with pre-authorization request but must be maintained as part of the provider's clinical documentation.
4. Approval
    a. Medication approval will be for a full course of treatment with medication being dispensed in 28 day increments. Evidence of non-compliance may cause cancellation of approved medication refills.
    b. Approval will be valid for 84 days from date of approval.
    c. EOHHS and the Medicaid Managed Care Organizations (MCO) will periodically review randomly selected, de-identified prior authorizations to ensure consistent application of this policy for all Medicaid enrollees.
    d. The health plan Medical Director will be accountable to ensure that all utilization criteria adhere to the prior-authorization criteria.
    e. Any request for a non FDA approved treatment regimen will be denied.
5. Treatment recommendations as of January 22, 2018:
    a. Preferred agents: Mavyret or Vosevi.
    b. Non-preferred agents: All other agents with the exception of ribavirin.
        i. Will be approved if a patient is completing a cycle therapy which was initiated prior to current policy implementation.
        ii. PA requests will be reviewed on a case by case basis. The PA request must include supporting, detailed clinical documentation of need, for an alternative, non-preferred agent.
6. Continuity of Treatment

    When transitioning between publicly funded delivery systems (e.g. between Fee for Service Medicaid and Managed Care Medicaid, between Managed Care Medicaid and Fee for Service Medicaid or between the department of Corrections and the Medicaid program), any authorization granted by the prior delivery system will be honored for the portion of the treatment that remains after the transition.