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CONFIDENTIAL

VIA ELECTRONIC MAIL AND CERTIFIED MAIL

March 28, 2016 Our File No. 351-01

Rita Landgraf, Secretary
Department of Health and Social Services
1901 N. Dupont Highway
New Castle, DE 19720
rita.landgraf@state.de.us

RE: Lawsuit Challenging Access to Hepatitis C Virus Treatment

Dear Secretary Landgraf:

Tycko and Zavareei LLP, Community Legal Aid Society, Inc., and the Center for Health Law and Policy Innovation of Harvard Law School represent one or more Delaware resident Medicaid enrollees diagnosed with Hepatitis C ("HCV") who have been prescribed medically necessary curative treatment. Our clients have been denied coverage due to Delaware's overly restrictive Medicaid authorization criteria. Unless the Delaware Division of Medicaid and Medical Assistance ("DMMA") of DHSS immediately removes its categorical coverage policy for HCV treatment contained in its Prior Authorization Conditions for Hepatitis C Agents dated April 1, 2016 and attached to this letter as Exhibit 1, our clients will have no alternative but to seek judicial intervention. Please be advised that if DMMA does not commit to changing this policy by April 15, 2016 we will proceed with litigation.

I. BACKGROUND

HCV is a chronic inflammatory disease that can lead to serious liver damage, infections, liver cancer and death. Even before the advanced stage of the disease, HCV can contribute to diagnoses of diabetes, lymphoma, fatigue, joint pain, depression, myalgia, arthritis and jaundice.

Until 2011, the standard of care for treatment of HCV was a three-drug treatment containing a protease inhibitor, interferon and ribavirin at a cost of approximately $170,000 per cure. The treatment provided, at best, a 70% cure rate and was accompanied by significant adverse side effects. *See* http://www.cdc.gov/hepatitis/Statistics/index.htm (last visited 1/25/16).

Starting in 2011, the United States Food and Drug Administration (FDA) began approving direct-acting anti-viral medications ("DAAs") to treat HCV. These medications are considered "breakthrough" drugs by the FDA because they *cure* HCV in more than 90% of the

patients who receive the treatment. Treatment guidelines approved by the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD/IDSA) 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 1/25/16).

The AASLD/ISDA Guidelines constitute the prevailing standard of care for HCV, as reflected in the HCV treatment policies of many public and private insurers. In some instances, where payor policies are flatly inconsistent with the prevailing clinical guidelines, private and public insurers have been subject to litigation. *See e.g., Jackson v. Sec'y of the Ind. Family and Soc. Servs. Admin.*, Case No. 1:15-cv-01874-SEB-MPB (S.D. Ind.); *B.E., et al. v. Teeter*, Case No. 2:16-cv-00227-JCC (W.D. Wash.); *Jones v. UnitedHealth Group, Inc.*, et al., Case No. 0:15-cv-61144-RLR (S.D. Fla.); *Kondell v. Blue Cross and Blue Shield of Fla., Inc.*, Case No. 0:15-cv-61118-RLR (S.D. Fla.); *Paszko, et al. v. O'Brien, et al*., Case No. 1:15-cv-12298-NMG (D. Mass.); *Andre v. Blue Cross, et al.*, Case No. BC582063 (Cal. Super. Ct.).

II. DMMA'S EXCLUSIONARY HCV PRIOR AUTHORIZATION CRITERIA

Prior to March 2016, DMMA limited access to DAAs to those with cirrhosis. In March 2016, DMMA announced its revised HCV Prior Authorization Policy. This policy limits coverage of DAAs to Medicaid enrollees with severe liver disease (as determined by the Metavir Fibrosis Score of F3 or F4) or enrollees with severe liver disease and certain qualifying co-morbid conditions. Individuals are also required to prove 90 days of abstinence from drugs and/or alcohol prior to treatment. *See* Ex. 1. Under the HCV Prior Authorization Policy, *all other Medicaid enrollees with HCV are excluded from coverage for DAAs*. As a direct result of this policy, at least 50% of Delaware Medicaid enrollees with HCV requesting coverage were denied medications likely to result in a cure. *See Medicaid Denial for Hep C Drugs Nearing 50% in Some States*, http://www.medscape.com/viewarticle/854708 (last reviewed 3/22/2016). This statistic does not include the many who have refrained from seeking coverage knowing such a request to be fruitless under DMMA's existing policy. *Hepatitis C: Delaware's Hidden Epidemic*, http://www.delawareonline.com/story/news/health/2015/08/21/delawares-hidden-epidemic/32147655/ (last reviewed 3/22/2016).

III. THE HCV TREATMENT POLICY VIOLATES THE MEDICAID ACT

DMMA's exclusionary policy violates the Medicaid Act in at least three different ways:

First, the Medicaid Act requires that DMMA provide medically necessary medical assistance, including prescription drug coverage, to qualified Medicaid enrollees. *See* 42 U.S.C. §§ 1396a(a)(10)(A); 1396a(a)(54); 1396r-8. The Act details the limited ways in which prescription drug coverage can be restricted. *See* 42 U.S.C. § 1396r-8(d)(1). None of those narrow circumstances are present here. Nor can DMMA claim that denying Medicaid enrollees access to a cure of their chronic disease is "in the best interests" of Medicaid recipients. *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652, 123 S. Ct. 1855, 155 L. Ed. 2d 889

(2003). DMMA's policy arbitrarily deprives enrollees of medically necessary treatment, contrary to the Medicaid Act's statutory purpose and governing jurisprudence. *See Weaver* v. *Reagen,* 886 F.2d 194 (8th Cir. 1989); *Allen* v. *Mansour,* 681 F. Supp. 1232 (E.D. Mich. 1986).

Second, the HCV Treatment Policy violates the Medicaid Act's "reasonable promptness" requirements. Section 1396a(a)(8) of the Medicaid Act requires 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). This provision of the Medicaid Act was added in order to prevent states from delaying access to treatment due to a shortage of state funds, such as through the use of waiting lists or a waiting period. *Sobky* v. *Smoley,* 855 F. Supp. 1123, 1148 (E.D. Cal. 1994). DMMA's exclusionary policy requires Medicaid enrollees with HCV who need treatment now to wait- even for years to receive coverage for a cure for their infection, while needlessly risking progression of the disease and accompanying deterioration of patients' health. It creates an illegal waiting period.

Third, DMMA's policy violates Medicaid comparability. Under Medicaid comparability provisions, 42 U.S.C. § 1396a(a)(l O)(B), the Medicaid program must ensure that comparable coverage is provided when individuals have comparable needs. *See Leonard* v. *Mackereth,* No. CIV.A. 11-7418,2014 WL 512456, at *8 (E.D. Pa. Feb. 10, 2014). DMMA automatically excludes coverage of a cure for HCV to many infected individuals, even though all Medicaid enrollees who are infected with the inflammatory disease all need the treatment in order to be cured.

The Center for Medicaid and Medicare Services ("CMS") agrees that exclusionary policies like DMMA's violate the Medicaid Act. On November 5, 2015, CMS issued guidance to State Medicaid Directors warning that coverage 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." *See* Ex. 2. To date, Delaware has ignored CMS guidance, and continues to impose restrictive criteria.

IV. CONCLUSION

DMMA must remove its restrictions on coverage of DAAs that are medically necessary to treat HCV. If DMMA does not commit to removing the restrictions by April 15, 2016, the undersigned intends to file a class action lawsuit to ensure that Delaware Medicaid enrollees with HCV receive the medically necessary prescription drug treatment to which they are entitled.

Sincerely,

Hassan Zavareei
Tycko & Zavareei LLP

Laura Waterland
Community Legal Aid Society, Inc.

s/Kevin Costello
Kevin Costello
Center for Health Law & Policy Innovation
Harvard Law School

cc: Matthew Denn, Attorney General for Delaware
Ann Woolfolk, DAG

EXHIBIT 1

Delaware Medicaid and Medical Assistance
Request for Prior Authorization
Hepatitis C Agents
Submit request via: Fax – 1-302-454-0224 or Website – WWW.DMAP.STATE.DE.US

Prior Authorization Conditions

General Requirements

- Medications can only be approved as part of a regimen that is FDA approved for the client's genotype. This includes indication, dosing regimen, and duration.
- Duration of approved therapy shall not exceed 12 weeks, and should be peg-interferon free when possible
- The client must have not used any illegal substances for 90 days prior to starting therapy. Drugs screens to confirm this are required.
- The client must have documented abstinence from alcohol use for 90 days prior to starting therapy.
- The clients must sign the informed consent form.
- Clients with co-morbid HIV must have undetectable HIV viral load or a CD4 count of at least 350 cells/µL.

Direct Acting Antivirals

- Documentation of fibrosis stage 3 or 4 preferably by noninvasive technology (Fibroscan) or serum tests (Fibrosure, Fibrotest); or secondarily by liver biopsy indicating advanced fibrosis (Metavir F3) or compensated cirrhosis (Metavir F4).
- Alternatively, cirrhosis can be documented by a combination of an ultrasound or CT scan along with extrahepatic manifestations or clinical findings such as the presence of ascites.
- Documentation of labs or biopsy showing fast progressing fibrosis that would require treatment earlier than the approved fibrosis stage

Approval of a nonpreferred agent requires

- A documented failure or contraindication to an alternative preferred regimen.
    - If the client has failed prior therapy, then documentation of the reason for failure is required. Simple noncompliance with previous therapy ***may*** be considered a contraindication to retreatment. If a preferred regimen is contraindicated due to a comorbid condition, then documentation of the other condition is required.

ATTACHMENTS NEEDED:

- ✓ Drug Screen for illegal substances
- ✓ Lab Test for Genotype
- ✓ Patient Consent Document
- ✓ Documentation of medical necessity for a nonpreferred agent

Delaware Medicaid and Medical Assistance
Request for Prior Authorization
Hepatitis C Agents
Submit request via: Fax – 1-302-454-0224 or Website – WWW.DMAP.STATE.DE.US

Client name: _____ DOB: _____

Medicaid ID Number: _____ Date of Request: _____

Practitioner Name: _____ NPI: _____

Office Phone Number: _____ Office Fax Number: _____

Diagnosis: _____

HCV Genotype:	Lab date: _____
HCV Pre-Treatment Viral Load: Iu/mL: or Copies/mL:	
Is the patient co-infected with HIV? If yes and receiving treatment, please indicate medication regimen, and labs showing CD4 count of at least 350 cell/uL:	☐ Yes ☐ No
Has client used illegal substances in 90 days prior to starting therapy?	☐ Yes ☐ No
Has the patient received a liver transplant?	☐ Yes ☐ No
If request is for a non-preferred medication, is documentation attached showing failure or contraindication to an alternative preferred regimen and imminent need? If a preferred regimen is contraindicated due to a comorbid condition, then documentation of condition is required.	☐ Yes ☐ No
Is interferon free regimen requested? Requested documentation must be attached.	☐ Yes ☐ No
Is informed consent document signed and attached?	☐ Yes ☐ No
Please list any previous therapy for Hepatitis C as well as reasons for any previous failures:	
Proposed Hepatitis C regimen: Include frequency, strength, and quantity, and duration:	

Physician Signature (required): _____ Date: _____

Delaware Medicaid and Medical Assistance
Request for Prior Authorization
Hepatitis C Agents
Submit request via: Fax – 1-302-454-0224 or Website – WWW.DMAP.STATE.DE.US

DELAWARE DMMA INFORMED CONSENT FORM FOR HEPATITIS C THERAPY

This document is to help you understand the drugs being used to treat hepatitis C.

- You must take all of these medications for the full 12 weeks. If you stop one, then the other will not work and it will need to be stopped as well.
- One of the commonly used medications is ribavirin. Ribavirin often has side effects. You may have flu like symptoms throughout the treatment. If severe side effects happen while taking ribavirin, you need to contact the physician's office for direction.
- The medicines used to treat hepatitis C are harmful during pregnancy. A baby may have serious birth defects or die if exposed during the pregnancy to these medicines. Contraceptive (birth control) measures must be used by females and males receiving these medicines to prevent severe birth defects or fetal deaths. The medicine may impact the unborn child for up to 6 months after it has been stopped.
    - Females: You are asked to provide information on two contraceptive methods (birth control) being used to avoid getting pregnant.
    - Males: While you are taking this drug, your partner must avoid becoming pregnant. Together you must use two contraceptive (birth control) methods. You are asked to provide information on two contraceptive methods (birth control) being used to avoid pregnancy
- Alcohol must be avoided to prevent further harm to the liver. The use of alcohol during treatment may lead to coverage of medications being cancelled.
- Illegal substance must be avoided. Exposure to another form of Hepatitis C would make it more challenging to treat the viral infection.
- If you fail to strictly follow the drug regimen, it may not be effective.

By signing this document, I acknowledge that I have read the above information, that I will abide by all parts of it, and that failure may result in termination of my medication for hepatitis C.

PRINTED NAME:_____
SIGNATURE:_____
DATE:_____

EXHIBIT 2

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and CHIP Services

NOVEMBER 5, 2015

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 172**

For State Technical Contacts

ASSURING MEDICAID BENEFICIARIES ACCESS TO HEPATITIS C (HCV) DRUGS

The Centers for Medicare & Medicaid Services (CMS) remains committed to Medicaid beneficiaries continuing to have access to needed prescribed medications, a commitment we know that states share. The purpose of this letter is to advise states on the coverage of drugs for Medicaid beneficiaries living with hepatitis C virus (HCV) infections. Specifically, this letter addresses utilization of the direct-acting antiviral (DAA) drugs approved by the Food and Drug Administration (FDA) for the treatment of chronic HCV infected patients.

Rules Regarding Medicaid Drug Coverage

Coverage of prescription drugs is an optional benefit in state Medicaid programs, though all fifty (50) states and the District of Columbia currently provide this benefit. States that provide assistance for covered outpatient drugs of manufacturers that have entered into, and have in effect, rebate agreements described in section 1927(b) of the Social Security Act (the Act) under their Medicaid fee-for-service (FFS) programs or Medicaid managed care plans are required to comply with the requirements of section 1927(d)(1) and (2) of the Act.

Section 1927(d)(1) of the Act provides that a state may subject a covered outpatient drug to prior authorization, or exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication as defined by section 1927(k)(6) of the Act, or the drug is included in the list of drugs or drug classes (or their medical uses), that may be excluded or otherwise restricted under section 1927(d)(2) of the Act.

Section 1927(k)(6) of the Act defines the term “medically accepted indication” as any use of a covered outpatient drug which is approved under the Food Drug And Cosmetic Act (FFDCA), or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i).

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 FFDCA, 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 is aware that, given the costs of these new DAA HCV drugs, states have raised concerns about the budgetary impact to their Medicaid programs and beneficiary access to needed care. The agency shares these concerns. However, the recent launch of multiple DAA HCV drugs in the marketplace is creating competition in this class that may result in downward pressure on the prices of these drugs. This competition may enhance the ability of states to negotiate supplemental rebates or other pricing arrangements with manufacturers to obtain more competitive prices for both their FFS and managed care programs, thereby reducing costs. CMS encourages states to take advantage of such opportunities.

To that end, manufacturers have a role to play in ensuring access and affordability to these medications. CMS has sent a letter to the manufacturers of these DAA HCV drugs, asking them to provide information regarding any value-based purchasing arrangements they offer for these drugs so that states might be able to participate in such arrangements.

Permissible Limitations to Medicaid Drug Coverage

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 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[1].

[1] The metavir scoring system is used to assess inflammation and fibrosis by histopathological evaluation of a liver biopsy of patients with hepatitis C. The stages, indicated by F0 through F4, represent the amount of fibrosis or scarring of the liver. F0 indicates no fibrosis while F4 represents cirrhosis; a chronic degenerative liver disease state in which normal liver cells are damaged and are then replaced by scar tissue. For more information about liver fibrosis please read Ramon Batallar and David A. Brenner, Liver fibrosis Journal of Clinical Investigation. 2005 Feb 1; 115(2): 209–218 by visiting http://www.ncbi.nlm.nih.gov/pmc/articles/PMC546435/

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.

While states have the discretion to establish certain limitations on the coverage of these drugs, such as preferred drug lists and use of prior authorization processes,[2] such practices must be consistent with requirements of section 1927(d) of the Act to ensure appropriate utilization.

As such, the effect of such limitations 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. States should, therefore, examine their drug benefits to ensure that limitations do not unreasonably restrict coverage of effective treatment using the new DAA HCV drugs.

CMS encourages states to exercise sound clinical judgment and utilize available resources to determine their coverage policies. These resources include pharmacy and therapeutics (P&T) committees, drug utilization review (DUR) boards, and comparative analysis of the costs to treat HCV patients in light of the efficacy of these newer regimens in terms of cure rates, when compared to those of preexistent therapies. Additionally, CMS notes the availability of guidelines for states to refer to regarding testing, managing, and treating HCV put forth by the American Association for the Study of Liver Diseases (AASLD), the Infectious Diseases Society of America (IDSA), and the International Antiviral Society-USA (IAS-USA), which can be found at http://www.hcvguidelines.org/full-report-view. CMS also suggests that states consider implementing programs that provide patients on HCV treatment with supportive care that will enhance their adherence to regimens, thereby increasing the success rates.

Coverage under Medicaid Managed Care Plans

CMS is also concerned that in many states, Medicaid managed care organizations (MCOs) or other managed care arrangements' conditions for payment for DAA HCV drugs appear to be more restrictive than coverage under the states' fee-for-service (FFS) programs. Furthermore, in states with multiple MCOs or arrangements, the conditions for payment for DAA HCV drugs often differ between various plans.

CMS reminds states that the drugs under the approved state plan must be available to individuals enrolled in Medicaid managed care arrangements. As with their FFS program, states are urged to carefully monitor the DAA HCV drug coverage policies of their MCOs to ensure enrollees have appropriate access. States have the option to include these drugs in the managed care contracts and capitation rates or to "carve out" the drugs used in the treatment of chronic HCV

[2] In accordance with section 1927(d)(5) of the Act, a state plan may establish a prior authorization program as a condition of coverage or payment for a covered outpatient drug; however, the program must provide responses by telephone or other telecommunication device within 24 hours of a request for prior authorization, and, except for those drugs restricted or excluded from coverage pursuant to section 1927(d)(2) of the Act, provide for the dispensing of at least a 72-hour supply of a covered outpatient prescription drug in an emergency situation.

infections from managed care contracts and capitation rates and instead provide access to these drugs through FFS or other arrangements.

Consistent with the regulation at 42 CFR §438.210, services covered under Medicaid managed care contracts (with MCOs, prepaid inpatient health plans, and prepaid ambulatory health plans) must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services for beneficiaries under FFS Medicaid. While managed care plans may place appropriate limits on DAA HCV drugs using criteria applied under the state plan, such as medical necessity, the managed care plan may not use a standard for determining medical necessity that is more restrictive than is used in the state plan.

CMS notes that managed care plans are permitted to use other utilization controls provided that the services, as controlled under the health plan's policies, can be reasonably expected to achieve their purpose. However, states should carefully monitor utilization controls and the HCV coverage policies of their managed care plans to ensure that the organizations are providing appropriate access to covered services and benefits consistent with 42 CFR §438.210.

CMS recognizes the challenges of defining policies in the face of new and innovative drug treatments. It will monitor the policies and conditions states impose for the coverage of DAA HCV drugs to ensure compliance with the requirements of the Act and access to effective, clinically appropriate, and medically necessary treatments for beneficiaries. CMS will monitor state compliance with their approved state plans, the statue, and regulations to assure that access to these medications is maintained.

CMS shares with states the common goal of ensuring access to quality care for Medicaid beneficiaries. Given the complexities that have arisen with the introduction of the DAA HCV drugs, CMS will continue to work with State Medicaid agencies to continue providing and improving care to persons infected with chronic HCV infections. If you have any questions, please contact John M. Coster, Ph.D., R.Ph., Director of the Division of Pharmacy, at John.Coster@cms.hhs.gov.

/s/

Alissa Mooney DeBoy
Acting Director
Disabled and Elderly Health Programs Group