SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK

PEOPLE OF THE STATE OF NEW YORK, by ERIC T. SCHNEIDERMAN, Attorney General of the State of New York,	:	**VERIFIED COMPLAINT**
Plaintiff,	:	Index No.:
— against —	:	Assigned Judge:
CAPITAL DISTRICT PHYSICIANS' HEALTH PLAN, INC.	:	
Defendant.	:	

Plaintiff, the People of the State of New York, by its attorney, ERIC T. SCHNEIDERMAN, Attorney General of the State of New York, alleges upon information and belief the following against Capital District Physicians' Health Plan ("CDPHP"):

NATURE OF THE ACTION

1. Chronic Hepatitis C infection is a serious disease that is easily cured with prescription medication – yet CDPHP, a health insurance carrier, has denied coverage of this curative treatment for a significant portion of its members with this disease. Through its plan documents, CDPHP represents to members and potential members that it will cover all medically necessary care for the treatment of disease. Contrary to this representation, however, CDPHP is denying coverage of Hepatitis C treatment unless members demonstrate advanced disease – such as liver scarring or serious complications – even though medical consensus recommends treatment for nearly all individuals with Hepatitis C infection. By refusing to cover Hepatitis C treatment for members who have not yet developed advanced liver disease, based on undisclosed considerations of the cost of

treatment, CDPHP is failing to satisfy its obligation to cover members' medically necessary care and is deceiving its members about the scope of their coverage.

2. Hepatitis C infection is a highly contagious and potentially fatal disease that can result in liver failure, liver cancer, brain damage, and kidney failure. Starting in late 2013, the Food and Drug Administration ("FDA") approved new medications to treat Hepatitis C infection that are significantly better than previously available treatment regimens, including having higher cure rates and fewer side effects.

3. While its plan documents assert that it will cover medically necessary care, CDPHP restricts coverage of Hepatitis C treatment based on disease severity. CDPHP's members diagnosed with chronic Hepatitis C infection with little or no liver scarring are denied coverage until their medical condition deteriorates and the liver becomes increasingly scarred, even if the member's treating physician recommends immediate treatment. Using its restrictive coverage criteria, in 2014 through 2015, CDPHP denied almost half of its members' claims for treatment with one of the most effective medications available.

4. CDPHP's determination to exclude coverage for individuals with early-stage liver scarring is not based on, or supported by, clinical guideline recommendations or the generally-accepted standard of care. Indeed, clinical guidelines have consistently recommended treatment of all patients with chronic Hepatitis C infection (with the limited exception of those with a short life expectancy, even with treatment) and highlight the importance of early treatment.

5. CDPHP's definitions of "medically necessary" lead members and potential members to believe that treatment for Hepatitis C infection will be covered by CDPHP, even if they have not developed advanced liver scarring. Nothing in the plan documents would lead reasonable consumers to understand that they would need to wait for their medical condition to deteriorate for treatment to

be covered by their health plans when they have a confirmed diagnosis of a potentially life-threatening disease, there is a medication that cures their condition, the medication is specifically approved by the FDA for that purpose, and that medication is on the plan formulary.

6. Moreover, as internal documents reveal, CDPHP revised its Hepatitis C medical necessity criteria specifically to restrict coverage based on cost considerations. CDPHP's medical necessity definition, however, fails to disclose to members and potential members that the cost of treatment will be a factor that CDPHP considers when evaluating if and when treatment is deemed medically necessary.

7. Based on the foregoing and as set forth more fully below, pursuant to New York Executive Law § 63(12), New York General Business Law ("GBL") Article 22-A § 349, Insurance Law § 3217-a(a)(1) and § 4324(a)(1), and Public Health Law § 4408(1)(a), the People of the State of New York, by Eric T. Schneiderman, Attorney General of the State of New York ("Plaintiff" or "OAG") brings this action against CDPHP for misrepresenting to members the scope of their coverage, including failing to disclose that it considers the expense of treatment when developing medical necessity criteria that guide coverage determinations under its plans. Plaintiff seeks injunctive relief, penalties and costs against Defendant.

JURISDICTION AND PARTIES

8. Plaintiff, the People of the State of New York, is represented by its chief legal officer, Eric T. Schneiderman, Attorney General of the State of New York, who brings this action pursuant to the authority granted him under New York Executive Law § 63(12) and GBL § 349.

9. This Court has jurisdiction over this action pursuant to New York Executive Law § 63(12), which authorizes the Attorney General to seek injunctive relief, restitution, and damages against any person that engages in repeated fraud or illegality in the conduct of business.

10. Further, GBL Article 22-A, § 349 empowers the Attorney General to seek injunctive relief, restitution, and civil penalties against any person who engages in deceptive acts and practices in the conduct of business.

11. CDPHP is a corporation organized and existing under the laws of the State of New York, having its principal place of business at 500 Patroon Creek Boulevard, Albany, New York 12206.

12. CDPHP is a health insurance carrier that is authorized by New York State law to conduct business and solicit subscribers to its insurance policies within the state. It has approximately 450,000 members and provides service to 24 counties throughout the Capital Area, North Country, Hudson Valley, Central New York, and Southern Tier.

13. Venue is proper in New York County under Civil Practice Law and Rules ("CPLR") § 503(a).

14. The Attorney General has provided Defendant with pre-litigation notice pursuant to GBL § 349(c).

FACTUAL ALLEGATIONS

I. CDPHP'S DEFINTIONS OF "MEDICALLY NECESSARY"

15. CDPHP offers several different commercial plans, on and off of the New York State of Health Marketplace ("Marketplace"), New York State's health insurance exchange established pursuant to the Patient Protection and Affordable Care Act ("ACA").

16. Each of these plans cover members' medical care if it is deemed "medically

necessary" as defined in the plans.

17. CDPHP's large group commercial plans (health plans for employers with over 100 employees) define "Medically Necessary" as:

> [T]hose Health Services defined by CDPHP's Medical Director, or his/her designee, that are necessary to prevent, treat and/or alleviate symptoms of an illness, disorder, or condition, are rendered at an appropriate level of intensity, can reasonably be expected to promote effective outcomes, are expected to provide significant, measurable clinical improvement within a reasonable and medically predictable period of time, are provided efficiently and facilitate quality of care. More specifically, this includes treatments needed to prevent, diagnose, correct, or cure conditions in the person that cause acute suffering, endanger life resulting in illness or infirmity, interfere with such person's ability for normal activity, or threaten a major handicap.

18. CDPHP's individual and small group commercial plans,[1] on and off the Marketplace, state:

> We Cover benefits described in this Contract as long as the health care service, procedure, treatment, test, device, Prescription Drug or supply (collectively, "service") is Medically Necessary. The fact that a Provider has furnished, prescribed, ordered, recommended, or approved the service does not make it Medically Necessary or mean that We have to Cover it.
>
> We may base Our decision on a review of:
> - Your medical records;
> - Our medical policies and clinical guidelines;
> - Medical opinions of a professional society, peer review committee or other groups of Physicians;
> - Reports in peer-reviewed medical literature;
> - Reports and guidelines published by nationally-recognized health care organizations that include supporting scientific data;
> - Professional standards of safety and effectiveness, which are generally-recognized in the United States for diagnosis, care, or treatment;
> - The opinion of Health Care Professionals in the generally-recognized health specialty involved;
> - The opinion of the attending Providers, which have credence but do not overrule contrary opinions.

[1] Individual health insurance plans are plans that individuals can enroll themselves and their families in directly, rather than going through an employer. Small group health plans are health plans offered by employers when they have fewer than 100 employees. Small businesses can shop for health plans to offer their employees on or off of the Marketplace.

Services will be deemed Medically Necessary only if:

- They are clinically appropriate in terms of type, frequency, extent, site, and duration, and considered effective for Your illness, injury, or disease;
- They are required for the direct care and treatment or management of that condition;
- Your condition would be adversely affected if the services were not provided;
- They are provided in accordance with generally-accepted standards of medical practice;
- They are not primarily for the convenience of You, Your family, or Your Provider;
- They are not more costly than an alternative service or sequence of services, that is at least as likely to produce equivalent therapeutic or diagnostic results;
- When setting or place of service is part of the review, services that can be safely provided to You in a lower cost setting will not be Medically Necessary if they are performed in a higher cost setting. For example we will not provide coverage for an inpatient admission for surgery if the surgery could have been performed on an outpatient basis.

19. CDPHP's "medically necessary" definitions do not list cost as a factor it considers in determining whether and when treatment for a disease will be covered (although relative cost may be considered when determining which treatment will be covered). Ignoring its own plan terms, CDPHP explicitly considered the cost of treatment when developing its specific medical necessity criteria for Hepatitis C treatment. See infra, Section IV. Members and potential members diagnosed with Hepatitis C were not apprised of this through the plan documents. They therefore could not, and did not, know that coverage for treatment of their disease could be limited due to cost.

20. Further, CDPHP's denial of Hepatitis C treatment absent liver scarring or advanced disease is not supported by the medical consensus and prevailing medical guidelines, which support treating nearly all individuals with HCV. That consensus has been confirmed through CDPHP's experience with the New York State external appeal process, which has

reversed each of CDPHP's medical necessity denials for one of the newer Hepatitis C treatments. See infra, ¶ 54.

II. BACKGROUND INFORMATION: HEPATITIS C

A. ABOUT HEPATITIS C

21. The Hepatitis C virus ("HCV") is a blood-borne virus that can cause both acute and chronic infection of the liver. Acute HCV infection occurs within the first six months after exposure to HCV, and approximately 75 to 85 percent of those acutely infected will go on to develop chronic HCV infection.

22. Chronic HCV infection is a serious, and potentially fatal, disease that can result in liver failure, liver cancer, brain damage, and kidney failure. Untreated HCV can result in increasingly extensive liver scarring, potentially culminating in cirrhosis. HCV is usually spread through blood transmission.

23. Cirrhosis is a fatal disease, and mortality data reflects chronic liver disease /cirrhosis is the twelfth leading cause of death in the United States.[2] Chronic hepatitis C is one of the leading causes of cirrhosis in the United States.[3]

24. HCV infection is a serious public health problem in this country, as well as in New York State. Because of the risks posed by HCV infection, the Centers for Disease Control has, since 2012, recommended anyone born between 1945 – 1965 be tested for HCV,[4] since this population has high rates of Hepatitis C, and the longer people live with this disease, the more

[2] Centers for Disease Control and Prevention, National Vital Statistics Reports, Deaths: Final Data for 2013 (Feb. 16, 2016), http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf.
[3] U.S. Department of Health and Human services, National Institute of Diabetes and Digestive and Kidney Diseases, Cirrhosis (April 2014), http://www.niddk.nih.gov/health-information/health-topics/liver-disease/cirrhosis/Pages/facts.aspx.
[4] Centers for Disease Control and Prevention, Hepatitis C Testing for Anyone Born During 1945-1965: New CDC Recommendations (Oct. 1, 2012), http://www.cdc.gov/features/HepatitisCTesting.

likely they are to develop life-threatening liver disease. Effective January 1, 2014, New York State has required medical providers to offer HCV screening to patients born between 1945 and 1965 and to provide or make a referral for follow-up health care to patients with a reactive HCV screening test.[5]

25. Until fairly recently, available therapies for chronic HCV had relatively low success rates, were burdensome to administer (such as requiring injections and numerous pills), had a long treatment period (24 – 48 weeks), and caused extreme side effects that were intolerable for many patients.

26. Starting in 2013, the FDA approved several new HCV treatments, with high cure rates (as high as 95%), significantly fewer side effects, shorter lengths of treatment, and significantly increased ease of administration. In particular, Sovaldi, Harvoni, Viekira Pak, and Zepatier (approved by the FDA on January 8, 2016) are all vastly superior treatments compared to the previous treatment regimens.

27. There are several ways to assess the progression of HCV infection, and one common way is to measure the amount of liver scarring using "Metavir fibrosis staging," where a higher score indicates evidence of more extensive liver damage. A Metavir score of F0 means no evidence of fibrosis, and the highest score, F4, indicates cirrhosis – scarring throughout the liver.

B. MEDICAL CONSENSUS ON TREATMENT OF HCV INFECTION

28. Since at least 2014, the general medical consensus has supported early treatment of nearly all individuals with chronic HCV infection as medically appropriate to prevent the serious problems that flow from HCV infection and to protect others from contracting this

[5] NYS PUB. HEALTH L. § 2171.

serious disease.

29. Two preeminent medical societies, the American Association for the Study of Liver Disease ("AASLD") and the Infectious Diseases Society of America ("IDSA"), previously in collaboration with the International Antiviral Society–USA,[6] publish Recommendations for Testing, Managing, and Treating Hepatitis C (herein referred to as the "Guidance").[7]

30. The Guidance is developed by a panel of over twenty-five experts appointed by the Boards of Directors of AASLD and IDSA. The goal of the Guidance is to provide healthcare professionals with "timely guidance" on treatment of chronic HCV.

Treatment for All Patients Recommended

31. In 2014, soon after the FDA started approving new and significantly improved treatments for HCV infection, the Guidance recommended "Treatment . . . for patients with chronic HCV infection."

32. At the same time, the Guidance recognized that there might be a rush for treatment with these new medications and that the infrastructure might not exist to immediately treat all eligible patients at once. For example, treatment might be limited based on the number of practitioners trained to treat patients with HCV infection. The Guidance therefore recommended prioritization of populations most in need when this type of limitation exists.

33. Many health plans, including CDPHP, used the Guidance's discussion of "prioritization" to justify limiting treatment coverage through restrictive medical necessity criteria that deny coverage to individuals with low-level liver fibrosis. The types of infrastructure limitations set out by the Guidance that would justify prioritization, however, are not limiting

[6] IAS-USA ended its relationship as a collaborating partner on December 31, 2015, but was involved in the project from mid-2013 through 2015.

[7] American Association for the Study of Liver Diseases and Infectious Diseases Society of America, HCV Guidance: Recommendations for Testing, Managing and Treating Hepatitis C, Introduction, http://www.hcvguidelines.org/full-report/introduction (last visited April 13, 2016).

factors for health plans, which members and employers specifically purchase to cover treatment when members become ill.

34. In or around June 2015, the AASLD, after discovering that health plans were using its "prioritization" language to deny coverage to members with HCV infection, released a clarification stating that "all patients who receive advice from their doctor to take the newest medications should not be denied," and that the Guidance "recognizes the need to treat all."[8]

35. The AASLD's clarification specifically addressed health plans' focus on the "prioritization" language, writing that it "adamantly disagree[s]" with payers' decision to deny treatment when prescribed by a doctor for his or her patient. The AASLD continued to unequivocally state: "*Our Guidance is not intended to be used by payers to deny access to treatment*."[9]

36. In October 2015, the Guidance eliminated all references to "prioritizing" treatment of patients with advanced fibrosis, noting that "data continue to accumulate that demonstrate the many benefits, within the liver and extrahepatic, that accompany HCV eradication," and that "the panel continues to recommend 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."[10]

37. Notably, the recommendation to treat nearly all individuals with chronic HCV includes individuals suffering from drug or alcohol addiction. Drug and alcohol use are not absolute contraindications to treatment of HCV; to the contrary, individuals suffering from

[8] American Association for the Study of Liver Diseases, AASLD Position on Treating Patients with Chronic Hepatitis C Virus: HCV Guidance FAQ, http://www.aasld.org/aasld-position-treating-patients-chronic-hcv (last visited April 13, 2016)(emphasis added).
[9] Id.
[10] AASLD and IDSA, When and in Whom to Initiate HCV Therapy, http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy (last visited April 13, 2016).

substance abuse can improve their medical condition with treatment. Indeed, individuals who engage in high-risk activities, such as needle sharing, are a treatment priority given the increased risk of transmission.

38. Moreover, "[t]here is strong evidence from various settings in which persons who inject drugs have demonstrated adherence to treatment and low rates of reinfection, countering arguments that have been commonly used to limit access to this patient population."[11]

Importance of Treating Early-Stage Fibrosis

39. As early as August 2014, the Guidance recommended early treatment of HCV infection, particularly "before the development of severe liver disease and other complications," given the many benefits associated with successful treatment.

40. Similarly, in April 2014, the National Institute of Diabetes and Digestive Kidney Diseases, part of the U.S. Department of Health and Human Services, wrote: "Advanced therapies for chronic hepatitis C now exist, and health care providers should treat people with chronic hepatitis C before they develop severe fibrosis or cirrhosis."[12]

41. Research shows that there are important clinical benefits of treating earlier fibrosis stages.[13] For example, studies have found that initiating therapy in patients with lower-stage fibrosis may extend the benefits of curing the disease and that delaying treatment can increase rates of liver-related mortality.

42. Further, there is a significant public health benefit to early treatment, since individuals who are cured can no longer transmit the disease. Modeling has shown that "even

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[11] Id.
[12] U.S. Department of Health and Human Services, National Institute of Diabetes and Digestive and Kidney Diseases, Cirrhosis (April 2014), http://www.niddk.nih.gov/health-information/health-topics/liver-disease/cirrhosis/Pages/facts.aspx.
[13] AASLD and IDSA, When and in Whom to Initiate HCV Therapy, http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy (last visited April 13, 2016).

modest increases in successful treatment of HCV infection among persons who inject drugs can decrease prevalence and incidence."[14]

III. CDPHP'S HEPATITIS C TREATMENT POLICY RESTRICTS COVERAGE EVEN WHEN TREATMENT IS MEDICALLY APPROPRIATE

43. Since at least early 2015, CDPHP's Chronic Hepatitis C policy has imposed numerous restrictions on coverage for treatment of members who have chronic HCV infection, including:

- Requiring at least a fibrosis score of F2[15] or otherwise being in need of "immediate treatment" (a very narrow category that includes severe complications or hepatocellular carcinoma while awaiting liver transplant);
- Requiring a "readiness" assessment that includes abstinence from illicit drugs or alcohol abuse for at least six months;
- Excluding members with decompensated cirrhosis (cirrhosis such that the liver is no longer well-functioning);
- Excluding members with reduced life expectancy due to co-morbidities;
- Requiring the authorizing provider to be a gastroenterologist, hepatologist, HIV specialist, or infectious disease specialist.

44. These restrictions are clearly contrary to prevailing medical guidelines and generally-accepted treatment standards, as set forth in Section II.B:

45. **Fibrosis Level/Immediate Need Requirement:** CDPHP requires "[e]vidence of severe hepatic fibrosis confirmed by METAVIR score F2, F3, or F4." This requirement forces a member's condition to deteriorate, in the form of developing advanced liver disease, before

[14] Id.
[15] Under the previous policy, in effect from May 2015 through December 2015, members were required to have a fibrosis score of F3.

treatment will be covered by the plan, unless the member otherwise qualifies for treatment due to a showing of "immediate need."

46. However, Harvoni, the medication that CDPHP covers for treatment of the most common form of HCV infection, is approved by the FDA for use regardless of fibrosis level. Further, there is no support in the medical literature for not treating early-stage HCV infection, and the Guidance has unequivocally and consistently supported treating all individuals with HCV infection (except those with short life expectancies that cannot be remediated by treating HCV or through other therapies).

47. **Drug and Alcohol Restrictions:** CDPHP's medical necessity criteria also exclude from coverage a group of individuals who would benefit significantly from treatment: individuals who suffer from dependence on drugs or alcohol.

48. There is no medical basis for rejecting coverage of treatment for this group of individuals, and as set forth in Paragraphs 37 through 38, there is a compelling medical basis for treating this population. This criterion broadly restricts coverage even to individuals whose physicians found them capable of completing their treatment regimens. Not only is treatment important from a public health perspective given the increased risk of transmission, but treatment may in turn empower these patients to address other pressing health issues, such as drug and alcohol abuse.

49. Indeed, based on an analysis of the relevant research, the Guidance concluded that requirements for pretreatment screening for illicit drug or alcohol use "should be abandoned, because they create barriers to treatment, add unnecessary cost and effort, and potentially exclude populations that are likely to obtain substantial benefit from therapy."[16]

[16] AASLD and IDSA, When and in Whom to Initiate HCV Therapy, http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy (last visited April 13, 2016).

50. **Decompensated Cirrhosis, Decreased Life Expectancy, and Specialist Restrictions:** Similarly, CDPHP is unduly restricting coverage by broadly refusing to cover treatment because the member has decompensated cirrhosis, any reduced life expectancy due to co-morbidities, or because the prescribing provider is not a specialist. Individuals with decompensated cirrhosis can be successfully treated, and indeed Harvoni is specifically approved for treatment of this population. The exclusion based on life expectancy is much broader than the Guidance's position that treatment is not recommended for individuals whose life expectancy is less than one year, even with treatment. Finally, requiring that the prescribing practitioner be a specialist may prevent members from ever receiving treatment for HCV: members who are already seeing a practitioner who is not a specialist, but who is trained to diagnose and treat chronic HCV might never receive treatment if they are required to find a new specialist.

51. CDPHP's array of restrictions and exclusions are contrary to generally-accepted standards of care and prevailing medical guidelines, and therefore improperly limit coverage of medically appropriate treatment for many of their members.

52. As a result of the above restrictions, many of CDPHP's members who sought coverage for treatment have been denied: of the 349 claims for Harvoni in 2014 and 2015, CDPHP approved just over 50% for coverage.

53. From October through December of 2014, CDPHP denied approximately 46% of the commercial (i.e., not Medicaid or Medicare) member requests for Harvoni, and of those requests, 80% had fibrosis levels F0 - F2.

54. Significantly, as of October 16, 2015, eight members (with fibrosis levels at F2 or under) appealed CDPHP's denial of Harvoni on medical necessity grounds to the New York State Department of Financial Services (such appeals are called "external appeals"), and all of

the denials were overturned. Each independent reviewer (reviewers are physicians) reversed CDPHP's denial of coverage on the grounds that there is no medical basis to restrict coverage based on fibrosis status.

55. Samples of the external reviewers' comments in their reversal letters include:

- "As per the AASLD guidelines, all patients with chronic active hepatitis C are eligible for treatment and should be treated with FDA approved antiviral therapy regardless of fibrosis score."
- "Evidence clearly supports treatment in all HCV-infected persons, except those with limited life expectancy (less than 12 months) due to non-liver related comorbid conditions."
- "The goal of treatment of HCV-infected persons is to reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure as evidenced by an SVR."
- "Although treatment is assigned *priority* for patients with advanced fibrosis including those with compensated cirrhosis[17] or extrahepatic manifestations, nowhere in the guidelines does it suggest treatment should be withheld in patients with less advanced disease, unless the option to defer treatment is the mutual decision of the patient and provider."
- "The determination was not reasonable or in the best interests of the patient, as it lacked essential components of current evidence and treatment paradigms used in the care of hepatitis C."
- Treating the member, who has a Metavir F0-F1 fibrosis, "represents the standard of care for her chronic hepatitis C, genotype 1a."
- "If treated now, rather than after she has developed more fibrosis or cirrhosis with resultant morbidity and mortality, her likelihood of cure is higher, and unnecessary suffering can be prevented."

IV. CDPHP'S RESTRICTIONS HAVE BEEN BASED ON UNDISCLOSED COST CONSIDERATIONS, NOT LACK OF MEDICAL NEED

56. As set forth above, the various restrictions and exclusions for coverage of chronic HCV infection treatment under CDPHP's policy do not reflect the findings of any clinical

[17] "Compensated cirrhosis" refers to cirrhosis with a still-functioning liver.

guidelines or studies that treatment is unnecessary, inappropriate or contraindicated for the populations excluded from coverage under CDPHP's medical necessity criteria.

57. Instead, CDPHP's decision to restrict coverage has been based on the potential expense to CDPHP of covering treatment for all of its member with chronic HCV infection.

58. Treatment of all individuals with chronic HCV infection was particularly concerning to CDPHP due to a combination of the high cost of treatment and the large numbers of individuals who were anticipated to be seeking treatment.

59. While developing its medical necessity criteria for HCV treatment, CDPHP routinely analyzed the cost of treating all members with HCV infection, and these expense projections directly impacted the development of its medical necessity criteria.

60. CDPHP's projections showed that covering treatment for all members with chronic HCV would – at the price at that time – be an enormous expense, costing many millions of dollars.

61. Participating CDPHP physicians were encouraged to conform their prescribing practices to align with the policy, to consider the cost of treatment to the health plans and to prioritize patients accordingly.

62. Notably, the restrictive medical necessity criteria in CDPHP's Chronic Hepatitis C Pharmaceutical Treatment Policy were not included in earlier versions of the policy, and first appeared in the version of the policy finalized on October 1, 2014 – several months after Sovaldi was approved by the FDA.

63. CDPHP's plan documents assert that it covers treatment that is "medically necessary" as defined in the policies, and these definitions list the various factors CDPHP will consider when making a determination of whether and when care will be deemed medically

necessary. The definitions do not include cost as a factor CDHP considers in determining whether and when treatment for a disease will be covered (although relative cost may be considered when determining which treatment will be covered). Members and potential members diagnosed with Hepatitis C were not apprised of this through the plan documents, and therefore could not, and did not, know that coverage for treatment of their disease could be limited due to cost.

V. CDPHP'S COVERAGE OF HEPATITIS C TREATMENT IS INCONSISTENT WITH ITS PLAN DOCUMENTS

64. As a result of its restrictive coverage for treatment of chronic Hepatitis C, CDPHP fails to cover treatment that meets its own plans' definitions of "medically necessary."

65. Under its own definitions, treatment for all individuals with chronic HCV infection, except those with less than one year of life expectancy even with treatment, is "medically necessary" and should be covered.

66. There is general medical consensus that treatment for chronic HCV, at any stage of the disease and regardless of fibrosis level, is needed to (a) cure the members' existing disease and (b) prevent the member's medical condition from deteriorating. Such deterioration could include, but is not limited to, irreversible harm to the liver, and even death.

67. As set forth above, the Guidance developed by the three leading medical societies in the relevant medical fields unambiguously states that treatment with the newest medications is clinically appropriate for all individuals with chronic HCV – not just those with advanced liver scarring or with significant complications from the disease. This Guidance, and its recommendation to treat nearly all individuals with chronic HCV, was routinely relied on by external reviewers when reviewing – and then reversing – CDPHP's claim denials. See supra at

¶ ¶ 54-55.

68. The Guidance and current medical literature leave no doubt that not treating members' chronic HCV adversely affects their medical condition.

69. There is no less costly alternative treatment to these newer medications that is as likely to produce equivalent therapeutic or diagnostic results.

70. Treatment that cures a serious and contagious disease such as chronic HCV infection is manifestly not for the "convenience" of the provider or the member.

71. Nearly all, if not all, of the sources of information and opinion CDPHP says it will consult in developing medical necessity criteria support treatment for nearly all individuals with chronic HCV when treatment is recommended by the treating physician.

72. Based on the foregoing, treatment for HCV infection is unquestionably "medically necessary" under the definitions in members' health plans. By denying coverage for treatment based on medically unsupportable restrictions, such as fibrosis level, CDPHP is failing to meet its obligations under its policies and is misleading members about the scope of their coverage for medically necessary care.

FIRST CAUSE OF ACTION:
NEW YORK EXECUTIVE LAW § 63(12)
REPEATED AND PERSISTENT FRAUD

73. New York Executive Law § 63(12) authorizes the Attorney General to bring an action to enjoin and obtain restitution and damages for "repeated fraudulent acts or … persistent fraud … in the carrying on, conducting or transaction of business."

74. As set forth above, CDPHP fails to disclose the role that cost plays in making medical necessity determinations. Further, CDPHP's plan documents mislead members into believing that

all medically necessary care will be covered, when in fact CDPHP refuses to cover treatment for Hepatitis C consistent with generally-accepted standards of care and prevailing medical guidelines, and inconsistent with the FDA's approved indications for the medications on its formulary. Rather than cover care for all members for whom treatment is medically necessary, it is only covering treatment for members whose care it deems *most* medically necessary.

75. By reason of the conduct alleged in Paragraphs 1 through 72 above, CDPHP has engaged in repeated fraudulent acts or persistent fraud in violation of New York Executive Law § 63(12).

SECOND CAUSE OF ACTION:
NEW YORK GENERAL BUSINESS LAW § 349
DECEPTIVE ACTS AND PRACTICES

76. New York General Business Law § 349 prohibits "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service" in New York State.

77. As set forth above, CDPHP fails to disclose the role that cost plays in making medical necessity determinations. Further, CDPHP's plan documents mislead members into believing that all medically necessary care will be covered, when in fact CDPHP refuses to cover treatment for Hepatitis C consistent with generally-accepted standards of care and prevailing medical guidelines, and inconsistent with the FDA's approved indications for the medications on its formulary. Rather than cover care for all members for whom treatment is medically necessary, it is only covering treatment for members whose care it deems *most* medically necessary.

78. By reason of the conduct alleged in Paragraphs 1 through 72 above, CDPHP has engaged in deceptive conduct in violation of New York General Business Law § 349.

THIRD CAUSE OF ACTION:
PURSUANT TO NEW YORK EXECUTIVE LAW § 63(12) – ILLEGALITY
VIOLATION OF GBL § 349

79. A violation of state law constitutes illegality within the meaning of New York Executive Law § 63(12) and is actionable thereunder when persistent or repeated.

80. CDPHP's repeated and persistent violations of GBL § 349 are thus violations of New York Executive Law § 63(12).

FOURTH CAUSE OF ACTION:
NEW YORK INSURANCE LAW § 3217-a(a)(1);
NEW YORK INSURANCE LAW § 4324(a)(1)
DISCLOSURE OF MEDICAL NECESSITY DEFINITION AND BENEFIT LIMITATIONS

81. Insurance Law § 3217-a(a)(1) and New York Insurance Law § 4324(a)(1) requires insurers to disclose "a description of coverage provisions; health care benefits; benefit maximums, including benefit limitations; and exclusions of coverage, including the definition of medical necessity used in determining whether benefits will be covered."

82. As set forth above, CDPHP does not fully define "medically necessary" in its plan documents because it fails to disclose that cost of treatment is one of the various factors used to determine whether care is deemed medically necessary.

83. By reason of the conduct alleged in Paragraphs 1 through 72 above, CDPHP has acted in violation of New York Insurance Law § 3217-a(a)(1) and New York Insurance Law § 4324(a)(1).

FIFTH CAUSE OF ACTION
PURSUANT TO NEW YORK EXECUTIVE LAW § 63(12) – ILLEGALITY
VIOLATION OF NEW YORK INSURANCE LAW §§ 3217-a(a)(1) AND 4324(a)(1)

84. A violation of state law constitutes illegality within the meaning of New York Executive Law § 63(12) and is actionable thereunder when persistent or repeated.

85. CDPHP's repeated and persistent violations of New York Insurance Law §§ 3217-a(a)(1) and 4324(a)(1) are thus violations of New York Executive Law § 63(12).

SIXTH CAUSE OF ACTION:
NEW YORK PUBLIC HEALTH LAW § 4408(1)(a)
DISCLOSURE OF MEDICAL NECESSITY DEFINITION AND BENEFIT LIMITATIONS

86. Public Health Law § 4408(1)(a) requires Health Maintenance Organizations to disclose "a description of coverage provisions; health care benefits; benefit maximums, including benefit limitations; and exclusions of coverage, including the definition of medical necessity used in determining whether benefits will be covered."

87. As set forth above, CDPHP does not fully define "medically necessary" in its plan documents because it fails to disclose that cost of treatment is one of the various factors used to determine whether care is deemed medically necessary.

88. By reason of the conduct alleged in Paragraphs 1 through 72 above, CDPHP has acted in violation of New York Public Health Law § 4408(1)(a).

SEVENTH CAUSE OF ACTION
PURSUANT TO NEW YORK EXECUTIVE LAW § 63(12) – ILLEGALITY
VIOLATION OF NEW YORK PUBLIC HEALTH LAW § 4408(1)(a)

89. A violation of state law constitutes illegality within the meaning of New York Executive Law § 63(12) and is actionable thereunder when persistent or repeated.

90. CDPHP's repeated and persistent violations of New York Public Health Law § 4408(1)(a) are thus violations of New York Executive Law § 63(12).

PRAYER FOR RELIEF

WHEREFORE, the People of the State of New York respectfully request that a judgment and order be issued:

A. Adjudging and decreeing that CDPHP has violated New York Executive Law § 63(12), New York General Business Law § 349, New York Insurance Law § 3217-a(a)(1), New York Insurance Law § 4324(a)(1), and New York Public Health Law § 4408(1)(a);

B. Permanently enjoining CDPHP from denying coverage of chronic HCV treatment except to the extent that treatment is contraindicated or otherwise not recommended pursuant to the medication's label and/or under the Guidance; this should include, but is not limited to, enjoining CDPHP from denying coverage based on members' fibrosis level and/or use of alcohol or drugs;

C. Permanently enjoining CDPHP from excluding appropriately trained non-specialists from authorizing treatment;

D. Directing CDPHP to revise its medical necessity criteria to reflect the changes set forth in B and C above;

E. Directing CDPHP to send a letter to all members whose claims for chronic HCV treatment were denied on medical necessity grounds since November 1, 2013 advising that the medical necessity criteria for treatment of HCV has changed since their claim was submitted and that they may now be eligible for coverage;

F. Directing CDPHP to send a letter to all medical providers in its network who have submitted claims for chronic HCV treatment since November 1, 2013, advising that

the medical necessity criteria for treatment of HCV have changed and enclosing a copy of the revised HCV prior authorization criteria;

G. Directing CDPHP to pay Plaintiff's costs, including additional costs in the amount of $2,000 pursuant to CPLR § 8303(a)(6);

H. Imposing civil penalties against CDPHP in the amount of $5,000 for each violation of GBL § 349, pursuant to GBL § 350-d, and penalties as deemed appropriate pursuant to the New York State Insurance Law and New York State Public Health Law; and

I. Granting all other relief that is just and proper.

Dated: New York, NY
April 14, 2016

Respectfully submitted,

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