Nos. 22-1491(L), 22-1492

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

UNITED STATES OF AMERICA and COMMONWEALTH OF VIRGINIA,

Plaintiffs-Appellants,

v.

WALGREEN CO.,

Defendant-Appellee.

On Appeal from the United States District Court
for the Western District of Virginia

BRIEF OF THE NATIONAL HEALTH LAW PROGRAM AS *AMICUS CURIAE* IN SUPPORT OF DEFENDANT-APPELLEE AND AFFIRMANCE

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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- In civil, agency, bankruptcy, and mandamus cases, a disclosure statement must be filed by **all** parties, with the following exceptions: (1) the United States is not required to file a disclosure statement; (2) an indigent party is not required to file a disclosure statement; and (3) a state or local government is not required to file a disclosure statement in pro se cases. (All parties to the action in the district court are considered parties to a mandamus case.)
- In criminal and post-conviction cases, a corporate defendant must file a disclosure statement.
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No. 22-1491(L), 22-1492 Caption: United States of America and Commonwealth of Virginia v. Walgreen Co.

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(name of party/amicus)

who is amicus curiae, makes the following disclosure:
(appellant/appellee/petitioner/respondent/amicus/intervenor)

1. Is party/amicus a publicly held corporation or other publicly held entity? ☐YES ☑NO

2. Does party/amicus have any parent corporations? ☐YES ☑NO
If yes, identify all parent corporations, including all generations of parent corporations:

3. Is 10% or more of the stock of a party/amicus owned by a publicly held corporation or other publicly held entity? ☐YES ☑NO
If yes, identify all such owners:

4. Is there any other publicly held corporation or other publicly held entity that has a direct financial interest in the outcome of the litigation? ☐YES ☑NO
If yes, identify entity and nature of interest:

5. Is party a trade association? (amici curiae do not complete this question) ☐YES ☐NO
If yes, identify any publicly held member whose stock or equity value could be affected substantially by the outcome of the proceeding or whose claims the trade association is pursuing in a representative capacity, or state that there is no such member:

6. Does this case arise out of a bankruptcy proceeding? ☐YES ☑NO
If yes, the debtor, the trustee, or the appellant (if neither the debtor nor the trustee is a party) must list (1) the members of any creditors' committee, (2) each debtor (if not in the caption), and (3) if a debtor is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of the debtor.

7. Is this a criminal case in which there was an organizational victim? ☐YES ☑NO
If yes, the United States, absent good cause shown, must list (1) each organizational victim of the criminal activity and (2) if an organizational victim is a corporation, the parent corporation and any publicly held corporation that owns 10% or more of the stock of victim, to the extent that information can be obtained through due diligence.

Signature: /s/ Martha Jane Perkins Date: 10/03/2022

Counsel for: National Health Law Program

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INTEREST OF THE *AMICUS CURIAE*[1]

The National Health Law Program (NHeLP) files this brief pursuant to Fed. R. App. P. 29. Without taking a position on the other legal issues in this case, NHeLP's brief supports affirming the district court's holding that Virginia's prior authorization criteria for necessary Hepatitis C medications violated the Medicaid Act. Founded in 1969, NHeLP advocates, educates, and litigates at the federal and state levels to further its mission of improving access to quality health care for low-income people. In particular, NHeLP has worked to ensure that Medicaid beneficiaries have access to necessary prescription drugs, including those used to treat Hepatitis C. *See, e.g., Edmonds v. Levine*, 417 F. Supp. 2d 1323 (S.D. Fla. 2006) (access to Neurontin in Florida Medicaid); *J.E.M. v. Kinkade*, No. 16-cv-04273-SRB (W.D. Mo. Feb. 2, 2017) (access to Hepatitis C drugs in Missouri Medicaid), https://healthlaw.org/wp-content/uploads/2019/06/40-Order-PI.pdf. As such, NHeLP has an interest in the outcome of this case.

[1] Pursuant to Fed. R. App. P. 29(a)(4)(E), no counsel for a party authored this brief in whole or in part, and no persons other than *amicus curiae* made a monetary contribution to its preparation or submission. The parties consented to the filing of this brief.

SUMMARY OF ARGUMENT

After the FDA approved breakthrough direct-acting antiviral drugs (DAAs) to treat Hepatitis C in 2013, they became the standard of care. DAAs offered people with Hepatitis C a cure for a serious, life-threatening illness that caused liver damage, liver cancer, liver failure, and death. Because these drugs were expensive, however, some states, including Virginia, refused to cover them for all Medicaid beneficiaries who needed them. They instead required Medicaid beneficiaries with Hepatitis C to meet arbitrary disease severity and sobriety requirements. This violated federal Medicaid law.

Created in 1965, Medicaid is a joint federal-state medical assistance program for people "whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396-1; *see id.* §§ 1396–1396w-6 ("the Medicaid Act"). State participation in Medicaid is optional. However, a state that chooses to participate, and thereby receive federal matching funds for program expenditures, "must comply with requirements imposed both by the Act itself and by the Secretary of Health and Human Services." *Schweiker v. Gray Panthers*, 453 U.S. 34, 37 (1981); *see also Antrican v. Odom*, 290 F.3d 178, 183 n.2 (4th Cir. 2002) ("[If states] choose to participate, and succeed in having their plans approved by the Secretary, they must implement and operate Medicaid programs that comply with detailed federally mandated standards.") The Medicaid Act requires states to cover

certain basic services and gives them the option to cover other services, including prescription drugs. 42 U.S.C. §§ 1396a(a)(10), 1396d(a).

States that choose to provide prescription drugs must adhere to detailed requirements for their coverage. *See* 42 U.S.C. §§ 1396a(a)(54), 1396r-8, 1396b(i)(10); *Edmonds*, 417 F. Supp. 2d at 1330 (S.D. Fla. 2006) (describing a "carefully constructed" statutory scheme for coverage of prescription drugs). States must cover all FDA-approved drugs offered by manufacturers that have entered into a rebate agreement with the government when the drugs are prescribed for medically accepted indications, with certain narrow exceptions. 42 U.S.C. §§ 1396r-8(a), 1396r-8(k)(2), 1396r-8(d)(1)(B). Medically accepted indications include uses for which the drugs are FDA-approved. *Id*. § 1396r-8(k)(6). Because the FDA approved DAAs for use in all people with chronic Hepatitis C, states were required to cover them for that entire population. Despite the U.S.'s arguments, states could not use the prior authorization process to circumvent this requirement. Virginia's coverage restrictions were illegal.

ARGUMENT

I. Direct-Acting Antivirals Are Lifesaving Treatment for People with Chronic Hepatitis C.

a. Background on Hepatitis C

Hepatitis C is a contagious and dangerous liver disease that results from infection with Hepatitis C virus (HCV). Acute HCV infection occurs within the first six months of exposure, and for most people becomes chronic Hepatitis C, a long-term, progressive illness that leads to degeneration of the liver through worsening scarring. CDC, *Hepatitis Questions and Answers for the Public, Overview and Statistics,* https://www.cdc.gov/hepatitis/hcv/cfaq.htm (last visited Oct. 3, 2022) ("CDC Hepatitis C Q&As").

Hepatitis C has also been associated with other health issues such as increased risk of diabetes, cardiovascular disease, and cognitive impairment. *See* Kirat Gill, et al., *Hepatitis C virus as a systemic disease: reaching beyond the liver*, 10 Hepatology Int.'l, 415 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4819925/. Left untreated, chronic Hepatitis C can result in devastating long-term health consequences, including liver damage, liver cancer, liver failure, and death. CDC Hepatitis C Q&A.

The progression of Hepatitis C is measured using a metavir score, which ranges from F0 through F4 and represents the degree of inflammation and fibrosis

(or scarring of the liver). The rate of progression varies markedly among individuals, and one study found that the disease progressed faster in people with the lowest metavir scores. *See* Marija Zeremski et al., *Fibrosis Progression in Patients With Chronic Hepatitis C Virus Infection*, 214 J. Infectious Diseases 1164 (2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6281340/.

A metavir score of stage F3 or F4 indicates advanced liver disease, with stage F4 referred to as cirrhosis. AASLD/IDSA, *When and in Whom to Initiate HCV Therapy*, (Nov. 6, 2019), https://www.hcvguidelines.org/evaluate/when-whom ("AALSD/IDSA Guidelines"); UpToDate, *METAVIR fibrosis and activity score* https://www.uptodate.com/contents/image?imageKey=GAST%2F98097 (last visited Oct. 3, 2022). Once people have advanced liver disease, they have a substantial risk of developing complications, including cancer, and they require long-term follow-up and cancer surveillance regardless of the treatment outcome. *See* AASLD/IDSA Guidelines. Liver damage done by cirrhosis is usually irreversible. UpToDate, *Patient information: Cirrhosis (Beyond the Basics)*, https://www.uptodate.com/contents/cirrhosis-beyond-the-basics (last visited Oct. 3, 2022).

As of 2016, an estimated 2.7 to 3.9 million people in the United States had chronic Hepatitis C. CDC, *Hepatitis C FAQs for the Public*, (May 23, 2016),

https://web.archive.org/web/20160701235921/http://www.cdc.gov/hepatitis/hcv/cfaq.htm. At that time, the CDC estimated that of the people infected with HCV, 75-85% would develop chronic disease, and of the people with chronic disease, 60-70% would develop chronic liver disease, 5-20% would develop cirrhosis over a period of 20-30 years, and 1-5% would die from cirrhosis or liver cancer. *Id.* Hepatitis C was the leading cause of cirrhosis and liver cancer and the most common reason for liver transplantation in the United States. *Id.* Approximately 19,000 people died every year from Hepatitis C-related liver disease. *Id.*

b. FDA Approval of Direct-Acting Antivirals for All People with Chronic Hepatitis C Led to a New Standard of Care for Treatment.

Prior to the approval of DAAs, treatment for Hepatitis C meant "months and months of painful drug injections" and cured only 40% to 50% of people. FDA, *Hepatitis C Treatments Give Patients More Options* (Mar. 4, 2017), https://www.fda.gov/consumers/consumer-updates/hepatitis-c-treatments-give-patients-more-options#. This prior treatment with drugs called interferons caused significant side effects, often making people feel ill during their 6-to-12-month course of treatment. *Id.* Sometimes patients with advanced liver disease could not even take the traditional treatment because the injections made them worse. *See id.*

This all changed with the introduction of DAAs, pills with a "90% to 100% cure rate" in as few as 12 weeks of treatment. *See id.* From 2013 to 2016, the FDA

approved eight DAAs to treat Hepatitis C, including the three DAAs at issue in this case—Sovaldi (400 MG tablets), Harvoni (90MG-400MG tablets), and Daklinza (60 MG tablets). *See* Hepatitis Central, *Medications to Treat Hepatitis C – A Timeline*, https://www.hepatitiscentral.com/medications-to-treat-hepatitis-c-a-timeline/ (last visited Oct. 3, 2022); JA737 (Op. 5). They were approved for the following use:

- Sovaldi was approved in 2013 "for the treatment of chronic hepatitis C (CHC) infection" with efficacy established in people with genotype[2] 1, 2, 3, or 4 infection.[3]

- Harvoni was approved in 2014 "for the treatment of chronic hepatitis C genotype 1 infection in adults,"[4] and subsequently in 2015 "for the treatment of chronic hepatitis C virus (HCV) genotype 1, 4, 5, or 6 infection."[5]

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[2] HCV "genotype" indicates "the strain of the virus to which [people] were exposed when they were infected" as determined by a blood test. U.S. Dep't of Veterans Affairs, *Genotypes: Hepatitis C*, https://www.hepatitis.va.gov/hcv/background/genotypes.asp (last visited Sept. 30, 2022). Approximately 75% of Americans infected with HCV have genotype 1 of the virus, 20-25% have genotypes 2 or 3, and small numbers of people have genotypes 4, 5, or 6. *Id.*

[3] Sovaldi's 2013 FDA label is available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204671s000lbl.pdf. In August 2015, the label was changed to indicate use of Sovaldi "for the treatment of genotype 1, 2, 3 or 4 chronic hepatitis C virus (HCV) infection." It is available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204671s002lbl.pdf.

[4] Harvoni's 2014 FDA label is available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205834s000lbl.pdf.

[5] Harvoni's 2015 FDA label is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/205834s006lbl.pdf.

- Daklinza was approved in 2015 "for the treatment of chronic HCV genotype 3 infection."[6]

The approval of these new DAA drugs was heralded as the "advent of interferon-free treatments for hepatitis C" and "a landmark shift" in the treatment of the disease. Richard Knox, *Treatments: FDA Expected To Approve New, Gentler Cure For Hepatitis C*, NPR (Dec. 5, 2013), https://www.npr.org/sections/healthshots/2013/12/05/248934833/fda-set-to-approve-hepatitis-drug. The FDA called the advances in treatment "transformative" and formally designated several DAAs as "breakthrough therapies." *See* FDA, *CDER Breakthrough Therapy Designation Approvals* (Dec. 31, 2021), https://www.fda.gov/media/95302/download (listing Sovaldi and Harvoni as breakthrough therapies for the treatment of chronic Hepatitis C).

The approval of DAAs resulted in a rapid and fundamental change to the standard of care for treatment of Hepatitis C. In 2015, the American Association for the Study of Liver Diseases (AASLD) issued a statement supporting the provision of DAAs to all people with Hepatitis C. Pointing to the approval of multiple DAAs "that offer nearly universal cure rates with minimal side effects," the AASLD statement "endorse[d] treating patients with HCV" with DAAs "as the standard of

[6] Daklinza's 2015 FDA label is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206843s000lbl.pdf.

care." PR Newswire, *Leading Liver Doctors: Hepatitis C Patients Must Be Treated* (Nov. 16, 2015), https://www.prnewswire.com/news-releases/leading-liver-doctors-hepatitis-c-patients-must-be-treated-300179479.html. AASLD explicitly opposed requiring people to wait for DAA treatment "until their disease has progressed and the liver is further damaged," explaining that "there is no medical evidence to justify that position and much to justify treating all patients." *Id.* In their 2016 Guidelines, AASLD and the Infectious Diseases Society of America ("AASLD/IDSA") gave a "strong recommendation for treatment for nearly all HCV-infected patients," excepting only those with short life expectancies that could not be remediated by treating HCV, by transplantation, or by other directed therapy. AASLD/IDSA, *Recommendations for Testing, Managing, and Treating Hepatitis C* 30, (2016), https://web.archive.org/web/20160803113405/http://hcvguidelines.org/sites/default/files/HCV-Guidance_July_2016_a.pdf ("2016 AASLD/IDSA Treatment Guidelines").

State health departments acknowledged the importance of DAAs as well, with the Virginia Department of Health writing in its 2016 report that DAAs "have high cure rates for Hepatitis C and minimal side effects" and are most effective when administered earlier in the progression of the disease. Va. Dep't of Health, Off. of Epidemiology, *Virginia Hepatitis C Epidemiologic Profile* 32 (2016), https://www.vdh.virginia.gov/content/uploads/sites/10/2016/06/Virginia-Hepatitis-

C-Epidemiologic-Profile-2016.pdf ("2016 Virginia Hepatitis C Epidemiologic Profile").

c. State Coverage Policies Prevented Medicaid Beneficiaries from Accessing this Lifesaving Treatment.

While DAAs were miraculous in their ability to cure a devastating chronic condition, they were also quite expensive. In 2015 and 2016, a full course of treatment for DAAs might cost state Medicaid programs as much as $96,000 (before accounting for federal matching funds). JA737 (Op. 5).[7] In a misguided effort to reduce costs, some state Medicaid agencies refused to provide these revolutionary, life-changing treatments to beneficiaries and instead adopted arbitrary coverage restrictions. *See* Letter from Jane Perkins, Nat'l Health L. Program, to Ron Wyden & Charles Grassley, U.S. Senate Comm. on Fin. 3-4 (Mar. 4, 2016), https://healthlaw.org/wp-content/uploads/2016/03/NHeLP-Letter-to-Wyden-Grassley-on-Sovaldi-FINAL-030416.pdf (providing examples); JA96-99 (CMS

[7] These cost measurements were, however, misleading given that over the long run, DAA treatments are cost effective. In 2016, even the Virginia Department of Health acknowledged that despite the upfront cost, DAAs would still be cost effective: "Although curative hepatitis C treatment can exceed $80,000, the cost of liver transplantation is estimated at $577,000. Studies show that DAAs are cost-effective when compared to the significant long-term costs of chronic hepatitis C. From 2010-2019, decompensated cirrhosis and hepatocellular cancer in people younger than 65 years are estimated to lead to 720,000 life years lost, $21.3 billion in societal costs, and indirect associated costs of $54.2 billion." 2016 Virginia Hepatitis C Epidemiologic Profile at 32 (internal citations omitted).

Release No. 172 on Nov. 5, 2015) (reminding states of their obligations under the Medicaid Act to provide DAA treatment).

Those states included Virginia. During the relevant time period for this case (January 2015 to July 2016), Virginia excluded coverage of DAAs for Medicaid beneficiaries with chronic Hepatitis C through "seemingly arbitrary and cost-based disease severity and substance use requirements." JA759 (Op. 27). Virginia only covered DAAs for beneficiaries whose metavir stage was F3 or F4, who had fibrosis scores of greater than or equal to .59, or who had documented cirrhosis. JA737-738 (Op. 5-6). It also required, as a prerequisite to DAA treatment, that beneficiaries had "not used drugs or alcohol in the prior six months, as confirmed by urine drug screen results or physician certification." JA738 (Op. 6).

As explained above, these restrictions had no basis in science or medicine and ran counter to the standard of care. The FDA approved the use of DAAs for people infected with chronic HCV regardless of fibrosis stage or drug or alcohol use. And the AASLD/IDSA Guidelines specifically rejected restricting access to treatment based on fibrosis stage, noting "strong and accumulating evidence against deferral" because DAAs decrease all-cause morbidity and mortality, prevent transmission of HCV, and improve quality of life for people treated "regardless of baseline fibrosis." 2016 AASLD/IDSA Treatment Guidelines at 40. The Guidelines concluded that "[d]eferral practices based on fibrosis stage alone are inadequate and shortsighted."

Id. The Guidelines also specifically rejected conditioning access to DAAs on sobriety (for any duration) prior to treatment. They noted that there are "no data to support" the utility of such restrictions and concluded they "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." *Id.* at 38 (emphasis added).[8]

State restrictions on coverage of DAAs had a devastating impact on Medicaid beneficiaries. For example, Ms. M, a low-income single mother in Missouri with Hepatitis C, experienced frequent pain and fatigue due to the disease and was so afraid of passing HCV on to her daughters that she bleached her bathtub every time she shaved her legs. Compl. ¶¶ 63, 66, 67, *J.E.M. v. Kinkade*, No. 16-cv-04273-SRB (W.D. Mo. Oct. 18, 2016), https://healthlaw.org/wp-content/uploads/2019/06/1-complaint.pdf. Although Ms. M was prescribed a DAA, Missouri denied her treatment because her fibrosis score was lower than F3. *Id.* ¶¶ 68-69, 73. Similarly, Sarah Jackson, an Indiana Medicaid beneficiary and recently postpartum mother, required DAAs to ensure she did not pass Hepatitis C on to her child via

[8] Not only did sobriety requirements have no clinical basis, they also further stigmatized people who use drugs, creating distrust with medical providers. Public health authorities and advocates made a concerted effort to push against that stigma. *See, e.g.*, NASTAD, *Science over Stigma: The Public Health Case Against HCV Treatment Sobriety Restrictions* (2017), https://nastad.org/sites/default/files/2021-12/PDF-Science-Over-Stigma.pdf.

breastfeeding. *See* Compl. ¶¶ 28-29, 31, *Jackson v. Sec'y of Ind. Fam. & Soc. Servs. Admin.*, No. 1:15-cv-01874 (S.D. Ind. Nov. 25, 2015). Indiana refused to cover her treatment because her Hepatitis C had not yet progressed to an advanced stage and she was not co-infected with HIV or post-liver transplant. *Id.* ¶ 29. In Pennsylvania, Dara Dundon, a Medicaid beneficiary who was diagnosed with Hepatitis C in 2005, requested coverage for DAAs four times, but each time was told she could not access the treatment until her condition got worse. *See* Ryan Loughlin & Joie Chen, *For many medicaid patients, hepatitis C wonder drugs are out of reach*, Aljeezera Am. (Dec. 10, 2015), http://america.aljazeera.com/watch/shows/america-tonight/articles/2015/12/10/for-many-medicaid-patients-hepatitis-c-wonder-drugs-are-out-of-reach.html.

DAAs offered Medicaid beneficiaries with Hepatitis C such Ms. M, Ms. Jackson, and Ms. Dundon a cure. State coverage restrictions not only prevented low-income Medicaid beneficiaries with Hepatitis C from receiving necessary treatment in accordance with the standard of care, they also violated the Medicaid Act, as described below.

II. The Medicaid Act Sets Forth a Specific Standard for the Scope of Coverage of Prescription Drugs, Mandating that States Cover Drugs Prescribed for Medically Accepted Indications.

Since it was enacted in 1965, the Medicaid Act has given states the option to cover "prescribed drugs" for enrollees." Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286, 351, § 1905(a)(12) (1965) (codified at 42 U.S.C. § 1396d(a)(12)). In 1990, Congress amended the Medicaid Act to establish detailed requirements for coverage of outpatient prescription drugs, placing the requirements in a new provision, section 1396r-8. Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388, 1388-143 to 1388-161, § 4401 (1990) (codified at 42 U.S.C. §§ 1396a(a)(54), 1396r-8, 1396b(i)(10)).

In an effort to control Medicaid spending while ensuring beneficiaries' access to prescription drugs, Congress made a deal with drug manufacturers. *See* H. Rep. No. 101-881, 1990 WL 200617, at *2108-2110 (1990) (describing the purpose of the amendment). To have their prescription drugs covered under the Medicaid program, manufacturers must provide rebates to the federal government or individual states. 42 U.S.C. § 1396r-8(a). In return, states must provide broad coverage of the manufacturers' FDA-approved prescription drugs. *See id*. §§ 1396r-8(k)(2) (defining covered outpatient prescription drugs), 1396r-8(d)(1) (listing permissible restrictions on the coverage of outpatient prescription drugs); *see also* H. Rep. No. 101-811, 1990 WL 200617, at *2110 (1990) (noting that after the

change in the law, states electing to cover prescription drugs "would be required to cover all of the drugs of any manufacturer" with a rebate agreement in place); *PhRMA v. Walsh*, 538 U.S. 644, 652 (2003) (describing the Medicaid drug rebate program); *Medicaid Drug Rebate Program (MDRP)* (updated Nov. 8, 2021), https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html (last visited Oct. 3, 2022) (same).

Specifically, states must cover all FDA-approved drugs when they are prescribed for a medically accepted indication. 42 U.S.C. §§ 1396r-8(k)(2), 1396r-8(d)(1)(B)(i); *see also* JA97 (CMS Release No. 172 on Nov. 5, 2015) (reminding states 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"). A medically accepted indication is a use that is FDA-approved or "supported by one or more citations included or approved for inclusion in any of the compendia" listed in section 1396r-8(g). 42 U.S.C. § 1396r-8(k)(6). By requiring states to cover prescription drugs for any medically accepted indication, Congress established a specific standard for the scope of coverage for outpatient prescription drugs.

To be sure, Congress did give states mechanisms to restrict coverage of prescription drugs, even when they are prescribed for a medically accepted

indication. The statute contains a list of drugs or classes of drugs that states are not required to cover, *see id.* § 1396r-8(d)(1)(B)(ii), (d)(2)-(3), allows states and manufacturers to agree on coverage restrictions for particular drugs (with approval from the Secretary), *see id*. § 1396r-8(d)(1)(B)(iii), and permits states to exclude coverage of drugs through a formulary if certain requirements are met, *see id*. § 1396r-8(d)(1)(B)(iv), (d)(4).

Prior authorization is not one of those mechanisms. *See id*. § 1396r-8(d)(1)(A), (d)(5). As Walgreens explained, prior authorization is a procedural tool—it is not a separate, substantive restriction on the scope of coverage. *See* Walgreens' Br. at 3, 44-45; *see also PhRMA v. Meadows*, 304 F.3d 1197, 1211 (11th Cir. 2002) (distinguishing between a formulary, which excludes coverage, and a prior authorization requirement, which conditions coverage on the prescribing provider following the prior authorization process). The text of the provision allowing states to require prior authorization makes clear that the process does not affect the scope of coverage. It permits states to "require, as a condition of coverage . . . the approval of the drug before its dispensing for any medically accepted indication." 42 U.S.C. § 1396r-8(d)(5) (emphasis added). That language contemplates that prior authorization does not change the coverage standard (any medically accepted indication), but is rather a procedural condition of coverage that must be met before a covered drug is dispensed. As Walgreens noted, to read the

statute otherwise would render section 1396r-8(d)(1)(B) meaningless. *See* Walgreen Br. 46. Indeed, when Congress enacted section 1396r-8, it explained that a prior authorization process should not defeat its intent to "prohibit[] States from excluding coverage of prescription drugs of manufacturers with agreements—i.e, assuring access by [Medicaid] beneficiaries to prescription drugs where medically necessary." H.R. Rep. No. 101-881, 1990 WL 200617, at *2110 (1990).

The prior authorization provision in section 1396r-8 is consistent with the Medicaid Act's broader provisions and purpose, which likewise prohibit states from using prior authorization to exclude coverage of other medically necessary services. As the 7th Circuit explained, utilization control procedures, including prior authorization, are "designed to control access, prevent fraud, or streamline efficiency" and do not allow "a state to shirk its primary obligation to cover medically necessary treatments." *Bontrager v. Ind. Fam. & Soc. Servs. Admin.*, 697 F.3d 604, 611 (7th Cir. 2012) (holding that a $1000 cap on dental services that "serves to exclude medically necessary treatment" was not a utilization control and was impermissible). Other courts have agreed. *See, e.g.*, *Samantha A. v. Dep't of Soc. & Health Servs.*, 256 P.3d 1138, 1142-43 (Wash. 2011) (holding that limits on in-home personal care services were not valid utilization controls because they were not aimed at targeting unnecessary utilization of care and services and were not based on individual need); *Allen v. Mansour*, 681 F. Supp. 1232, 1239 (E.D. Mich.

1986) (holding that a policy excluding coverage of liver transplants for beneficiaries with cirrhosis due to alcohol consumption unless they have abstained from alcohol for two years was not a permissible utilization control, as "[p]rocedures to promote utilization control cannot justify precluding funding of medically necessary procedures").

Thus, as with other Medicaid services, courts have concurred that states cannot use prior authorization to restrict the scope of coverage for prescription drugs. For example, in *Edmonds*, Florida used a prior authorization process to restrict coverage of Neurontin and its generic equivalent to FDA-approved uses and two off-label uses that the State "determined merit coverage," 417 F. Supp. 2d at 1331-32, even though other off-label uses qualified as medically accepted indications, *id*. at 1336. The court found that the restriction violated the Medicaid Act: "While [the state Medicaid agency] may *condition* drug coverage for medically accepted indications upon certain prior authorization procedures being followed, *see* § 1396r-8(d)(1)(A), (d)(5), the agency may not *exclude* coverage, i.e., deny reimbursement, for a covered drug under these subsections . . . ." *Id*.; *see also K-V Pharm. Co. v. Cook*, No. 1:12-cv-2491-CAP, 2014 WL 11833266, at *3 (N.D. Ga. Apr. 7, 2014) ("[T]he Medicaid Act does not authorize a state to use a prior authorization program to deny coverage for a covered drug."). *Cf. Walsh*, 538 U.S. at 665 (plurality opinion) (noting that a prior authorization process that did not affect the scope of coverage

could not be upheld against a preemption challenge "if it severely curtailed Medicaid recipients' access to prescription drugs").

The U.S. argues that if states cannot use prior authorization to exclude coverage of medically necessary drugs, then prior authorization serves no purpose. U.S. Br. 26-27, 30. But that ignores that states use prior authorization for various purposes, including to ensure that they do not cover drugs unless they have been prescribed for a medically accepted indication, and to implement quantity limits that are "necessary to discourage waste." *See* 42 U.S.C. § 1396r-8(d)(6). States also use prior authorization "to protect patients from inappropriate prescriptions," *see Walsh*, 538 U.S. at 663, and to steer providers and patients to preferred drugs that they have determined to be less costly and equally effective, *see id*. at 663-64 (noting that prior authorization can be used "to encourage the use of cost-effective medications without diminishing safety or efficacy"). The fact that Virginia continued to require prior authorization for DAAs after it removed its coverage restrictions in 2017 undermines the U.S.'s argument that prior authorization is only useful as a tool to deny coverage of medically necessary drugs.[9] *See* JA672; JA726, JA728.

[9] While states are permitted to use prior authorization, its value may be questionable. In 2022, Virginia eliminated its prior authorization requirement for Hepatitis C treatment. *See* Katie Masters, *Virginia Medicaid is removing its final barrier to treatment for hepatitis C*, Virginia Mercury (Dec. 13, 2021), https://www.virginiamercury.com/2021/12/13/virginia-medicaid-is-removing-its-

III. Virginia's Prior Authorization Criteria for DAAs Violated the Medicaid Act.

Virginia refused to provide Medicaid coverage for the DAAs at issue—Sovaldi, Harvoni, and Daklinza—for people with Hepatitis C unless: (1) their metavir stage was F3 or F4, their fibrosis score was .59 or higher, or they had documented cirrhosis; and (2) they had not used drugs or alcohol in the prior six months, as confirmed by urine drug screen results or physician certification. JA737-738 (Op. 5-6). Those coverage criteria, which Virginia implemented through a prior authorization process, violated the Medicaid Act because they excluded coverage of FDA-approved drugs (offered by manufacturers with a rebate agreement in place) when they were prescribed for a medically accepted indication. *See* 42 U.S.C. §§ 1396r-8(a), 1396r-8(k)(2), 1396r-8(d)(1)(B).

As explained above, any use that is approved by the FDA qualifies as a medically accepted indication. *Id*. § 1396r-8(k)(6). The FDA approved the three DAAs at issue here for use in all people with chronic Hepatitis C, with no restriction based on fibrosis stage or alcohol or drug use. *See supra* notes 3-6 (FDA labels). As

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final-barrier-to-treatment-for-hepatitis-c/. Virginia made the change after advocates requested removal because prior authorization procedures create "an undue administrative burden on prescribers, which takes away time and resources from other life-saving care" and "delay time-sensitive medications for our most vulnerable residents." *See, e.g.*, Letter from Va. Hepatitis Coal. to Drug Utilization Rev. Bd. 2 (Sept. 9, 2021), https://nvhr.org/wp-content/uploads/2021/09/VA-HCV-Treatment-Access-Letter_September-2021_Final.pdf.

the district court correctly found, and the parties agree, none of the permissible restrictions on coverage in section 1396r-8(d)(1)(B) apply. JA758-759 (Op. 26-27). As a result, Virginia was required to cover DAAs when prescribed for any Medicaid beneficiary with chronic Hepatitis C. It could not evade that responsibility by framing its coverage exclusion as a prior authorization process.

Notably, other courts have ruled in favor of Medicaid beneficiaries' challenges to similar coverage policies. *See B.E. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500 (W.D. Wash. May 27, 2016) (finding plaintiffs likely to succeed on claims that Washington's policy excluding coverage of DAAs for patients without another diagnosis, such as HIV who have a fibrosis score of F0 through F2 violated the Medicaid Act); *Ryan v. Birch*, No. 17-cv-00904-KLM, 2017 WL 3896440 (D. Colo. Sept. 5, 2017) (finding plaintiffs sufficiently stated facts supporting claims that requiring a metavir score of F2 or higher for DAA treatment violated the Medicaid Act); *J.E.M. v. Kinkade*, No. 16-cv-04273-SRB (W.D. Mo. Feb. 2, 2017), https://healthlaw.org/wp-content/uploads/2019/06/40-Order-PI.pdf (finding plaintiffs likely to succeed on claims that Missouri's policy requiring three months of negative drug and alcohol screens for DAA coverage violated the Medicaid Act); *Jackson v. Sec'y of Indiana Fam. & Soc. Servs. Admin.*, 279 F. Supp. 3d 816 (S.D. Ind. 2016) (finding plaintiff sufficiently stated facts supporting a claim that covering DAAs only for people with chronic hepatitis C genotype 1 who have a metavir score

of F3 or higher, have a co-infection with HIV or AIDS, or are post-liver transplant violated the Medicaid Act).

CONCLUSION

For the foregoing reasons, *amicus curiae* asks that this Court affirm the district court's holding that Virginia's prior authorization criteria for medications necessary to treat Hepatitis C violated the Medicaid Act.

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Respectfully submitted,

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I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Times New Roman, a proportionally spaced font. I certify that the foregoing brief complies with the requirements of Fed. R. App. P. 32(a)(7)(B) and 29(a)(5), and that the total number of words in this brief is 4,597 according to the count of Microsoft Word, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

/s/Martha Jane Perkins
Martha Jane Perkins

CERTIFICATE OF SERVICE

I certify that on this day, October 3, 2022, I electronically filed the forgoing brief with the Clerk of the Court by using the CM/ECF system.

/s/Martha Jane Perkins
Martha Jane Perkins

UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

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