No. 22-1927

IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

CHRISTOPHER FAIN and SHAUNTAE ANDERSON, individually and on behalf of all others similarly situated,

Plaintiffs-Appellees,

v.

WILLIAM CROUCH, in his official capacity as Cabinet Secretary of the West Virginia Department of Health and Human Resources; CYNTHIA BEANE, in her official capacity as Commissioner of the West Virginia Bureau for Medical Services; and WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES,

Defendants-Appellants.

On Appeal from the United States District Court
for the Southern District of West Virginia

BRIEF OF THE NATIONAL HEALTH LAW PROGRAM AND CENTER FOR MEDICARE ADVOCACY AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

- 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.
- In criminal cases, the United States must file a disclosure statement if there was an organizational victim of the alleged criminal activity. (See question 7.)
- Any corporate amicus curiae must file a disclosure statement.
- Counsel has a continuing duty to update the disclosure statement.

No. 22-1927 Caption: Fain et al. v. Crouch et al.

Pursuant to FRAP 26.1 and Local Rule 26.1,

National Health Law Program
(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: 12/07/2022

Counsel for: National Health Law Program

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

DISCLOSURE STATEMENT

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Pursuant to FRAP 26.1 and Local Rule 26.1,

Center for Medicare Advocacy
(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

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Signature: /s/ Martha Jane Perkins Date: 12/07/2022

Counsel for: Center for Medicare Advocacy

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INTEREST OF *AMICI CURIAE*[1]

The *amici curiae* file this brief pursuant to Fed. R. App. P. 29.

Founded in 1969, the National Health Law Program (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 and underserved people, particularly those eligible for Medicaid. NHeLP has worked to ensure that Medicaid beneficiaries have access to medically necessary gender affirming services.

The Center for Medicare Advocacy is a national, nonprofit law organization that works to advance access to comprehensive Medicare coverage, health equity, and quality health care for older adults and people with disabilities. Founded in 1986, the organization advocates on behalf of beneficiaries in administrative and legislative forums, and serves as legal counsel in litigation of importance to Medicare beneficiaries and others seeking health care coverage, including those who are dually eligible for Medicare and Medicaid.

As such, the *amici curiae* have 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 the *amici curiae* made a monetary contribution to its preparation or submission.

SUMMARY OF ARGUMENT

States must operate their Medicaid programs pursuant to a state plan approved by the Secretary of the U.S. Department of Health and Human Services (HHS). Contrary to the West Virginia Department of Health and Human Resources's (DHHR) argument, Courts do not defer to every state plan approval.[2] Indeed, courts decline to give deference to approvals that do not address the particular policy or practice at issue in the case. The Court should not defer to the approval of the West Virginia state plan because HHS agency did not actually engage in any interpretation as to whether the policy excluding coverage of gender affirming care passed statutory muster.

In addition, while DHHR contends otherwise, gender affirming surgery is not an optional Medicaid service, and West Virginia cannot justify its refusal to cover the surgery by labelling it a "utilization control procedure" or by pointing to budgetary constraints.

Finally, the inferences DHHR draws from Medicare's decision not to issue a *national* policy regarding coverage of gender affirming surgery are erroneous. Medicare covers gender affirming surgery. Most medical services covered by Medicare are not governed by a national policy.

[2] Throughout the brief, the *amici* refer to the Appellants as DHHR.

ARGUMENT

I. Approval of West Virginia's State Medicaid Plan Is Not Entitled to Deference.

Enacted in 1965, title XIX of the Social Security Act establishes the cooperative federal-state health care coverage program known as Medicaid. *See* 42 U.S.C. §§ 1396-1396w-6 (the "Medicaid Act"). The Centers for Medicare & Medicaid Services (CMS) within HHS is responsible for administering the program at the federal level. States do not have to participate in Medicaid, but all states have chosen to do so. Each participating state must designate a single state agency that is responsible for administering the program at the state level. *Id*. § 1396a(a)(5). West Virginia has designated the Bureau for Medical Services within DHHR as the single state Medicaid agency. W. Va. Code § 9-2-13(a)(3); *West Virginia State Plan Amendment WV-13-0017* (approved Sept. 16, 2016), https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/WV/WV-13-0017.pdf.

Each participating state must operate its program according to a comprehensive, written state plan that has been approved by the Secretary of HHS. 42 U.S.C. §§ 1396a, 1396c. The state plan describes the nature and scope of the state's program and affirms the state's commitment to adhere to the requirements imposed by the Medicaid Act and its associated regulations. 42 C.F.R. § 430.10. *See*

Frew ex rel. Frew v. Hawkins, 540 U.S. 431, 433 (2004) ("[O]nce a State elects to join the program, it must administer a state plan that meets federal requirements."); *Antrican v. Odom*, 290 F.3d 178, 188 (4th Cir. 2002) ("[F]or those States that opt to participate in the [Medicaid] program, the requirements of the Medicaid Act are mandatory.").

The state plan "consists of a standardized template, issued and updated by CMS, that includes both basic requirements" common to every state and "individualized content that reflects the characteristics of the State's program." 42 C.F.R. § 430.12(a). A state generally signifies its acceptance of the basic requirements and identifies the individualized characteristics of its program by checking boxes on the template. For example, the state plan designations will indicate which optional population groups the state has elected to cover and which optional services individuals are entitled to receive.

A state must amend its state plan when necessary to address: 1) changes in federal law, regulations, policy, or court decisions; or 2) material changes in state law, policy, or organization or in the operation of its program. *Id*. § 430.12(c). CMS regional staff review each state plan amendment to determine whether it complies with federal Medicaid law and policy. *Id*. §§ 430.14, 430.15. While regional staff can approve a state plan amendment, only the CMS Administrator, in consultation with the Secretary of HHS, can issue a disapproval. *Id*. §§ 430.15(b), (c).

In return for administering an approved state plan that complies with federal requirements, each participating state receives federal funding for a portion of "the total amount expended . . . as medical assistance under the State plan." 42 U.S.C. § 1396b(a)(1); *id*. § 1396d(b) (establishing reimbursement formulas). Generally, the federal government pays approximately 74 percent of West Virginia's Medicaid costs. Federal Financial Participation in State Assistance Expenditures; Federal Matching Shares for Medicaid, the Children's Health Insurance Program, and Aid to Needy Aged, Blind, or Disabled Persons for October 1, 2023 Through September 30, 2024, 87 Fed. Reg. 74429, 74431 (Dec. 5, 2022). West Virginia is currently receiving an additional 6.2 percent in federal matching funding due to the COVID-19 public health emergency. *See* Families First Coronavirus Response Act, Pub. L. No. 116-127, § 6008, 134 Stat. 178, 208 (2020).

DHHR argues that the district court erred in not giving deference to CMS's "implicit judgment" that West Virginia's state plan complies with federal law. Br. of Appellants 18, 38, ECF No. 19. However, DHHR's policy excluding coverage of gender affirming surgery is not included in West Virginia's state plan, *see West Virginia Medicaid State Plan*, Attachment 3 (last updated March 2022), https://dhhr.wv.gov/bms/CMS/SMP/Pages/WV-State-Medicaid-Plan.aspx; thus, CMS made no judgment at all about whether the policy complies with the Medicaid

Act.[3] No deference is warranted in these circumstances. *See, e.g., Ark. Dep't of Health & Hum. Servs. v. Ahlborn*, 547 U.S. 268, 289-91 (2006) (refusing to defer to federal agency decisions because they addressed a different issue than the one posed in the case); *Neb. Pharmacists Ass'n, Inc. v. Neb. Dep't of Soc. Servs.*, 863 F. Supp. 1037, 1047 (D. Neb. 1994) (finding that approval of a state plan amendment that did not address the particular practice challenged in the case did not constitute "thorough and reasoned consideration to which this court would be obligated to defer") (cleaned up); *Aitchinson v. Berger*, 404 F. Supp. 1137, 1148 (S.D.N.Y. 1975) (holding approval of the state plan "is not more than slightly persuasive" when "the so-called approval does not appear to have followed explicit attention to the question now confronted"), *aff'd*, 538 F.2d 307 (2d Cir. 1976).

Further, even when the state plan does address a challenged policy, no deference is owed to the approval when the relevant Medicaid Act provision is unambiguous, *see, e.g., Cal. Ass'n of Rural Health Clinics v. Douglas*, 738 F.3d 1007 (9th Cir. 2013); *Genesis Health Care, Inc. v. Soura*, 165 F. Supp. 3d 443 (D.S.C. 2015), or where CMS failed to articulate an explanation for the approval, *see Ariz. Alliance for Cmty. Health Ctrs. v. Ariz. Health Care Cost Containment*

[3] DHHR does not know when the policy was initially adopted. Br. of Appellants 4 n.1. If the policy was articulated in the state plan, DHHR would know that date, as each page of the state plan contains an approval date and an effective date.

Sys., 47 F.4th 992, 1004 (2022) (holding that CMS's approval is not entitled to deference because the record "contains no evidence regarding CMS's reasoning for approving Arizona's plan and SPAs"); *Conn. Primary Care Ass'n, Inc. v. Wilson-Coker*, No. 3:02cv626, 2006 WL 2583083 at *8 (D. Conn. Sept. 5, 2006) (noting that "deference . . . even at its highest levels, is not a rubber stamp" and declining to defer to approval of a state plan amendment where CMS did not "actually evaluate" the challenged practice or "engage in any interpretation as to whether [the challenged practice] passes statutory muster") (cleaned up). *Cf. Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235 (9th Cir. 2013) (deferring to approvals of state plan amendments in which CMS outlined its interpretation of the Medicaid Act and articulated its reasoning for concluding the amendments in question complied with the statute). Here, even assuming for the sake of argument that the availability and comparability provisions of the Medicaid Act are ambiguous with respect to coverage of gender affirming surgery, DHHR can point to nothing in the record showing that CMS considered the State policy to be in compliance with those provisions, much less that CMS engaged in the kind of reasoned decision-making required to entitle its approval to deference.

II. Coverage of Gender Affirming Surgery in Medicaid Is Not Optional.

The Medicaid Act sets forth the categories of health care services that beneficiaries can receive. For categorically needy populations, states must cover certain basic categories of services and have the option to cover additional categories. 42 U.S.C. §§ 1396a(a)(10)(A) (requiring states to cover at least the services described in section 1396d(a)(1)-(5), (17), (21), (28), (29), and (30), 1396d(a); 42 C.F.R. § 440.210 (listing mandatory services for the categorically needy). For example, mandatory categories of services include inpatient hospital services, outpatient hospital services, laboratory and x-ray services, and services provided by a physician. 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(1), (2)(A), (3)(A), (5)(A). Optional service categories for adults include physical therapy and outpatient prescription drugs, among others. *Id.* §§ 1396a(a)(10)(A), 1396d(a)(11), (12). For both mandatory and optional coverage categories, states must cover the services in sufficient "amount, duration, and scope to reasonably achieve their purpose." 42 C.F.R. § 440.230(b). States may place appropriate limits on covered services "based on such criteria as medical necessity or on utilization control procedures." *Id.* § 440.230(d); *see* 42 U.S.C. § 1396a(a)(30)(A).

DHHR contends that because neither the Medicaid Act nor its implementing regulations list gender affirming surgery as a mandatory service by name, it is an optional service. Br. of Appellants 40-41. That argument ignores the structure of the

statute. The Medicaid Act does not explicitly list each specific treatment, service, or test that falls within each mandatory or optional service category. To do so would be impossible. No court has interpreted the Medicaid Act in a way that supports DHHR's argument. *Cf. Beal v. Doe*, 432 U.S. 438, 444 (1977) (noting that the statute makes no reference to particular medical procedures, but rather requires states to cover "broad categories of medical treatment")[4]; *Alvarez v. Betlach*, 572 Fed. Appx. 519 (9th Cir. 2014) (finding that incontinence briefs (which are not explicitly enumerated covered services in the Medicaid Act) fall within a mandatory category and Arizona must cover them when medically necessary); *Hern v. Beye*, 57 F.3d 906 (10th Cir. 1995) (finding that abortions (which are not explicitly enumerated as covered services in the Medicaid Act) fall within several mandatory categories and

[4] DHHR incorrectly suggests that *Beal* supports the argument that states do not have to cover medically necessary care that falls within a mandatory category. *See* Br. of Appellants at 39. The decision in *Beal* rested on the premise that the excluded abortion services were not medically necessary. In fact, in ruling that the Medicaid Act does not require states to cover "nontherapeutic" abortions, the Court was careful to distinguish between the exclusion of medically necessary and medically unnecessary services, stating: "Although serious statutory questions might be presented if a state Medicaid plan excluded *necessary* medical treatment from its coverage, it is hardly inconsistent with the objectives of the Act for a State to refuse to fund *unnecessary* though perhaps desirable medical services." *Beal*, 432 U.S. at 444 (emphasis added).

Colorado must cover them when medically necessary and eligible for federal funding).

DHHR further argues that because CMS has not issued guidance that specifically speaks to Medicaid programs' obligation to cover gender affirming surgery, coverage is not required. Br. of Appellants 12, 30-31. Once again, DHHR interprets too much from the federal agency's silence. The lack of agency guidance on a topic does not that imply any particular point of view on that topic. This is especially true in the context of the Medicaid program, which is a comprehensive health care program that requires participating states to cover hundreds, if not thousands, of specific services that fall within the broad categories set forth in the Medicaid Act. Given the breadth of the program, CMS's failure to issue guidance on any particular service should not be construed to convey any substantive position on behalf of the agency. To read meaning into the lack of guidance would be to effectively require the agency to issue guidance when it is not compelled to do so. *See generally Norton v. S. Utah Wilderness All.*, 542 U.S. 55 (2004). Indeed, DHHR does not, and cannot, point to any court that has found that states are only required to cover a particular service (that fits within a mandatory service category) when CMS has issued specific guidance to that effect.

In addition, to the extent that DHHR suggests that the policy excluding coverage of gender affirming surgery is a permissible utilization control, they are

wrong. Br. of Appellants 44. While federal regulations do not define "utilization control procedures," courts have made clear that any such procedures a state implements cannot preclude access to medically necessary services. *See, e.g.*, *Bontrager v. Ind. Fam. & Soc. Servs. Admin.*, 697 F.3d 604, 611 (7th Cir. 2012) (explaining that utilization control procedures 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"); *Cruz v. Zucker*, 195 F. Supp. 3d 554 (S.D.N.Y. 2016) ("[A]ny limiting criteria other than medical necessity must ultimately serve the broader aim of 'assuring that individuals will receive necessary medical care.'" (quoting *Alexander v. Choate*, 469 U.S. 287, 303 (1985))) (subsequent history omitted); *Allen v. Mansour*, 681 F. Supp. 1232, 1239 (E.D. Mich. 1986) ("Procedures to promote utilization control cannot justify precluding funding of medically necessary procedures.").

Finally, DHHR argues that it cannot cover gender affirming surgery due to budgetary constraints, Br. of Appellants 12-13. This Court has made clear that states cannot avoid the requirements imposed by the Medicaid Act because of financial concerns. *Pashby v. Delia*, 709 F.3d 307, 331 (4th Cir. 2013) ("[S]tate budgetary concerns cannot be the conclusive factor in decisions regarding Medicaid.") (cleaned up) (quoting *Indep. Living Ctr. of S. Cal., Inc. v. Maxwell–Jolly*, 572 F.3d 644, 659 (9th Cir. 2009), *vacated and remanded on other grounds,* 565 U.S. 606 (2012)). Its

decision in this regard concurs with the holdings of other Circuits. *See, e.g.*, *Ala. Nursing Home Ass'n v. Harris*, 617 F.2d 388, 396 (5th Cir. 1980) ("Inadequate state appropriations do not excuse noncompliance [with the Medicaid Act]."); *Bontrager*, 697 F.3d at 611 ("[P]otential budgetary concerns . . . do not outweigh Medicaid recipients' interests in access to medically necessary health care."); *Ark. Med. Soc'y, Inc. v. Reynolds*, 6 F.3d 519, 531 (8th Cir. 1993) ("[T]he state may not ignore the Medicaid Act's requirements in order to suit budgetary needs."); *Indep. Living Ctr. of S. Cal., Inc.,* 572 F.3d at 659 ("A budget crisis does not excuse ongoing violations of federal [Medicaid] law. . . .").

III. Medicare Covers Gender Affirming Surgery, and the Agency's Decision Not to Issue a National Policy Is of No Significance.

Medicare is the federal health insurance program for those who are at least age 65 or who have certain disabilities. 42 U.S.C. §§ 1395-1395lll; *see also MacKenzie Med. Supply, Inc. v. Leavitt,* 506 F.3d 341, 343 (4th Cir. 2007). As with Medicaid, CMS is responsible for administering the program. Medicare coverage is contingent on a service falling into a defined benefit category and also being "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A). CMS may issue National Coverage Determinations ("NCDs") as policy statements that grant, limit, or exclude Medicare coverage for a particular item or service. *Id.* § 1395ff(f)(B); 42 C.F.R. § 405.1060(a). NCDs are binding on all Medicare adjudicators and contractors,

including Medicare Administrative Contractors ("MACs"), which process Medicare claims for specific geographic regions. 42 C.F.R. § 405.1060(a)(4); *see also* CMS, *A/B MAC Jurisdictions* (June 2021), https://www.cms.gov/files/document/ab-jurisdiction-map-jun-2021.pdf (showing, *inter alia*, MAC responsible for West Virginia, Virginia, North Carolina, and South Carolina). Notably, most covered medical services are not governed by an NCD – only 336 such policies are currently in place. *See* CMS, *National Coverage NCD Report Results*, https://www.cms.gov/medicare-coverage-database/reports/national-coverage-ncd-report.aspx?chapter=all&sortBy=title. In the absence of an NCD, coverage determinations are made locally by MACs within the boundaries established by Medicare law. *See* CMS, Pub. 100-03, *Medicare National Coverage Determination Manual*, Chapter 1, Foreword § A (2004), https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/R10NCD.pdf.

In 2014, Medicare eliminated an NCD that barred coverage of gender affirming surgery, finding the care to be "safe and effective." Dep't of Health & Human Servs., Departmental Appeals Bd., Decision No. 2576 at 8 (May 30, 2014), https://www.hhs.gov/sites/default/files/static/dab/decisions/board-decisions/2014/dab2576.pdf. Since then, MACs have determined coverage of gender affirming surgery on a case-by-case basis; surgical care found to be

reasonable and necessary for an individual is covered. In 2016, CMS declined a formal request to issue a new NCD for gender affirming surgery because information on the care that was *specific to the Medicare population* was limited at that time. *See generally* CMS, *Decision Memo for Gender Dysphoria and Gender Reassignment Surgery* (2016), https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=282 ("CMS Decision Memo") (explaining, *inter alia*, at § II.B, that "[n]early 80% of transgender beneficiaries are under age 65"); *see also* JA776-777 (expert rebuttal report of Dr. Loren S. Schechter describing how factors such as age and additional medical conditions may increase the risk for surgery generally). CMS emphasized:

> To clarify further, the result of this decision is not national non-coverage rather it is that no national policy will be put in place for the Medicare program. In the absence of a national policy, MACs will make the determination on whether or not to cover gender reassignment surgery based on whether gender reassignment surgery is reasonable and necessary for the individual beneficiary. . . .

CMS Decision Memo at § IX.

In short, given that most medical services are not addressed by NCDs, CMS's own explanation as to why it declined to issue a national policy on gender affirming surgery after revoking the nationwide ban, and the fact that Medicare *does cover* reasonable and necessary gender affirming surgery for its beneficiaries, no inferences about the agency's opinions on Medicaid coverage of gender affirming

surgery can be drawn from its decision not to issue a national policy for Medicare beneficiaries.

CONCLUSION

For the foregoing reasons, the *amici curiae* ask that this Court affirm the district court's decision.

Dated: December 7, 2022

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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 3,198 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, December 7, 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