PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 17-2237

CHILDREN'S HOSPITAL OF THE KING'S DAUGHTERS, INC.,

Plaintiff - Appellee,

v.

ALEX M. AZAR II, in his official capacity, Secretary, Department of Health and Human Services; SEEMA VERMA, in her official capacity, Administrator, Centers for Medicare & Medicaid Services; CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants - Appellants.

Appeal from the United States District Court for the Eastern District of Virginia, at Norfolk. Rebecca Beach Smith, Chief District Judge. (2:17-cv-00139-RBS-LRL)

Argued: May 9, 2018 Decided: July 23, 2018

Before TRAXLER, AGEE, and WYNN, Circuit Judges.

Affirmed in part and vacated in part by published opinion. Judge Wynn wrote the opinion, in which Judge Traxler and Judge Agee concurred.

ARGUED: Samantha L. Chaifetz, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellants. Geraldine E. Edens, MORGAN, LEWIS & BOCKIUS LLP, Washington, D.C.; Christopher Howard Marraro, BAKER & HOSTETLER, LLP, Washington, D.C., for Appellee. **ON BRIEF:** Chad A. Readler, Acting Assistant Attorney General, Mark B. Stern, Tara S. Morrissey, Civil Division,

UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Dana J. Boente, United States Attorney, OFFICE OF THE UNITED STATES ATTORNEY, Alexandria, Virginia; Brian R. Stimson, Acting General Counsel, Janice L. Hoffman, Associate General Counsel, Susan M. Lyons, Deputy Associate General Counsel for Litigation, David L. Hoskins, Lindsay S. Goldberg, Office of the General Counsel, Centers for Medicare & Medicaid Services Division, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Washington, D.C., for Appellants. Susan Feigin Harris, MORGAN, LEWIS & BOCKIUS LLP, Houston, Texas, for Appellee.

WYNN, Circuit Judge:

Defendant-Appellant Alex Azar, in his official capacity as Secretary of the U.S. Department of Health & Human Services (the "Secretary"), appeals an order of the U.S. District Court for the Eastern District of Virginia enjoining the Secretary from enforcing a Medicaid policy set forth in a Frequently Asked Questions document ("FAQ 33"). *See Children's Hosp. of the King's Daughters, Inc. v. Price*, 258 F. Supp. 3d 672 (E.D. Va. 2017). The FAQ 33 policy purported to clarify the methodology for calculating the maximum amount of financial assistance available to hospitals, like Plaintiff-Appellee Children's Hospital of the King's Daughters, Inc. ("Children's Hospital"), that serve a disproportionate number of low-income or special needs patients (commonly referred to as "disproportionate share hospitals" or "DSHs"). Under the methodology in FAQ 33, Children's Hospital would have to repay $19.1 million in DSH payments it received from the Medicaid program.

The district court enjoined the Secretary from enforcing the FAQ 33 policy against Children's Hospital for two reasons: (1) the promulgation of the FAQ 33 policy failed to comply with the procedural requirements set forth in the Administrative Procedural Act ("APA") and (2) the FAQ 33 policy contradicted the plain and unambiguous language of the governing statute.

For the reasons that follow, we conclude that the district court correctly determined that the policy set forth in FAQ 33 constituted a "legislative rule" and, therefore, that the APA mandated that the agency establish the FAQ 33 policy through notice-and-comment rulemaking. *See* 5 U.S.C. § 553(a)–(c). We thus affirm the district

court's judgment enjoining the Secretary from enforcing the policy set forth in FAQ 33 against Children's Hospital. Because we conclude that the policy violated the APA's procedural requirements, we decline to reach the substantive challenge by Children's Hospital to the FAQ 33 policy and vacate the part of the district court's opinion addressing whether that policy conflicts with the language of 42 U.S.C. § 1396r-4(g).

I.

Medicaid, 42 U.S.C. § 1396 *et seq.*, is a cooperative federal-state program through which the federal government provides financial assistance to state Medicaid programs, which in turn provide medical insurance to qualifying individuals. *Children's Hosp.*, 258 F. Supp. 3d at 677. Although states have some discretion in determining which individuals are qualified to participate in their Medicaid programs, the vast majority of beneficiaries qualify to participate because their "income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396-1. Additionally, Medicaid programs "provide[] benefits to children with certain serious illnesses, *without regard to their family's income*." *Children's Hosp.*, 258 F. Supp. 3d at 678 (emphasis added) (citing §§ 1396a(cc), 1382(a)(3)(c)). Because their eligibility does not depend on income and resources, such Medicaid-eligible children often have private insurance coverage.

Children's Hospital is a non-profit pediatric hospital located in Norfolk, Virginia. Most of Children's Hospital's pediatric patients are eligible to participate in the Medicaid program, either because of their poverty or because they have a qualifying illness or disability. *See id.* (noting that Children's Hospital's "Medicaid Inpatient Utilization

Ratio ('MIUR') (the ratio of Medicaid inpatient days to total hospital days) was 69.65% in 2012," the highest MIUR in Virginia).

The Medicaid statute provides for state Medicaid programs to make "payment adjustment[s]" to certain hospitals, like Children's Hospital, that "serve a disproportionate number of low-income patients with special needs." §§ 1396a(a)(13)(A)(iv), 1396r-4(c). The statute further establishes an *aggregate* limit on the amount of payment adjustments state programs can allocate to all qualifying DSHs in their state. § 1396r-4(f)(3). In a provision titled "Amount of adjustment subject to uncompensated costs," the statute also caps the amount of DSH funding any *particular* hospital may receive in a given year at:

> [T]he costs incurred during the year of furnishing hospital services (as determined by the Secretary and net of payments under this subchapter, other than under this section, and by uninsured patients) by the hospital to individuals who either are eligible for medical assistance under the State plan or have no health insurance (or other source of third party coverage) for services provided during the year. For purposes of the preceding sentence, payments made to a hospital for services provided to indigent patients made by a State or a unit of local government within a State shall not be considered to be a source of third party payment.

§ 1396r-4(g)(1)(A). In a 1994 guidance document, the agency characterized the "first part" of this hospital specific limit as the hospital's "Medicaid 'shortfall'"—"the cost of services furnished to Medicaid patients, less the amount paid under the non-DSH payment method under the State plan." J.A. 172. "The second part of the formula is the cost of services provided to patients who have no health insurance or source of third party payment for services provided during the year, less the amount of payments made by these patients." *Id.* Together, these two parts of the hospital specific limit constitute a

DSH's "uncompensated care costs." *See* Medicaid Program; Disproportionate Share Hospital Payments, 73 Fed. Reg. 77,904, 77,904 (Dec. 19, 2008) (codified at 42 CFR pts. 447 & 455).

In a regulation promulgated in 2008 to implement new statutory DSH reporting and auditing requirements, the Centers for Medicare & Medicaid Services ("CMS"), a division of the Department of Health & Human Services, set forth the methodology for calculating the "payment adjustment." 42 C.F.R. § 447.299. In particular, a section titled "Total annual uncompensated care costs" provides:

> The total annual uncompensated care cost equals the total cost of care for furnishing inpatient hospital and outpatient hospital services to Medicaid eligible individuals and to individuals with no source of third party coverage for the hospital services they receive less the sum of regular Medicaid [fee-for-service] rate payments, Medicaid managed care organization payments, supplemental/enhanced Medicaid payments, uninsured revenues, and Section 1011 payments for inpatient and outpatient hospital services. This should equal the sum of paragraphs (c)(9), (c)(12), and (c)(13) subtracted from the sum of paragraphs (c)(10) and (c)(14) of this section.

§ 447.299(c)(16). Of particular relevance to this appeal, Section 447.299(c)(10) defines the "Total Cost of Care for Medicaid [Inpatient/Outpatient] Services" as "The total annual costs incurred by each hospital for furnishing inpatient hospital and outpatient hospital services to Medicaid eligible individuals." And Section 447.299(c)(9) defines "Total Medicaid [Inpatient/Outpatient] Payments" as the sum of Medicaid fee-for-service payments, Medicaid managed care payments, and supplemental Medicaid payments.

The dispute between Children's Hospital and the Secretary turns on whether payments by private insurance companies to Children's Hospital on behalf of Medicaid-

eligible patients should be accounted for in determining Children's Hospital DSH payment adjustment. In a Frequently Asked Questions document released in 2010, FAQ 33, which was not promulgated through notice-and-comment rulemaking, CMS took the position that

> days, costs, and revenues associated with patients that are eligible for Medicaid and also have private insurance *should be included in the calculation of the hospital-specific DSH limit*. As Medicaid should be the payer of last resort, hospitals should also offset both Medicaid and third-party revenue associated with the Medicaid eligible day against the costs for that day to determine any uncompensated amount.

Children's Hosp., 258 F. Supp. 3d at 679–80 (emphasis added). Until it understood FAQ 33's import in October 2016—as a result of an audit by an outside auditor working on behalf of Virginia's Medicaid program—Children's Hospital did not include payments from private insurers in calculating its payment adjustment. The auditor determined that Children's Hospital was obliged to repay $19.1 million to the State Medicaid program as a result of DSH overpayments Children's Hospital received because it failed to include private insurance payments in its payment adjustment calculation.

On March 7, 2017, Children's Hospital filed a complaint seeking declaratory and injunctive relief. Children's Hospital sought a declaration that FAQ 33's requirement that private insurance payments be included in calculating the payment adjustment is contrary to the plain and unambiguous language of Section 1396r-4(g)(1), and therefore is unlawful and must be vacated under the Administrative Procedure Act, 5 U.S.C. § 706(2)(c). Alternatively, Children's Hospital argued that the FAQ 33 policy constituted a substantive amendment to the calculation methodology set forth in the 2008 rule and

therefore that CMS unlawfully sought to effect a regulatory policy change without completing notice-and-comment rulemaking. Children's Hospital sought an injunction barring the Secretary from enforcing FAQ 33's policy of requiring inclusion of private insurance payments in calculating the payment adjustment.

In an opinion and order entered June 20, 2017, the district court concluded that the FAQ 33 policy amounted to a substantive rule that should have been promulgated through notice-and-comment rulemaking and that the policy conflicted with the plain and unambiguous language of Section 1396r-4(g)(1). *Children's Hosp.*, 258 F. Supp. 3d at 687, 689. The district court preliminarily enjoined the Secretary from enforcing the policy set forth in FAQ 33 against Children's Hospital. *Id.* at 692. At the request of the parties, the district court subsequently converted its preliminary injunction opinion and order into an award of summary judgment to Children's Hospital and, therefore, an appealable final judgment. The Secretary timely appealed.

II.

On appeal, the Secretary makes two arguments: (1) that the FAQ 33 policy constitutes an "interpretative"—rather than "legislative"—rule and therefore need not have been the product of notice-and-comment rulemaking, and (2) that the policy set forth in FAQ 33 amounts to a reasonable administrative construction of the governing statutory language and therefore is entitled to judicial deference. We review both questions de novo. *Ray Commc'ns, Inc. v. Clear Channel Commc'ns, Inc.*, 673 F.3d 294, 297 (4th Cir. 2012) (reviewing de novo legal determinations underlying an award of summary judgment).

A.

The APA requires that all "rules" be issued through a statutorily prescribed notice-and-comment process. *See* 5 U.S.C. § 553(a)–(c). "Rules issued through the notice-and-comment process are often referred to as 'legislative rules' because they have the 'force and effect of law.'" *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015) (quoting *Chrysler Corp. v. Brown*, 441 U.S. 281, 302–03 (1979)). By contrast, "the APA provides that, unless another statute states otherwise, the notice-and-comment requirement 'does not apply' to 'interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice.'" *Id.* at 1203–04. (quoting § 553(b)(A)).

According to Children's Hospital, FAQ 33 amounts to a "legislative rule," and therefore should have been issued through the notice-and-comment process prescribed in Section 553(a)–(c). On the other hand, the Secretary argues that the rule is "interpretive" and therefore did not need to go through the notice-and-comment process.

The Supreme Court recently acknowledged that the "precise meaning" of the term "interpretive rule" in the APA "is the source of much scholarly and judicial debate," and expressly declined to "wade into that debate." *Id.* at 1204; *see also Am. Mining Cong. v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1108–09 (D.C. Cir. 1993) (describing the distinction between interpretive and legislative rules as "enshrouded in considerable smog" (internal quotation marks omitted)); *Jerri's Ceramic Arts, Inc. v. Consumer Prod. Safety Comm'n*, 874 F.2d 205, 207 (4th Cir. 1989) (recognizing that the "distinction between 'interpretative' rules and 'something more,' i.e., 'substantive' or 'legislative' rules, is not always easily made"). Nonetheless, the *Perez* Court stated that "the critical

feature of interpretive rules is that they are 'issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers.'" *Perez*, 135 S. Ct. at 1204 (quoting *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995)).

This Court has recognized that "courts are in general agreement that interpretative rules simply state what the administrative agency thinks the statute means, and only 'remind' affected parties of existing duties." *Jerri's*, 874 F.2d at 207. Put differently, "[a]n interpretive rule is merely a clarification or explanation of an *existing statute or rule*." *Chen Zhou Chai v. Carroll*, 48 F.3d 1331, 1341 (4th Cir. 1995) (emphasis added) (quoting *Guardian Fed. Sav. & Loan Ass'n v. Fed. Sav. & Loan Ins. Corp.*, 589 F.2d 658, 664 (D.C. Cir. 1978)); *see also Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014) ("Interpretative rules are those that clarify a statutory or regulatory term, remind parties of existing statutory duties, or merely track preexisting requirements and explain something the statute or regulation already required." (internal quotation marks omitted)).

By contrast, "a substantive or legislative rule, pursuant to properly delegated authority, has the force of law, and creates new law or imposes new rights or duties." *Jerri's*, 874 F.3d at 207 (citations omitted). To that end, "[a] rule is legislative if it supplements a statute, adopts a new position inconsistent with existing regulations, or otherwise effects a substantive change in existing law or policy." *Mendoza*, 754 F.3d at 1021 (citations omitted). Likewise, a rule is legislative if it "expand[s] the footprint of a regulation by imposing new requirements, rather than simply interpreting the legal norms Congress or the agency itself has previously created." *Iowa League of Cities v. E.P.A.*, 711 F.3d 844, 873 (8th Cir. 2013) (citations omitted).

We conclude that the policy set forth in FAQ 33 falls on the legislative end of the "spectrum," *N.H. Hosp. Ass'n v. Azar*, 887 F.3d 62, 70 (1st Cir. 2018), because (1) the policy of requiring DSHs to account for private insurance payments in calculating a DSH's uncompensated care costs does not derive from the statute or the 2008 rule and (2) the agency relied on—and continues to rely on—the Secretary's statutorily delegated authority to "determine[]" what constitutes "costs incurred" for purposes of calculating a DSH's payment adjustment as the legal basis supporting the policy. *See* 42 U.S.C. § 1396r-4(g)(1)(A).

As to the first reason—that the policy in FAQ 33 does not derive from the statute or 2008 rule—the statute provides that a qualifying hospital's payment adjustment shall not exceed the hospital's "costs incurred" in providing services to Medicaid-eligible and uninsured patients. *Id.* The amount of "costs incurred" are to be "determined by the Secretary and net of payments [by Medicaid] and by uninsured patients." *Id.* Payments by private insurers are not, therefore, one of the two types of "payments" that the statute explicitly requires a DSH to "net" out in determining its "costs incurred." Likewise, the 2008 rule's formula for calculating "total annual uncompensated care" expressly requires hospitals to subtract only Medicaid payments and payments by uninsured individuals. 42 C.F.R. § 447.299(c)(16). Payments by private insurers, therefore, are not among the "payments" that the 2008 rule expressly requires DSHs to account for in determining their "total annual uncompensated care."

The Secretary concedes "[t]he regulatory formula does not specifically address payments by Medicare or private insurers, and offers no explicit instructions to States or

hospitals as to how to account for Medicaid-eligible patients who have additional insurance." Appellant's Br. 26. Nevertheless, the Secretary argues that the policy in FAQ 33 has its genesis in the 2008 rule and its preamble because those provisions characterize the calculation as determining a DSH's "*uncompensated* care costs." *See* 42 C.F.R. § 447.299(c)(16) (emphasis added); 73 Fed. Reg. at 77,910-11. According to the Secretary, because care provided by a DSH that is reimbursed by a private insurer is "compensated," the policy set forth in FAQ 33 derives from the 2008 rule and its preamble.

We disagree. The calculation methodology in the rule itself does not mention—let alone specifically address—payments by private insurers. § 447.299(c)(16). Additionally, the preamble defines "uncompensated care costs" as "the costs incurred by that hospital in furnishing services during the year to Medicaid patients and the uninsured, *less other Medicaid payments made to the hospital, and payments made by uninsured patients*." 73 Fed. Reg. at 77,904 (emphasis added). Again, that definition does not mention private insurance payments, and conspicuously omits payments by private insurers from the two types of "payments" that DSHs must deduct when calculating "uncompensated care costs." And the preamble to the 2008 rule refers to data fields in a form for calculating and reporting "total uncompensated care costs." 73 Fed. Reg. at 77,921. Once again, none of those data fields addresses payments by private insurers. *Id.*

The Secretary also emphasizes that the preamble to the 2008 rule directs DSHs to include payments by *Medicare* in calculating their hospital-specific limit,

notwithstanding that the statute does not explicitly address whether Medicare payments should be netted out. *See* 73 Fed. Reg. at 77,912. The Secretary maintains that this language indicated that CMS intended for non-Medicaid payments to be accounted for in calculating a DSH's "costs incurred." But again, neither that specific provision in the preamble nor the preamble in general mentions payments by private insurers, much less addresses whether such payments must be deducted. Accordingly, FAQ 33's policy of requiring DSHs to deduct payments by private insurers in calculating their "costs incurred" does not derive "from an existing [statute or regulation] whose meaning compels or logically justifies the proposition," thereby weighing in favor of treating the FAQ 33 policy as a legislative rule. *Mendoza*, 754 F.3d at 1021 (citation omitted).

The second consideration supporting our conclusion that the policy in FAQ 33 amounts to a legislative rule—that the agency relies on the Secretary's statutorily delegated authority to "determine[]" what constitute "costs incurred" for purposes of calculating a DSH's uncompensated care costs as the legal basis supporting the policy—is closely connected to the statute's and 2008 rule's silence as to whether DSHs must net out private insurance payments in calculating their "costs incurred." As the First Circuit explained in concluding that FAQ 33 constituted a legislative rule, "[t]his textual silence on whether to offset [private insurance] payment[s] leads us to believe that any authority that the Secretary may have to adopt the rule at issue would most likely flow from Congress's delegation of a power to make a decision that Congress chose not to make itself." *N.H. Hosp.*, 887 F.3d at 71. The Secretary concedes as much, asserting that the

policy set forth in FAQ 33 reflects a "reasonable exercise of the Secretary's expressly delegated authority to determine how to calculate 'costs incurred.'" Appellant's Br. 40.

When an agency relies on expressly delegated authority to establish policy—as the Secretary does with regard to FAQ 33—courts generally treat the agency action as legislative, rather than interpretive, rulemaking. *Iowa League of Cities*, 711 F.3d at 873 ("When an agency creates a new 'legal norm based on the agency's *own authority*' to engage in supplementary lawmaking, as delegated from Congress, the agency creates a legislative rule." (quoting *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95 (D.C. Cir. 1997))); *Walton v. Greenbrier Ford, Inc.*, 370 F.3d 446, 452 (4th Cir. 2004) ("Legislative regulations are those in which 'Congress has explicitly left a gap for the agency to fill, [thus] there is an express delegation of authority to the agency to elucidate the specific provision of the statute by regulation.'" (alteration in original) (quoting *Chevron U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 843–44 (1984)). As the First Circuit correctly held with regard to the policy in FAQ 33, in particular, even if we were to "accept arguendo the Secretary's stated position that Congress granted the Secretary the 'latitude' to decide what, if any, other sources of payments made in connection with Medicaid-covered costs need be offset from the total costs of providing such services, . . . when Congress leaves such a policy choice to the agency, we should lean toward finding that the agency's making of that choice requires notice and comment." *N.H. Hosp.*, 887 F.3d at 70–71 (citations omitted). "Otherwise, it would be 'difficult to imagine what regulations *would* require notice and comment procedures.'" *Id.* (quoting *Mendoza*, 754 F.3d at 1021). Put differently, even if Congress authorized the Secretary to require DSHs to account for

private insurance payments in exercising his statutorily delegated discretion to define "costs incurred," the absence of statutory or regulatory language compelling—or even suggesting such a policy—required the agency to promulgate its FAQ 33 policy through notice-and-comment rulemaking.

The statute's and 2008 rule's silence as to private insurance payments—and the Secretary's reliance on his delegated authority to determine what constitute "costs incurred"—also sets this case apart from the principal case relied on by the Secretary, *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87 (1995). *Guernsey* involved a provision in the Medicare statute that provides for hospital reimbursement based on "reasonable costs," defined as the "costs actually incurred" for providing services to beneficiaries. 514 U.S. at 91 (quoting 42 U.S.C. § 1395x(v)(1)(A)). The statute further authorized the Secretary to promulgate regulations establishing the methodology to be used for determining "reasonable costs," directing the Secretary to "consider, among other things, the principles generally applied by national organizations." *Id.* (quoting 42 U.S.C. § 1395x(v)(1)(A)). Pursuant to that authority, on an annual basis, the Secretary promulgated regulations establishing methods for determining reasonable cost reimbursement. *Id.* at 92. Those regulations required hospitals to follow "[s]tandardized definitions, accounting, statistics, and reporting practices that are widely accepted in the hospital and related fields." *Id.* (quoting 42 C.F.R. § 413.20(a)). After promulgating an annual regulation, the agency distributed an informal Medicare reimbursement guideline—which was not promulgated through notice-and-comment rulemaking—

stating that, in determining "reasonable costs" incurred, hospitals must amortize the cost of refinancing bonds over the life of the old bonds. *Id.* at 90-91.

Emphasizing that generally accepted accounting practices did not require amortizing the cost of the bond refinancing, the hospital argued that the amortization requirement was inconsistent with the regulation and therefore should have been promulgated through notice-and-comment rulemaking. The Supreme Court disagreed, concluding that the informal reimbursement guideline constituted a "prototypical" interpretive rule. *Id.* at 99. In reaching this conclusion, the Court explained that the policy set forth in the guideline was required both by a statutory provision prohibiting the Medicare program from cross-subsidizing other health insurance programs and vice versa and by a regulation providing "that only the actual cost of services rendered to beneficiaries *during a given year* [could] be reimbursed." *Id.* (emphasis added). Accordingly, unlike the policy set forth in FAQ 33—in which the Secretary purports to exercise his delegated authority to define "costs incurred" in a manner not specifically addressed in the statute or regulation—the policy at issue in *Guernsey* derived "from an existing document whose meaning compels or logically justifies the proposition," *Mendoza*, 754 F.3d at 1021—namely both the statute and its implementing regulation.

In sum, we conclude that the policy set forth in FAQ 33 constitutes a legislative, rather than interpretive, rule. Because that policy amounts to a legislative rule, the APA required that agency promulgate the policy through notice-and-comment rulemaking. 5 U.S.C. § 553(a)-(c). The Secretary failed to do so, and Children's Hospital faces the prejudicial result of being obliged to repay at least $19.1 million to the State Medicaid

program. *See Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 659–60 (2007) ("In administrative law, . . . there is a harmless error rule."); *Utility Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 755 (D.C. Cir. 2001) (noting prejudice can arise from a party's inability to comment on a rule before an agency promulgates it); *Children's Hosp.*, 258 F. Supp. 3d at 689–91. Therefore, the district court properly enjoined the Secretary from enforcing the FAQ 33 policy against Children's Hospital.

B.

In addition to concluding that the policy in FAQ 33 violated the APA's procedural requirements, the district court further held that the policy conflicts with the plain and unambiguous language of Section 1396r-4(g)(1). *Children's*, 258 F. Supp. 3d at 689. In particular, the district court concluded that the statutory language does not authorize "the Secretary [to] define 'costs' to include private insurance payments." *Id.* at 686-87.

Courts have recognized that there is no bright-line rule as to whether a court that has decided to vacate an agency action on procedural grounds should nonetheless address a substantive claim. *See NRDC v. EPA*, 643 F.3d 311, 321 (D.C. Cir. 2011) (noting that case law provides "little direction on whether, having determined to vacate on procedural grounds, we should nonetheless address substantive claims"). Given this absence of authority, we do not fault the district court for addressing Children's Hospital's substantive claim.

Nevertheless, because it is unnecessary for us to address that claim to affirm the district court's judgment, we decline to address Children's Hospital's substantive

challenge and, for the same reason, vacate the district court's decision as to that claim.[1] However, our decision to vacate the district court's ruling as to Children's Hospital substantive claim should not be read as expressing or implying any view on the merits of that claim or the validity of any amendment to the 2008 rule.

III.

For the foregoing reasons, we affirm the judgment of the district court enjoining the Secretary from enforcing the policy set forth in FAQ 33 against Children's Hospital, and vacate the district court's opinion to the extent it concludes that that policy conflicts with the language of Section 1396r-4(g), but without prejudice to Children's Hospital's right to raise that argument in another proceeding.

AFFIRMED IN PART AND VACATED IN PART

[1] This approach also is consistent with the approach taken by other courts that have invalidated the policy in FAQ 33 on procedural grounds. S*ee N.H. Hosp.*, 887 F.3d at 77; *Children's Health Care v. Centers for Medicare & Medicaid Servs*., No. 16-cv-4064, 2017 WL 3668758, at *9 (D. Minn. June 26, 2017) (declining to reach substantive challenge after vacating FAQ 33 on procedural grounds because "it would be merely advisory for this Court to decide whether Defendants would exceed their statutory authority if they attempted to promulgate the rule expressed in FAQ 33 by following the required procedures"); *Texas Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 240 n.5 (D.D.C. 2014) ("Considerations of judicial economy and restraint counsel against deciding whether 42 U.S.C. § 1396r–4(g)(1)(A) could support a validly promulgated rule that codified [FAQ 33's] policy in the future.").