United States Court of Appeals
For the First Circuit

No. 17-1615

NEW HAMPSHIRE HOSPITAL ASSOCIATION; MARY HITCHCOCK MEMORIAL HOSPITAL; LRGHEALTHCARE; SPEARE MEMORIAL HOSPITAL; VALLEY REGIONAL HOSPITAL, INC.,

Plaintiffs, Appellees,

v.

ALEX AZAR, United States Secretary of Health and Human Services;* CENTERS FOR MEDICARE AND MEDICAID SERVICES; SEEMA VERMA, in her official capacity as Administrator, Centers for Medicare and Medicaid Services,

Defendants, Appellants.

APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW HAMPSHIRE

[Hon. Landya B. McCafferty, U.S. District Judge]

Before

Kayatta, Selya, and Lipez,
Circuit Judges.

Tara S. Morrissey, Attorney, Appellate Staff, Civil Division, U.S. Department of Justice, with whom Chad A. Readler, Acting Assistant Attorney General, Civil Division, U.S. Department of Justice, John J. Farley, Acting U.S. Attorney, Mark B. Stern,

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* Pursuant to Fed. R. App. P. 43(c)(2), Secretary of Health and Human Services Alex Azar has been substituted for former Acting Secretary of Health and Human Services Eric D. Hargan, who had in turn been substituted for former Acting Secretary of Health and Human Services Don J. Wright.

Attorney, Appellate Staff, Civil Division, U.S. Department of Justice, Heather Flick, Acting General Counsel, Centers for Medicare and Medicaid Services Division, U.S. Department of Health and Human Services, Janice L. Hoffman, Associate General Counsel, Centers for Medicare and Medicaid Services Division, U.S. Department of Health and Human Services, Susan M. Lyons, Deputy Associate General Counsel for Litigation, Centers for Medicare and Medicaid Services Division, U.S. Department of Health and Human Services, David L. Hoskins, Attorney, Office of the General Counsel, Centers for Medicare and Medicaid Services Division, U.S. Department of Health and Human Services, and Lindsay S. Goldberg, Attorney, Office of the General Counsel, Centers for Medicare and Medicaid Services Division, U.S. Department of Health and Human Services, were on brief, for appellants.

Ann M. Rice, Deputy Attorney General, Civil Bureau, State of New Hampshire, and Nancy J. Smith, Senior Assistant Attorney General, Civil Bureau, State of New Hampshire, on brief for State of New Hampshire, Department of Health and Human Services, amicus curiae.

W. Scott O'Connell, with whom Morgan C. Nighan and Nixon Peabody LLP were on brief, for appellees.

Geraldine E. Edens, Christopher H. Marraro, Baker & Hostetler LLP, Susan Feign Harris, and Morgan Lewis & Bockius LLP on brief for Children's Hospital Association, amicus curiae.

April 4, 2018

KAYATTA, **Circuit Judge**. When hospitals treat Medicaid patients, the Medicaid payments received from the government often do not cover the full costs of care. In 1981, Congress authorized the payment of additional sums to lessen the burden on hospitals that treat a high number of indigent patients. Years later, concerned that this payment adjustment overshot the mark in some instances, Congress passed another law seeking to cap such payments at each hospital's "costs incurred." Of particular relevance to this litigation is to what extent "costs incurred" equals the total costs of service, rather than the costs net of payments from other sources, namely, Medicare and private insurance. This question arises because some patients qualify for coverage under both Medicaid and either Medicare or private insurance.

Rather than specifying expressly the full extent to which "costs incurred" are limited to costs net of other sources of payment, Congress identified two specific sources of payment that must be offset against total costs, but otherwise simply stated that "costs incurred" are "as determined by the Secretary" of the United States Department of Health and Human Services. In 2008, the Secretary promulgated a regulation. But the regulatory text, like the statute, contained no express direction on the question at issue. Then, in 2010, the Secretary announced, in the form of answers to "Frequently Asked Questions" posted on medicaid.gov, that the payments to be offset against total costs

in calculating "costs incurred" also included reimbursements received from Medicare and private insurance. For ease of reference, we will call this pronouncement "the FAQs" or "the FAQs announcement."

Ruling in favor of the plaintiff hospitals and their association, the district court found that the set-off rule announced in the FAQs represented a substantive policy decision that could not be adopted without notice and comment. For the following reasons, we affirm the district court's ruling on this same ground, without reaching the plaintiffs' other challenges.

I.

Medicaid is a cooperative federal-state health insurance program that enables states to provide medical assistance to the disabled, the elderly, and families with dependent children, "whose income and resources are insufficient to meet the costs of necessary medical services." 42 U.S.C. § 1396-1. The program is funded by both the federal and state governments, but is administered by the states. 42 C.F.R. § 430.0. Although participation in Medicaid is voluntary, a state that elects to participate must comply with the requirements imposed by federal statute and regulations promulgated by the Secretary. See Stowell

v. Ives, 976 F.2d 65, 68 (1st Cir. 1992) (quoting Wilder v. Va. Hosp. Ass'n, 496 U.S. 498, 502 (1990)).

Once a participating state establishes a state plan that complies with the Medicaid Act, the federal government reimburses the state for certain patient care costs. See 42 U.S.C. §§ 1396a, 1396b. The state, in turn, reimburses the medical facilities that provided the care. These Medicaid reimbursements often do not cover the hospitals' full costs of treating Medicaid-eligible individuals.

Concerned about the financial burden thus placed on hospitals that treat largely indigent communities, Congress amended the Medicaid statute in 1981 to "take into account the situation of hospitals which serve a disproportionate number of low income patients with special needs." Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 2173, 95 Stat. 357 (codified as amended at 42 U.S.C. § 1396a(a)(13)(A)(iv)). Giving practical effect to its intent, Congress provided a "payment adjustment" for hospitals deemed "disproportionate share hospitals" ("DSH"). See 42 U.S.C. § 1396r-4(c). Several years later, Congress became aware of reports that certain types of hospitals had received payment adjustments "that exceed the net costs, and in some instances the total costs, of operating the facilities." H.R. Rep. No. 103-111, at 211 (1993). According to these reports, the excess funds were then being redirected to

finance other state government projects, such as road construction and maintenance. Id. at 211-12. In 1993, Congress responded to this unintended consequence by imposing a cap on the DSH payment adjustment ("the DSH cap"). See Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13621, 107 Stat. 312 (codified at 42 U.S.C. § 1396r-4(g)). This hospital-specific DSH cap limited the payment adjustment to the "costs incurred" in treating Medicaid-eligible individuals, less Medicaid payments received.[1] 42 U.S.C. § 1396r-4(g)(1)(A). The provision now states, in relevant part:

> A payment adjustment during a fiscal year shall not . . . exceed[] the 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.

Id.

[1] In addition to Medicaid-eligible individuals, the DSH payment adjustment also provides payments for treating individuals with no health insurance, and the statutory cap includes costs incurred in treating these patients, less "payments . . . by uninsured patients." 42 U.S.C. § 1396r-4(g)(1)(A). For the purpose of this appeal, however, we are only concerned with costs incurred in treating Medicaid-eligible individuals and any related payments.

In 2003, Congress made a further amendment to the Medicaid statute. This time, Congress expanded the government's enforcement mechanism by requiring states, as a condition of receiving DSH payments, to submit both an annual report and an annual audit of their qualifying hospitals' expenses and received DSH payments. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1001(d), 117 Stat. 2066 (codified at 42 U.S.C. § 1396r-4(j)). The reporting provision of this act requires states to identify each hospital within the state that received a payment adjustment and the amount of that adjustment, as well as "[s]uch other information as the Secretary determines necessary to ensure the appropriateness of the payment adjustments made under this section." 42 U.S.C. § 1396r-4(j)(1)(B). In turn, the audit requirement in the 2003 legislation requires the state to "verif[y]," by "independent certified audit," that, among other things, the payment adjustment complied with the statutory cap and that "[o]nly the uncompensated care costs of providing inpatient hospital and outpatient hospital services to individuals described in [42 U.S.C. § 1396r-4(g)(1)(A)] are included in the calculation of the hospital-specific limits." Id. § 1396r-4(j)(2)(B)-(C).

So, in three steps, Congress provided for additional payments to certain hospitals, imposed a limit on those payments, and then created a mechanism for verifying compliance with the

limit. No party claims that this statutory scheme in so many words expressly addresses the underlying question that gives rise to this case: how to treat, in determining Medicaid payment adjustments, costs associated with individuals eligible for both Medicaid and other health coverage, namely, Medicare or private insurance. For these individuals -- to whom the parties refer as "dual eligibles" or those with "dual coverage" -- the additional coverage may kick in to reimburse hospital costs before Medicaid does, as Medicaid is often the "payer of last resort." Massachusetts v. Sebelius, 638 F.3d 24, 26 (1st Cir. 2011) (citation omitted). So, the question arose: In calculating the DSH cap, should states deduct Medicare and private insurance payments for those with dual coverage when determining the hospitals' "costs incurred"?

In 2008, the Secretary promulgated a rule following notice and comment. But in so doing, the Secretary exercised authority not under section 1396r-4(g)(1)(A) (which established the DSH cap), but rather under the Secretary's delegated authority to define the scope of information necessary to satisfy the 2003 Modernization Act's reporting requirement. See Disproportionate Share Hospital Payments, 73 Fed. Reg. 77,904, 77,904 (Dec. 19, 2008) (stating that the rule "implement[s] the reporting

requirement in Section 1923(j)(1) of the Act"[2]). This regulation requires states, as a condition of receiving DSH payments, to report eighteen categories of information to the Centers for Medicare and Medicaid Services ("CMS") -- the arm of the United States Department of Health and Human Services responsible for administering the Medicaid program -- including "Total Medicaid Uncompensated Care." Id. at 77,950-51. But here too, the regulatory text is silent on the proper treatment of costs and revenues associated with dual eligibles.

The regulation's preamble, on the other hand, does address the issue, albeit only to the extent of adding Medicare payments as a type of reimbursement that need be offset from the associated costs. Responding to a comment, the preamble instructs that, "in calculating th[e] uncompensated care costs" of treating dual eligibles, "it is necessary to take into account both the Medicare and Medicaid payments made." Id. at 77,912.

In 2010, the Secretary provided further guidance. In a "Frequently Asked Questions" document posted on medicaid.gov,[3] but

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[2] Section 1923 of the Act is codified at 42 U.S.C. § 1396r-4.

[3] As best we can tell, this document is no longer accessible through general navigation on medicaid.gov. As of publication of this opinion, however, it is available at the following link: https://www.medicaid.gov/medicaid/financing-and-reimbursement/downloads/part-1-additional-info-on-dsh-reporting-and-auditing.pdf. Consistent with First Circuit policy, a copy of the relevant page will be available on the public docket.

issued without notice and comment, the Secretary stated that both Medicare payments and private insurance payments associated with individuals also eligible for Medicaid should be deducted in calculating the DSH cap. The relevant statements appear in the responses to FAQs 33 and 34.

Several New Hampshire hospitals and the New Hampshire Hospital Association (collectively, "plaintiffs") subsequently filed this challenge to the procedural propriety of the two FAQs as well as to the substance of the policy articulated in the FAQs. The conflict arose in 2014, when the New Hampshire Department of Health and Human Services retained an independent accounting firm to conduct its statutorily required audit of DSH payments made to New Hampshire hospitals for fiscal year 2011. The auditor's report followed the Secretary's guidance articulated in the FAQs. In calculating the DSH cap, it thus reduced the total "costs incurred" by the plaintiff hospitals by the amount of payments received from both Medicare and private insurance in connection with treating Medicaid-eligible patients. According to this calculation, the plaintiff hospitals had received a significant overpayment in fiscal year 2011. The regulatory scheme requires the state to recover this sum. See 42 C.F.R. § 433.312.

Plaintiffs first petitioned CMS to withdraw the FAQs. CMS denied their petition. Plaintiffs then brought a challenge in federal district court under the Administrative Procedure Act,

seeking declaratory and injunctive relief. They alleged that because the rule articulated in the FAQs effected a substantive regulatory change, it was procedurally improper for having been issued without the notice-and-comment procedures prescribed by the APA. This impropriety, according to plaintiffs, rendered the agency's action invalid as both being taken "without observance of procedure required by law," 5 U.S.C. § 706(2)(D), as well as being "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," id. § 706(2)(A). Plaintiffs also argued that Congress itself, by specifying only two sources of payment to be offset against total costs (payments from Medicaid and from uninsured patients), had precluded the Secretary from requiring that all sources of reimbursement be offset.

The district court granted plaintiffs' request for a preliminary injunction. Approximately a year later, the district court granted plaintiffs' motion for summary judgment and permanently enjoined the Secretary from enforcing FAQs 33 and 34. In a nutshell, the court concluded that the rule set forth a substantive policy for which the APA required the agency to follow notice-and-comment procedures, and was thus procedurally improper under 5 U.S.C. § 706(2)(A) and (D). Having so ruled, the district court saw no need to reach plaintiffs' substantive challenge and thus did not address whether the agency, after notice and comment, could issue the same rule.

On April 3, 2017, approximately one month after the district court granted plaintiffs' motion for summary judgment, the Secretary promulgated a rule following notice and comment that amended the reporting requirement at issue in this litigation. See Disproportionate Share Hospital Payments -- Treatment of Third Party Payers in Calculating Uncompensated Care Costs, 82 Fed. Reg. 16,114 (Apr. 3, 2017) (codified at 42 C.F.R. § 447.299). The amendment defined "costs incurred" as "costs net of third-party payments, including, but not limited to, payments by Medicare and private insurance." Id. at 16,122 (codified at 42 C.F.R. § 447.299(c)(10)). This rule, in effect, codified the policy previously announced in the FAQs. Because the new rule did not become operative until June of 2017, it does not apply to the fiscal years at issue in this action. Plaintiffs challenge the substance of the 2017 regulatory amendment in a separate action, and we do not decide the merits of that challenge here.

II.

For purposes of this appeal, we 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. The issue is whether the Secretary has exercised that latitude in a procedurally proper manner. Resolution of that issue requires us to consider two

questions: First, is the decision to add Medicare and private party insurance reimbursements to the list of payments that must be offset against total costs in calculating "costs incurred" the type of decision that must be effected through notice-and-comment procedures under the APA? Second, if so, did the Secretary employ such procedures?

A.

The APA generally requires that before a federal agency adopts a rule it must first publish the proposed rule in the Federal Register and provide interested parties with an opportunity to submit comments and information concerning the proposal. 5 U.S.C. § 553. Failure to abide by these requirements renders a rule procedurally invalid. See Warder v. Shalala, 149 F.3d 73, 75 (1st Cir. 1998); see also Hoctor v. U.S. Dep't of Agric., 82 F.3d 165, 167 (7th Cir. 1996) (stating that, unless an exception applies, a "rule promulgated by an agency that is subject to the [APA] is invalid unless the agency" follows notice-and-comment procedures). As the Secretary points out, however, exempted from this requirement are "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b). And the Secretary argues that the FAQs in question fit comfortably within this exception from the notice-and-comment requirement, as a form of interpretive rule. Whether this is so is a question of law that we review de

novo, without the benefit of any definition in the APA itself. Warder, 149 F.3d at 79.

An interpretive rule is issued by an agency merely to "advise the public of the agency's construction of the statutes and rules which it administers." Perez v. Mortg. Bankers Ass'n, 135 S. Ct. 1199, 1204 (2015) (quoting Shalala v. Guernsey Mem'l Hosp., 514 U.S. 87, 99 (1995)). Although interpretive rules "do not have the force and effect of law," id., they nevertheless may have a substantial impact on regulated entities, see Levesque v. Block, 723 F.2d 175, 182 (1st Cir. 1983). The alternative to an interpretive rule is a legislative rule (interchangeably called a substantive rule), for which, absent another exception, the APA requires the agency to follow notice-and-comment procedures. See 5 U.S.C. § 553. We have said that a legislative rule is one that "creates rights, assigns duties, or imposes obligations, the basic tenor of which is not already outlined in the law itself." La Casa Del Convaleciente v. Sullivan, 965 F.2d 1175, 1178 (1st Cir. 1992).

Somewhere along a spectrum, a rule transitions from being interpretive to being legislative. But, in a refrain now frequently recited, the point at which a rule crosses that line is a question "enshrouded in considerable smog." Id. at 1177 (quoting Gen. Motors Corp. v. Ruckelshaus, 742 F.2d 1561, 1565 (D.C. Cir. 1984)); see also Mortg. Bankers Ass'n, 135 S. Ct. at 1204

(declining to "wade into" the "scholarly and judicial debate" concerning the term's "precise meaning"). Nevertheless, in this case five considerations lead us to conclude that the rule announced in the FAQs is legislative.

1.

First, we look at the words of the statute. In a subsection titled "Amount of adjustment subject to uncompensated costs," the statutory text provides that a hospital-specific payment adjustment shall not exceed the hospital's "costs incurred" in furnishing hospital services to Medicaid-eligible individuals and those without health insurance, which it says are "as determined by the Secretary and net of payments [by Medicaid] and by uninsured patients." 42 U.S.C. § 1396r-4(g)(1). The House Report on the 1993 legislation confirms that Congress was well aware of the difference between "net" and "total" costs. See H.R. Rep. No. 103-111, at 211-12 (noting reports that DSH payments had exceeded "the net costs, and in some instances the total costs, of operating" healthcare facilities). But rather than specifying the precise manner in which costs should be calculated, Congress used the unqualified term "costs incurred" in the statute. 42 U.S.C. § 1396r-4(g)(1)(A). The statute then requires the Secretary to net out two specific types of reimbursements, but otherwise leaves it to the Secretary to "determine[]" the meaning of "costs incurred." Id. This textual silence on whether to

offset other sources of payment 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. And, as the D.C. Circuit has said, "[w]here Congress has specifically declined to create a standard, the [agency] cannot claim its implementing rule is an interpretation of the statute." Mendoza v. Perez, 754 F.3d 1002, 1022 (D.C. Cir. 2014).

The Secretary accepts that the statute leaves "unaddressed" the question of whether to offset Medicare and private insurance payments, and agrees that "Congress expressly delegated authority to the Secretary to address such issues." The Secretary nevertheless posits that an agency need not "always . . . exercise expressly delegated authority by regulation." That may be true. But, as our case law makes clear, when Congress leaves such a policy choice to an agency, we should lean toward finding that the agency's making of that choice requires notice and comment. See Warder, 149 F.3d at 80; La Casa Del Convaleciente, 965 F.2d at 1179; Levesque, 723 F.2d at 182. Otherwise, it would be "difficult to imagine what regulations would require notice and comment procedures." Mendoza, 754 F.3d at 1021.

Thus, contrary to the Secretary's argument, this is not a case like Guernsey Memorial Hospital. There, the Secretary argued, and the Court appeared to agree, that the only plausible

interpretation of the statutory and regulatory scheme was the one advanced by the Secretary. See 514 U.S. at 98-99. The Secretary was thus simply following the statutory command, and was not making a discretionary policy judgment. We would have a similar situation in this case if, for example, Congress had expressly specified that all sources of third party reimbursements be offset from costs incurred, and the Secretary then implemented that directive by identifying Medicare payments as just such a reimbursement.

In sum, assuming that the Secretary has the authority asserted here, the text read in context suggests that any such authority is the result of Congress's decision to delegate a substantive policymaking choice to the Secretary.

2.

Second, we look at the explanation or lack thereof given by the agency in adopting a policy. Had the Secretary merely been interpreting the governing statute and regulation, then one would expect that the agency's justification for the rule would rely on an interpretive methodology. See Warder, 149 F.3d at 78 (noting that the agency discussed "relevant statutes, regulations, legislative history, and administrative materials before reaching its conclusion"); Metro. Sch. Dist. of Wayne Twp. v. Davila, 969 F.2d 485, 490 (7th Cir. 1992) (stating that the Secretary's reliance on "the language of both the statute and an implementing regulation, and the legislative history of the Act" in a letter

announcing the rule was an "important" factor "weigh[ing] in favor of a determination that the rule is interpretive" (internal citation omitted)); Gen. Motors Corp., 742 F.2d at 1565 (noting that the agency's "entire justification for the rule" in the Federal Register "is comprised of reasoned statutory interpretation, with reference to the language, purpose and legislative history of" the statute). Here, however, in announcing and explaining the FAQs, the Secretary offered no meaningful hint that the Secretary derived the policy announced in the FAQs from an interpretation of the statute or the regulation. And to the degree that the Secretary articulated the same policy in the preamble to the 2008 regulation, that announcement is no different. Although not dispositive, such an announcement, without reasoned interpretive explanation, looks to us more as if the Secretary is using delegated power to announce a new policy out of whole cloth, rather than engaging in an interpretive exercise.

Even now, on appeal, the Secretary does not meaningfully contend that the agency's rule is the result of a strictly interpretive exercise. The Secretary does place weight on the terms "uncompensated" costs and "costs incurred," as used in both the statute and the regulation. But the Secretary nowhere argues that further defining or applying these terms necessarily calls only for interpretation rather than policymaking. To the contrary, the Secretary repeatedly and expressly refers to the agency's

position as a "policy," and even goes so far as to characterize the rule as an exercise of a delegated authority to make "policy judgments."

The Secretary does stress that the agency has "broad methodological leeway" to interpret terms like "costs." Verizon Commc'ns, Inc. v. FCC, 535 U.S. 467, 500 (2002). While the cases relied on by the Secretary may stand for the proposition that the agency has broad authority in this realm, see Abraham Lincoln Mem'l Hosp. v. Sebelius, 698 F.3d 536, 549-50 (7th Cir. 2012); Kindred Hosps. E., LLC v. Sebelius, 694 F.3d 924, 928-29 (8th Cir. 2012); Cheshire Hosp. v. N.H.-Vt. Hospitalization Serv., Inc., 689 F.2d 1112, 1119 (1st Cir. 1982), the existence of authority is not our concern in our current procedural inquiry. Rather, assuming the agency has the authority to establish the rule at issue (a question we do not decide), we are concerned only with the manner in which the agency can exercise that authority. And, cutting against the Secretary's position, the agency's description of that authority as "broad" nudges us along the spectrum toward finding an act more akin to a legislative rule for which notice and comment is required.

That being said, it is certainly true that the "agency's own characterization" of its rule as interpretive warrants attention. Warder, 149 F.3d at 80. But the probative value of the Secretary's own characterization of a pronouncement as

interpretive is limited, and we do not place on it more weight than its merits can bear. See La Casa Del Convaleciente, 965 F.2d at 1178 (describing the agency's own characterization as "not conclusive"). Otherwise, we would create an easy end run around the APA's procedural protections.

3.

Third, we look to whether the rule is "inconsistent with another rule having the force of law," Warder, 149 F.3d at 81 (quoting Chief Prob. Officers v. Shalala, 118 F.3d 1327, 1337 (9th Cir. 1997)), or otherwise "alter[s] or enlarg[es] obligations imposed by a preexisting regulation," Aviators for Safe & Fairer Regulation, Inc. v. FAA, 221 F.3d 222, 226-27 (1st Cir. 2000). As the Secretary points out, the FAQs do not explicitly conflict with any existing regulations. But mere consistency, while perhaps necessary, cannot be sufficient to render a rule interpretive when the range of "consistent" choices includes materially different policy options that alter or enlarge existing obligations.[4]

[4] To illustrate the point, the D.C. Circuit, in an apt analogy, said:

> Consistency with the statute may be enough to sustain a rule duly promulgated after notice and comment, just as consistency with the Commerce Clause, Art. I, § 8, cl. 3, may be enough to sustain the constitutionality of a statute. But no one would say, for instance, that the detailed provisions of the Clean Air Act were interpretations of the language of the Constitution.

Otherwise, the first time an agency promulgates a rule on a subject it could always avoid notice and comment by pointing out that the new rule does not conflict with any prior regulation.

4.

Fourth, we consider the manner in which the Secretary's actions fit within the statutory and regulatory scheme. See Warder, 149 F.3d at 81. In Warder, the agency issued an administrative ruling classifying certain wheeled medical braces as "durable medical equipment" rather than "braces" for Medicare reimbursement purposes. 149 F.3d at 75. A "comprehensive classification of equipment" in the statutes and regulations as either braces or durable medical equipment, id. at 81, including several qualitative criteria, id. at 76-77, informed the agency's decision. Thus, in addressing a "small overlap in this scheme," id. at 81, the agency in Warder constructed its decision using the tools of statutory interpretation, id. at 78. Here, by contrast, the statute has a gap rather than an overlap, and it is a gap that the Secretary has sought to fill by exercising what it tells us is its policy prerogative.

5.

Finally, pragmatic considerations reinforce our decision to classify the rule at issue in this case as legislative. The

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Catholic Health Initiatives v. Sebelius, 617 F.3d 490, 496 (D.C. Cir. 2010).

precise question addressed by the rule -- whether to offset Medicare and third party reimbursements -- calls for a categorical resolution that affects a broad range of payments and scenarios and likely involves large sums of money. Additionally, in contrast to the circumstances present in Aviators, 221 F.3d at 227, the Secretary points to no evidence that the agency consistently implemented the statute between 1993 and 2010 in accord with the Secretary's present policy. Indeed, at oral argument the Secretary was unable to point to any evidence that the agency had ever previously enforced the policy articulated in the FAQs.

Instead, the Secretary can only point to the fact that in one letter in 2002 to state Medicaid directors on the subject of payments for prisoner inmate care and supplemental upper payment limits, CMS noted that the DSH cap must be calculated "net of Medicaid payments (except DSH) made under the state plan and net of third party payments." That sentence simply paraphrases the statute, albeit replacing "uninsured payments" with "third party payments." See 42 U.S.C. § 1396r-4(g)(1)(A). Read literally, in hindsight, the substituted term is broad enough to include Medicare and private insurance payments. But such a statement in a single letter that emphasizes the offset "of Medicaid payments" falls far short of demonstrating any longstanding -- or even short-standing

-- actual implementation of the statute as calling for the offset of Medicare and private insurance payments.[5]

In short, the FAQs announced a new policy on a matter of some considerable import. In such circumstances, the burdens that might weigh against requiring notice and comment for interstitial, minor, or confirmatory pronouncements guiding agency operation are much more easily justified in order to ensure the benefits of notice and comment.

B.

Our conclusion that the decision to require the set-off of Medicare and private insurance reimbursements in calculating "costs incurred" cannot be implemented without notice and comment brings us to our next inquiry: Whether the agency followed the necessary procedures in issuing its policy.

The Secretary concedes that the FAQs were not themselves the result of notice and comment. Instead, the Secretary points to the notice and comment that preceded the promulgation of the 2008 regulation. The Secretary then argues that the FAQs are exempt from notice and comment as a mere interpretive explanation of that regulation. A logically necessary intermediate step in this argument is that, if the decision to offset Medicare and

[5] We note, too, that the letter was written years before the adoption of the 2008 regulation that the Secretary says is the object of the FAQ's interpretive exercise.

private insurance payments from total costs is indeed a legislative decision delegated to the Secretary, then the Secretary made that decision in promulgating the 2008 regulation, with the FAQs serving only to add a mere interpretative gloss to the regulation. Under this view, the FAQs did not alter, enlarge, or otherwise effect a substantive regulatory change, and thus functioned outside the scope of actions that require lawmaking power. See Aviators, 221 F.3d at 226-27; see also Warder, 149 F.3d at 80 ("[A] rule is exempt from notice and comment as an interpretive rule if it does not 'effect a substantive change in the regulations.'" (quoting Guernsey Mem'l Hosp., 514 U.S. at 100)).

The 2008 regulation provides an unlikely vehicle for exercising the Secretary's delegated power to "determine[]" costs incurred under the DSH cap. 42 U.S.C. § 1396r-4(g)(1)(A). It never addresses the substance of the cap, nor even purports to implement the cap legislation itself. Rather, it claims to implement the reporting requirement of the 2003 Modernization Act. See 73 Fed. Reg. at 77,904. The regulation then lays out various categories of information that must be reported to the Secretary, including "Total Medicaid Uncompensated Care," which it defines as the "total amount of uncompensated care attributable to Medicaid inpatient and outpatient services." 42 C.F.R. § 447.299(c)(11)

(2012).[6] It further clarifies that this "amount should be the result of subtracting the amount identified in § 447.299(c)(9) from the amount identified in § 447.299(c)(10)." Id. Subsection (c)(10) presents the "total annual costs incurred by each hospital for furnishing inpatient hospital and outpatient hospital services to Medicaid eligible individuals," while subsection (c)(9) lists the various Medicaid payments deducted.

The Secretary points to two terms as the basis of the rule: "costs incurred" as used in subsection (c)(10), and "uncompensated" care as used in subsection (c)(11), which, as explained above, is defined to incorporate "costs incurred." The Secretary argues that the subsequent FAQs simply fleshed out in an interpretive manner that those two terms meant that Medicare and third party insurance payments need be offset.

If the DSH cap statute itself left the Secretary the broad latitude the Secretary claims in deciding whether to classify Medicare and third party insurance payments as requiring set-offs in calculating "costs incurred," then the regulation itself cannot reasonably be read as manifesting the exercise of that latitude. Rather, the regulatory text, as the Secretary concedes, is silent

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[6] We cite the 2012 version of the rule because the rule originally promulgated in 2008 contained several technical, but substantial errors. These were corrected in 2009. See 74 Fed. Reg. 18,656, 18,656-57 (Apr. 24, 2009). The current version of the rule, however, incorporates the Secretary's 2017 amendment, which is not at issue in this case.

as to the proper treatment of third-party payments, i.e., payments from Medicare and private insurance. And the portions of the regulation from which the Secretary claims to derive the rule -- the terms "uncompensated" and "costs incurred" -- merely parrot the statutory language. Indeed, the term "costs incurred" is exactly the term used in the statute and the term "uncompensated costs" is the caption of the pertinent statutory subsection. See 42 U.S.C. § 1396r-4(g)(1)(A). Nothing in this regulation mentions -- either directly or indirectly -- payments from Medicare or from private insurance.

So the sequence is this: Congress specified that the DSH payment adjustment not exceed "uncompensated costs," which it defined as "costs incurred" less received Medicaid payments, and one specified other source of payments, and charged the Secretary with more precisely determining "costs incurred." Without providing such further definition, the Secretary enacted a regulation that in material respects simply parrots the statute. Then, in a purportedly interpretive rule published a few years later on the Medicaid website, the Secretary announced that "costs incurred" excludes payments received from Medicare and private insurance associated with individuals eligible for dual coverage.

Thus, the Secretary exercised delegated power not through notice-and-comment regulation, but in a guidance document issued without the APA's procedural protections. To deem this

adequate would mean an agency could largely eliminate pre-decision public comment on the merits of the agency's exercise of its delegated powers to make substantive choices: The agency would simply adopt a regulation parroting the statute, and then reveal its choice through a rule "interpreting" the regulation. As the D.C. Circuit has recognized,

> the purpose of the APA would be disserved if an agency with a broad statutory command . . . could avoid notice-and-comment rulemaking simply by promulgating a comparably broad regulation . . . and then invoking its power to interpret that statute and regulation in binding the public to a strict and specific set of obligations.

Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec., 653 F.3d 1, 7 (D.C. Cir. 2011).

The Secretary argues that the regulation here does more than parrot the pertinent statutory term. For one, while the statute spells out that costs incurred relate to "hospital services," the regulation further specifies that the costs incurred must be attributable to "inpatient hospital and outpatient hospital services." Similarly, while the statute says that costs incurred should net out Medicaid payments, the regulation specifies three particular categories of Medicaid payments, and includes payments under Section 1011. See 42 C.F.R § 447.299(c)(6)-(8), (13). But these specifications that go beyond the statutory text have no bearing whatsoever on the issue

at hand, as evidenced by the fact that the Secretary relies on none of these added specifications as providing any basis for deeming "costs incurred" to be limited to costs net of Medicare or other third party insurance payments.

As a fallback position, the Secretary argues that the agency established the relevant policy in the preamble to the 2008 reporting regulation, rather than in its text. The preamble does clearly state, at least with respect to individuals eligible for both Medicare and Medicaid (but not private insurance payments), that Medicare payments should be deducted from the hospitals' "costs incurred." See 73 Fed. Reg. at 77,912. But this argument fails because, if the agency did establish its rule in the preamble, it is procedurally improper for the same reasons we deemed the FAQs announcement procedurally improper. Although the 2008 regulation was subject to notice and comment, the preamble, like the FAQs announcement, was not. See Leslie Salt Co. v. United States, 55 F.3d 1388, 1393 (9th Cir. 1995) ("It is undisputed that the preamble has not been subjected to notice and comment."). A rule stated in a preamble is subject to the same analysis of whether its articulated policy is interpretive or legislative, and if it is the latter, it is procedurally improper. See id. at 1393-94 (conducting this analysis for a rule articulated in a preamble); Fertilizer Inst. v. EPA, 935 F.2d 1303, 1307-09 (D.C. Cir. 1991) (same). Thus, because we concluded that the relevant policy choice

is one that must be made through notice and comment, the agency's implementation of this delegated lawmaking authority in a preamble is procedurally improper.

Finally, to the degree the Secretary argues that we should defer to the preamble to discern the meaning of the regulation, we are similarly unconvinced. Because the adoption of a substantive policy in a preamble added to a regulation after notice and comment is procedurally improper, cf. Leslie Salt Co., 55 F.3d at 1393-94; Fertilizer Inst., 935 F.2d at 1307-09, such a policy cannot be the source of an interpretation to which a court defers, see Encino Motorcars, LLC v. Navarro, 136 S. Ct. 2117, 2125 (2016) ("Chevron deference is not warranted where the regulation is 'procedurally defective' -- that is, where the agency errs by failing to follow the correct procedures in issuing the regulation."(quoting United States v. Mead Corp., 533 U.S. 218, 227 (2001))). But even if that were not the case, we would harbor doubts about whether deference is appropriate here. It is true that, in certain circumstances, we have deferred to a regulation's preamble as an agency's interpretation of its own ambiguous regulation. See, e.g., Rucker v. Lee Holding Co., 471 F.3d 6, 12 (1st Cir. 2006). But here, we see no ambiguity in the relevant sense. As we explained above, we assume, without deciding, that the agency has the power to adopt a policy following notice and comment that excludes dual-eligible Medicare payments from the

definition of "costs incurred." Had the regulation been ambiguous about whether the agency intended to adopt this policy, then deferring to the preamble to resolve the ambiguity may have been appropriate. But that is not the case. Nowhere in the regulatory text does the Secretary mention Medicare payments or individuals eligible for dual-coverage, nor does the text provide any other hook -- beyond the terms also used in the statute -- to which the Secretary can point to demonstrate ambiguity about whether the Secretary intended to adopt the rule at issue. It is insufficient that there may be ambiguity about what rule the agency would adopt, given the choice. Where the agency is granted broad delegated authority, but makes no overtures in the regulatory text about its intention to adopt a policy pursuant to that authority, there is no relevant ambiguity that can be resolved by the preamble.

Our conclusion that deference is inappropriate in this circumstance is buttressed by what we see as strong policy considerations. The Secretary concedes that both the statutory and regulatory texts are silent on the operative question of whether "costs incurred" includes Medicare payments and private insurance payments. We have determined that this issue reflects a substantive policy choice for which the APA requires notice and comment. Thus, if deference to the preamble allowed the agency to implement its dual-eligible policy, the agency would be able to execute a substantive policy choice without notice and comment.

We find such a subversion of the APA's procedural requirements unacceptable.

III.

Because we affirm the district court's decision on the grounds that the Secretary's rule is procedurally improper for having failed to observe the notice-and-comment procedures prescribed by the APA, we decline to reach plaintiffs' substantive challenge under 5 U.S.C. § 706(2)(C). In so doing, we neither express nor imply any view on whether the agency can adopt the policy articulated in the FAQs following notice-and-comment rulemaking. Nor do we accept the plaintiffs' invitation to pass judgment upon the validity of the 2017 regulation; that is a matter for another day.

For the foregoing reasons, the district court's decision is affirmed.