United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 11, 2017 Decided July 25, 2017

No. 16-5255

ALLINA HEALTH SERVICES, DOING BUSINESS AS UNITED HOSPITAL, DOING BUSINESS AS UNITY HOSPITAL, DOING BUSINESS AS ABBOTT NORTHWESTERN HOSPITAL, ET AL.,
APPELLANTS

v.

THOMAS E. PRICE, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
APPELLEE

Appeal from the United States District Court
for the District of Columbia
(No. 1:14-cv-01415)

Stephanie A. Webster argued the cause for appellants. With her on the briefs were *Pratik A. Shah*, *Christopher L. Keough*, *James H. Richards*, and *Hyland Hunt*.

Stephanie R. Marcus, Attorney, U.S. Department of Justice, argued the cause for appellee. With her on the brief was *Mark B. Stern*, Attorney.

Before: HENDERSON, KAVANAUGH, and MILLETT, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* KAVANAUGH.

KAVANAUGH, *Circuit Judge*: Several hospitals have challenged the formula used by the Department of Health and Human Services for calculating certain Medicare reimbursement adjustments for fiscal year 2012. As relevant here, the hospitals argued before the District Court that HHS violated the Medicare Act by changing the reimbursement adjustment formula without providing the public with notice and opportunity for comment.

The District Court ruled that HHS did not violate the Medicare Act's procedural requirements. The District Court reasoned that (i) the Medicare Act incorporates the Administrative Procedure Act's exception to notice-and-comment rulemaking for interpretive rules and (ii) HHS's issuance of the reimbursement adjustment formula here constituted an interpretive rule. The District Court granted summary judgment to HHS.

We disagree with the District Court. We conclude that HHS violated the Medicare Act when it changed its reimbursement adjustment formula without providing notice and opportunity for comment. We reverse the judgment of the District Court and remand for proceedings consistent with this opinion.

I

A

Through the Medicare program, the Federal Government provides health insurance to Americans who are 65 or older, as well as to disabled Americans. *See generally* Social Security Amendments of 1965, Pub. L. No. 89-97, sec. 102, 79 Stat.

286, 291-332 (codified as amended at 42 U.S.C. § 1395 *et seq.*). The Department of Health and Human Services administers and oversees Medicare. Patients can obtain insurance under different Medicare "parts." Two of those parts are relevant here. Medicare Part A provides Medicare enrollees with government-administered health insurance through which the Government makes direct payments to hospitals for healthcare services provided. *See* 42 U.S.C. §§ 1395c to 1395i–5. Part C provides enrollees with government-subsidized enrollment in private insurance plans. *See id.* §§ 1395w–21 to 1395w–29.

HHS contracts with companies known as fiscal intermediaries to reimburse healthcare service providers for services rendered to Medicare Part A patients. Fiscal intermediaries make initial payments to hospitals for a given cost year. Those initial payments are based on estimates of the hospitals' actual costs. The initial payments are later adjusted based on providers' actual cost reports.

A provider who disagrees with a fiscal intermediary's reimbursement or adjustment decision may appeal that decision to the Provider Reimbursement Review Board within HHS. *See* 42 U.S.C. § 1395*oo*. The Board may affirm, modify, or reverse the fiscal intermediary's decision. *Id.* § 1395*oo*(d). But importantly, the Board does not have the authority to declare statutes or regulations invalid. *See Bethesda Hospital Association v. Bowen*, 485 U.S. 399, 406 (1988); 42 C.F.R. § 405.1842(f)(2)(ii).

As relevant here, the Medicare Act authorizes reimbursement adjustments in order to increase payments to hospitals that treat a disproportionately high number of low-income patients. *See* 42 U.S.C. § 1395ww(d)(5)(F)(i)(I). That adjustment is known as the "disproportionate share hospital

adjustment." The adjustment is calculated for each hospital by adding two fractions that together approximate the proportion of low-income patients treated at that hospital over a certain time period. *See id.* § 1395ww(d)(5)(F)(vi). HHS calculates and publishes one of those fractions – the Medicare fraction – for each hospital in the Nation every year. HHS requires the fiscal intermediaries to use HHS's published Medicare fractions in calculating each hospital's final reimbursement adjustment. *See* 42 C.F.R. § 412.106(b)(2), (5).

Among other things, the Medicare fraction incorporates the number of each hospital's patient days for patients "entitled to benefits under part A" of Medicare. 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I). The meaning of that phrase has been the subject of much debate (and litigation). The dispute is over whether the phrase "entitled to benefits under Part A" should be read to refer not only to Part A enrollees, but also to patients enrolled in a Part C plan.

For reasons that are beyond the scope of this opinion, HHS now believes that the phrase "entitled to benefits under Part A" should also include patients enrolled in a Part C plan. HHS therefore contends that Part C patient days should be included in the Medicare fractions. Many hospitals disagree. They argue that Part C enrollees are *not* "entitled to benefits under Part A" and that Part C days therefore should *not* be included in Medicare fractions.

That difference in interpretation makes a huge difference in the real world. Part C enrollees tend to be wealthier than Part A enrollees. Including Part C days in Medicare fractions therefore tends to lead to lower reimbursement rates. Ultimately, hundreds of millions of dollars are at stake for the Government and the hospitals. *See Northeast Hospital Corp. v. Sebelius*, 657 F.3d 1, 5 (D.C. Cir. 2011).

Before 2004, HHS had *not* treated Part C enrollees as "entitled to benefits under Part A." *See id.* at 15. In 2004, however, HHS promulgated a rule announcing that Part C enrollees *are* "entitled to benefits under Part A" and that HHS would therefore include Part C days in Medicare fractions. *See* Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates, 69 Fed. Reg. 48,916, 49,099 (Aug. 11, 2004). That 2004 rule would have applied HHS's changed interpretation prospectively to all Medicare fraction calculations from fiscal year 2005 onward. However, this Court vacated the 2004 rule on the grounds that it was not a logical outgrowth of the proposed rule and had therefore been improperly issued without notice and opportunity for comment. *See Allina Health Services v. Sebelius*, 746 F.3d 1102, 1107-09 (D.C. Cir. 2014). As a result, HHS can no longer rely on the 2004 interpretation.

In 2013, HHS promulgated a new rule again announcing that HHS would treat Part C enrollees as "entitled to benefits under Part A" and that HHS would therefore include Part C days in Medicare fractions. *See* 78 Fed. Reg. 50,496, 50,614 (Aug. 19, 2013). The 2013 rule is prospective only: It applies to Medicare fractions calculated for fiscal year 2014 and beyond. *Id.* at 50,619. It does not address the definition of "entitled to benefits under Part A" for any fiscal years before 2014. In sum, HHS has no promulgated rule governing the interpretation of "entitled to benefits under Part A" for the fiscal years before 2014.

B

In June 2014, HHS published the Medicare fractions to be used in calculating disproportionate share hospital adjustments for fiscal year 2012. At the top of the spreadsheet containing

those fractions, HHS noted that it had included Part C days in the Medicare fractions. The spreadsheet contained the 2012 Medicare fractions for all hospitals nationwide.

Plaintiffs in this case are hospitals that provide health care to low-income Medicare patients and that are therefore entitled to disproportionate share hospital adjustments. Those hospitals here challenge HHS's June 2014 decision to include Part C days in the 2012 Medicare fractions.

As required by statute, the hospitals first sought review by the Provider Reimbursement Review Board within HHS. But the hospitals believed that the Board did not have the authority to resolve the hospitals' challenges because the hospitals' challenges related to the validity of several HHS regulations. Under HHS's rules implementing the Medicare statute, the Board may not review challenges "either to the constitutionality of a provision of a statute, or to the substantive or procedural validity of a regulation." 42 C.F.R. § 405.1842(f)(1). The hospitals therefore sought expedited judicial review, which is available under the statute when the Board certifies that it does not have authority to resolve a provider's challenge. When the Board so certifies, the provider may bring suit in district court without proceeding through the full Board review process. *See* 42 U.S.C. § 1395*oo*(f)(1).

Here, the Board agreed with the hospitals that it did not have the authority to resolve the hospitals' challenge. That no-authority determination allowed the hospitals to promptly bring suit in District Court challenging HHS's decision to include Part C days in the Medicare fractions for fiscal year 2012.

In the District Court, HHS moved to dismiss the hospitals' case on the ground that the case was premature. HHS argued that the Board's no-authority determination was erroneous, and

that the District Court therefore did not have authority to consider the challenges to the Medicare fractions until the Board ruled on that claim. The hospitals responded that the Board's no-authority determination was not reviewable by the District Court and that, in any event, the Board's no-authority determination was correct. The District Court agreed with HHS that the District Court could review the Board's no-authority determination. The District Court agreed with the hospitals, however, that the Board's no-authority determination was correct. The District Court therefore denied HHS's motion to dismiss.

Both sides then moved for summary judgment on the merits of the hospitals' challenges. The hospitals contended that HHS violated the Administrative Procedure Act and the Medicare Act by including Part C days in the fiscal year 2012 Medicare fractions without first providing the public with notice and opportunity for comment. They also argued that the calculations were arbitrary and capricious. HHS responded that its decision was procedurally and substantively proper.

The District Court granted summary judgment to HHS. First, the District Court held that the June 2014 decision to include Part C days in the 2012 Medicare fractions was an "interpretive rule" under the APA. As a result, the District Court concluded that HHS's publication of the fiscal year 2012 Medicare fractions was statutorily exempt from the APA's notice-and-comment requirements. Second, the District Court held that the Medicare Act incorporated the APA's notice-and-comment exception for interpretive rules. The District Court therefore held that HHS had not violated the Medicare Act's procedural requirements. Third, the District Court held that HHS's decision to include Part C days in the 2012 Medicare fractions was not arbitrary and capricious.

The hospitals now appeal the District Court's grant of summary judgment to HHS. This Court reviews a district court's grant of summary judgment de novo. *See Southeast Alabama Medical Center v. Sebelius*, 572 F.3d 912, 916 (D.C. Cir. 2009).

II

HHS's Provider Reimbursement Review Board concluded that it lacked authority to decide this dispute. The Board therefore certified the case for expedited judicial review in the District Court. The District Court concluded that it had authority to decide the case. We must first consider whether the District Court correctly concluded that it had authority to decide the case now, or whether the dispute instead should have been decided first by HHS's Provider Reimbursement Review Board.

HHS argues that the dispute should have been decided first by the Board. The hospitals raise two alternative points in response. They contend that the District Court may not review the Board's no-authority determination. The hospitals also argue in the alternative that even if the District Court may review the Board's no-authority determination, the Board here was correct to conclude that it did not have authority to hear the hospitals' challenge. We agree with the hospitals on both alternative arguments.

To begin, the hospitals are correct that a district court may not review the Board's no-authority determination at HHS's request. The Medicare Act states that providers – and only providers – "*shall*" have "the right to obtain" expedited judicial review "*whenever* the *Board* determines . . . that it is without authority to decide" a particular question. 42 U.S.C.

§ 1395*oo*(f)(1) (emphasis added).[1] In other words, providers are guaranteed expedited judicial review when the Board makes a no-authority determination, as the Board did here. The statute conditions expedited judicial review in the district court on the existence of that no-authority determination, *not* on whether that determination is correct.

The statutory structure confirms that reading of the text. A provider may bring suit in the district court even when the Board fails to make a timely determination of its authority to decide a case. *See id.* ("If the Board fails to render such determination within such period, the provider may bring a civil action (within sixty days of the end of such period) with

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[1] As relevant here, the statutory provision for expedited judicial review reads: "Providers shall also have the right to obtain judicial review of any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the Board determines (on its own motion or at the request of a provider of services as described in the following sentence) that it is without authority to decide the question, by a civil action commenced within sixty days of the date on which notification of such determination is received. If a provider of services may obtain a hearing under subsection (a) of this section and has filed a request for such a hearing, such provider may file a request for a determination by the Board of its authority to decide the question of law or regulations relevant to the matters in controversy (accompanied by such documents and materials as the Board shall require for purposes of rendering such determination). The Board shall render such determination in writing within thirty days after the Board receives the request and such accompanying documents and materials, and the determination shall be considered a final decision and not subject to review by the Secretary. If the Board fails to render such determination within such period, the provider may bring a civil action (within sixty days of the end of such period) with respect to the matter in controversy contained in such request for a hearing." 42 U.S.C. § 1395*oo*(f)(1).

respect to the matter in controversy contained in such request for a hearing."). As the hospitals rightly point out, it would be "nonsensical if judicial review could be defeated by disagreement with the Board's no-authority decision, even though the Board's failure to make such a decision undisputedly confers federal court jurisdiction." Allina Reply Br. 5.

Put simply, Congress has allowed providers to seek immediate judicial review when the Board concludes that an extensive and time-consuming administrative process before the Board would likely be pointless. Requiring parties in district court to fully brief and re-litigate the Board's assessment of its own lack of authority – a question that may often be inextricably linked to the merits of a provider's challenge – runs entirely counter to that statutory scheme.[2]

In any event, even if we were wrong about that point, the Board here was correct in deciding that it did not have authority to resolve the hospitals' challenge. Under HHS regulations implementing the statute's expedited judicial review procedure, the Board "must grant" expedited judicial review if the legal question raised "is a challenge either to the constitutionality of a provision of a statute, or to the substantive or procedural validity of a regulation." 42 C.F.R. § 405.1842(f)(1). The hospitals here pressed two arguments before the Board. Both arguments challenged the "substantive or procedural validity" of different regulations. *Id.* § 405.1842(f)(1)(ii). First, the hospitals argued that HHS erred when it chose to apply the formula from the vacated 2004 rule

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[2] We recognize that our decision here breaks with other courts of appeals that have concluded that the Board's no-authority determinations are reviewable. *See, e.g.*, *Providence Yakima Medical Center v. Sebelius*, 611 F.3d 1181, 1187 n.7 (9th Cir. 2010).

in calculating the 2012 fractions. The hospitals' first argument therefore raised the question of the 2004 rule's continuing legal validity. Second, the hospitals argued that HHS violated various procedural requirements by promulgating a new regulation without notice-and-comment rulemaking. That argument turned on whether the decision to include Part C days in the 2012 Medicare fractions constituted a new regulation, and if it did, whether that new regulation was procedurally valid. Both of the hospitals' arguments raise legal questions about the "substantive or procedural validity of a regulation." *Id.* The Board's no-authority determination was correct. The District Court correctly concluded that it had authority to decide the case now.

III

A

We turn therefore to the hospitals' claim that HHS violated the Medicare Act by failing to provide for notice and comment before including Part C days in the 2012 Medicare fractions. We agree with the hospitals that HHS unlawfully failed to provide for notice and comment.

The Medicare Act describes in fairly straightforward language when notice and comment is necessary. Paragraph (2) of Section 1395hh(a) provides:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect

> unless it is promulgated by the Secretary by regulation under paragraph (1).

42 U.S.C. § 1395hh(a)(2). Paragraph (1), in turn, requires the HHS Secretary to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs" under the Medicare Act. *Id.* § 1395hh(a)(1). With a few exceptions not relevant here, "the Secretary shall provide for notice of the proposed regulation" to allow "for public comment thereon." *Id.* § 1395hh(b)(1).

In other words, as relevant here, the Medicare Act requires notice-and-comment rulemaking for any (1) "rule, requirement, or other statement of policy" that (2) "establishes or changes" (3) a "substantive legal standard" that (4) governs "payment for services." *Id.* § 1395hh(a)(2). All four requirements are readily met here.

First, HHS's inclusion of Part C days in the fiscal year 2012 Medicare fractions is, at the very least, a "requirement." Fiscal intermediaries are *commanded* to use HHS's Medicare fractions in calculating adjustment amounts. *See* 42 C.F.R. § 412.106(b)(2), (5). Those fractions treat Part C enrollees as "entitled to benefits under Part A." The fiscal intermediaries are therefore *required* to include Part C days in their calculations as they determine reimbursement adjustments. In short, HHS promulgated a "requirement" when it announced that the 2012 Medicare fractions would include Part C days.

Second, HHS's inclusion of Part C days in the fiscal year 2012 Medicare fractions represents a change in HHS's standards. Before 2004, HHS's standard practice was to *exclude* Part C days from Medicare fractions. *See Northeast Hospital Corp. v. Sebelius*, 657 F.3d 1, 15 (D.C. Cir. 2011). HHS's 2004 rule attempted to change that standard so that the

Medicare fractions would *include* Part C days. *Id.* at 14. But that rule was vacated. *See Allina Health Services v. Sebelius*, 746 F.3d 1102, 1111 (D.C. Cir. 2014) (*Allina I*). Although HHS promulgated a new rule in 2013 that includes Part C days in Medicare fractions, that rule applies only prospectively to reimbursement adjustments for fiscal years 2014 and beyond.[3] As a result, the pre-2004 standard of excluding Part C days from Medicare fractions remains the baseline practice from which this Court must evaluate any decisions for 2012. The decision to include Part C days in the 2012 Medicare fractions is therefore a change from prior practice.

Third, HHS's inclusion of Part C days in the fiscal year 2012 Medicare fractions establishes a "substantive legal standard." "Substantive law" is law that "creates, defines, and regulates the rights, duties, and powers of parties." BLACK'S LAW DICTIONARY (10th ed. 2014). A "substantive legal standard" at a minimum includes a standard that "creates, defines, and regulates the rights, duties, and powers of parties." That is precisely what HHS's 2012 Medicare fractions do. The fiscal intermediaries must use HHS's published Medicare fractions in determining how much the hospitals will be reimbursed. HHS's fractions therefore define the scope of hospitals' legal rights to payment for treating low-income patients.

Fourth, HHS's inclusion of Part C days in the fiscal year 2012 Medicare fractions governs "payment for services." The fractions are used to calculate the payment that providers will receive for providing healthcare services to low-income patients. The inclusion of Part C days means that the providers will now receive lower payments.

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[3] The 2013 rule is the subject of pending litigation in the District Court. We express no views on the merits of that case.

In sum, HHS's decision to include Part C days in the 2012 Medicare fractions is covered by the text of Section 1395hh(a)(2). The Medicare Act therefore required HHS to engage in notice-and-comment rulemaking before deciding to include Part C days in the 2012 Medicare fractions. Because HHS did not undertake notice-and-comment rulemaking, the 2012 Medicare fractions are procedurally invalid.

B

HHS's arguments to the contrary are not persuasive.

First, HHS argues that the fractions are not a "rule, requirement, or statement of policy" because the fractions apply only to the parties in this particular case for the year 2012. That argument is factually inaccurate. HHS published Medicare fractions for *every hospital in the country*. All of those fractions include Part C days. Indeed, during oral argument, HHS forthrightly acknowledged that it would "generally" maintain a "consistent interpretation" for all hospitals for a given year, meaning that the policy applied to the hospitals in this case would apply to all hospitals nationwide. Tr. of Oral Arg. at 29:20-21. Moreover, as the hospitals point out, the 2012 Medicare fractions will be the basis not just for 2012 adjustments, but also for interim 2013 payments until HHS publishes the 2013 fractions. *See* 42 C.F.R. § 413.64(e). In other words, the decision to include Part C days in the 2012 Medicare fractions affects more hospitals than just the parties in this particular case for this particular year.

Second, HHS argues that the Medicare Act incorporates the APA's exceptions to notice-and-comment requirements.

According to HHS, even if the decision to include Part C days in the fiscal year 2012 Medicare fractions is a rule, it is at most an "interpretive rule" for purposes of the APA. As a result, it is exempt from the APA's – and, by extension, the Medicare Act's – notice-and-comment requirements.

The problem with that argument is that the Medicare Act does not incorporate the APA's interpretive-rule exception to the notice-and-comment requirement. (Therefore, we need not decide whether HHS's decision to include Part C days in the 2012 Medicare fractions was in fact an interpretive rule.)

Unlike the APA, the text of the Medicare Act does not exempt interpretive rules from notice-and-comment rulemaking. On the contrary, the text expressly *requires* notice-and-comment rulemaking. The Medicare Act states: "*No* rule, requirement, or other statement of policy . . . shall take effect *unless* it is promulgated" through notice-and-comment rulemaking. 42 U.S.C. § 1395hh(a)(2) (emphasis added); *id.* § 1395hh(b)(1). The provision does not include an exception for interpretive rules. By contrast, the APA requires notice and comment only for "proposed rule making" and exempts "interpretative rules, general statements of policy, [and] rules of agency organization, procedure, or practice" from notice-and-comment requirements. 5 U.S.C. § 553(b). We must respect Congress's use of different language and its establishment of different notice-and-comment requirements in the Medicare Act and the APA. *Cf.* WILLIAM N. ESKRIDGE JR., INTERPRETING LAW: A PRIMER ON HOW TO READ STATUTES AND THE CONSTITUTION 109-10 (2016) ("Where a statute repeatedly uses one term or phrase, one expects that a materially different phraseology demands a different reading."); ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 170 (2012) ("[A] material variation in terms suggests a variation in meaning.").

Moreover, Congress knew how to incorporate the APA's notice-and-comment exceptions into the Medicare Act when it wanted to. After all, the Medicare Act expressly incorporates other APA notice-and-comment exceptions. Specifically, the Medicare Act incorporates the APA's "good cause" exception. *See* 42 U.S.C. § 1395hh(b)(2) (Notice-and-comment rulemaking requirement "shall not apply where— . . . subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection."). But in the Medicare Act, Congress did not incorporate the APA's interpretive-rule exception to notice-and-comment requirements.

We recognize that we are breaking with several other courts of appeals by holding that the Medicare Act does not incorporate all of the APA's exceptions to the notice-and-comment requirement. *See, e.g.*, *Via Christi Regional Medical Center, Inc. v. Leavitt*, 509 F.3d 1259, 1271 n.11 (10th Cir. 2007); *Baptist Health v. Thompson*, 458 F.3d 768, 776 n.9 (8th Cir. 2006); *Omni Manor Nursing Home v. Thompson*, 151 Fed. App'x 427, 431 (6th Cir. 2005); *Warder v. Shalala*, 149 F.3d 73, 79 n.4 (1st Cir. 1998).[4] But we respectfully disagree with those opinions. As discussed, we conclude that the Medicare Act does not incorporate the APA's interpretive-rule exception to the notice-and-comment requirement.

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[4] As HHS points out, this Court's prior decision in *Monmouth Medical Center v. Thompson*, 257 F.3d 807, 814 n.2 (D.C. Cir. 2001), noted the question of whether the Medicare Act incorporates the APA's interpretive-rule exception. But as HHS recognizes, *Monmouth* did not "expressly decide the question" raised here. HHS Br. 44.

C

Finally, even if HHS were correct that the Medicare Act somehow incorporated the APA's notice-and-comment exception for interpretive rules, HHS would still not prevail here. That is because another provision of the Medicare Act, Section 1395hh(a)(4), expressly required notice and comment in this case. Section 1395hh(a)(4) reads in full:

> If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

42 U.S.C. § 1395hh(a)(4). In other words, if a regulation includes a "provision that is not a logical outgrowth of a previously published notice of proposed rulemaking," that provision may not become legally operative until it has gone through notice-and-comment rulemaking. *Id.*

Section 1395hh(a)(4) applies with full force here. This Court vacated HHS's 2004 rule treating Part C enrollees as "entitled to benefits under Part A" because the 2004 rule "was not a logical outgrowth of the proposed rule." *Allina I*, 746 F.3d at 1109. HHS therefore had to provide a "further opportunity for public comment and a publication of the provision again as a final regulation" before HHS could re-impose the rule. 42 U.S.C. § 1395hh(a)(4). HHS did not do so. And HHS could not circumvent this requirement by claiming that it was acting by way of adjudication rather than rulemaking. The statutory text says that the vacated rule may not "take effect" at all until there has been notice and comment.

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Because we conclude that HHS has failed to provide notice and comment as required by the Medicare Act, we need not consider whether HHS's decision was arbitrary and capricious. We reverse the judgment of the District Court and remand for proceedings consistent with this opinion.

So ordered.