United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued October 12, 2017 Decided December 26, 2017

No. 16-5307

CLARIAN HEALTH WEST, LLC, DOING BUSINESS AS CLARIAN WEST MEDICAL CENTER,
APPELLEE

v.

ERIC HARGAN, ACTING SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
APPELLANT

Appeal from the United States District Court
for the District of Columbia
(No. 1:14-cv-00339)

Katherine Twomey Allen, Attorney, U.S. Department of Justice, argued the cause for appellant. With her on the briefs was *Michael S. Raab*, Attorney.

Z.W. Julius Chen argued the cause for appellee. With him on the briefs were *Christopher L. Keough* and *Stephanie A. Webster*.

Before: GARLAND, *Chief Judge*, HENDERSON, *Circuit Judge*, and EDWARDS, *Senior Circuit Judge*.

Opinion for the Court filed by *Senior Circuit Judge* EDWARDS.

EDWARDS, *Senior Circuit Judge*: This case involves a challenge to the legality of a Department of Health and Human Services ("HHS") decision to set forth certain policies regarding the means of calculating reimbursements for Medicare providers in an instruction manual without engaging in notice-and-comment rulemaking. Because we find that nothing required the agency to proceed otherwise, we must respect its selected approach. *See Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1206 (2015) (emphasizing that courts may not "improperly impose[] on agencies an obligation beyond the 'maximum procedural requirements' specified by [statute or regulation]" (quoting *Vermont Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978))).

Under Part A of the Medicare program, hospitals are compensated prospectively based on the estimated likely cost of patient care. *Prospective Payment for Medicare Inpatient Hospital Services*, 49 Fed. Reg. 234 (Jan. 3, 1984); 42 U.S.C. § 1395ww(d)(2). On some occasions, when the prospective payments appear to have been insufficient, hospitals also receive supplemental or "outlier" payments. 42 U.S.C. § 1395ww(d)(5)(A)(ii); *see also Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 49 (D.C. Cir. 2015).

In 2003, the Secretary of HHS promulgated a regulation, through notice-and-comment rule making, that altered the way such "outlier payments" are calculated. *Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Under the Acute Care Hospital Inpatient and Long-Term Care Hospital Prospective Payment Systems*, 68 Fed. Reg. 34,494 (June 9, 2003). As part

of the regulation, HHS determined that the payments should be subject to recalculation—or "reconciliation"—after certain hospital cost reports were finalized in order to ensure that the payments corresponded with the hospitals' actual experienced costs. *See id.* at 34,501; 42 C.F.R. § 412.84(i)(4). The regulation did not determine how hospitals would be selected for this reconciliation procedure.

In 2010, HHS established instructions governing the selection process. Set forth in a manual for Medicare payment contractors, the instructions provided two criteria for payments that should be recalculated and reconciled. Medicare Claims Processing Manual, ch. 3, § 20.1.2.5(A) (Dec. 3, 2010), *reprinted in* Joint Appendix ("J.A.") 129-30 [hereinafter CMS Manual]. In 2012, HHS and its contractor determined that Appellee Clarian Health West ("Clarian" or "Appellee") met the criteria for outlier payments made to it for services provided in fiscal year 2007. The hospital was subjected to reconciliation, and it was ultimately required to pay back over $2 million in outlier payments.

Clarian challenged the 2010 Manual instructions before the District Court. It asserted, *inter alia*, that both the Administrative Procedure Act ("APA"), 5 U.S.C. § 553, and the Medicare Act, 42 U.S.C. §§ 1395hh(a)(1), (b)(1), required HHS to promulgate the criteria for selecting hospitals for reconciliation by regulation after notice-and-comment rule making. And because the Manual instructions were not established in that manner, Clarian claimed that both the instructions and the reconciliation taken pursuant to them were procedurally invalid.

The District Court found merit in Clarian's procedural challenge and granted its motion for summary judgment. *Clarian Health West, LLC v. Burwell*, 206 F. Supp. 3d 393

(D.D.C. 2016). It concluded that the Medicare statute's procedural requirement was broader than the APA's and determined that, because the instructions did not fall within any of the APA's exceptions to notice-and-comment rule making, they were necessarily procedurally invalid under the Medicare Act. *See id.* at 420. HHS appealed the District Court's judgment to this court.

We conclude that the Manual instructions embody a general statement of policy, not a legislative rule, setting forth HHS's enforcement priorities. Policy statements do not establish binding norms. *Pac. Gas & Elec. Co. v. Fed. Power Comm'n*, 506 F.2d 33, 38 (D.C. Cir. 1974). And they are not "rules" that must be issued through notice-and-comment rule making. *Perez*, 135 S. Ct. at 1203. Nor are the instructions subject to the Medicare Act's independent notice-and-comment requirement because they do not establish or change a substantive legal standard. Because neither the APA nor the Medicare Act required that the Manual instructions be established by regulation, we reverse the decision of the District Court.

I. Background

A. Statutory and Regulatory Background

Congress established the Medicare program in 1965 to "provide[] federally funded health insurance for the elderly and disabled." *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1226-27 (D.C. Cir. 1994); 42 U.S.C. § 1395 *et seq.* HHS administers the program through the Centers for Medicare and Medicaid Services ("CMS"). It originally reimbursed hospitals based on the "reasonable costs they incurred in providing services to Medicare patients." *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 205 (D.C. Cir. 2011). Members of Congress

became concerned that this system failed to effectively incentivize hospitals to control their costs. To address this issue, in 1983 Congress adopted a "prospective payment system" under which hospitals receive a fixed payment for inpatient services. *Id.* "Congress believed that [this system] would encourage efficiency 'by rewarding cost-effective hospital practices.'" *Id.* (quoting *Methodist Hosp. of Sacramento*, 38 F.3d at 1227).

Under the prospective payment system, CMS pays hospitals a set amount per patient which is adjusted to roughly reflect the average cost incurred by hospitals nationwide for treating patients with the same diagnosis. 42 U.S.C. § 1395ww(d)(2), (4); *see also Cape Cod Hosp.*, 630 F.3d at 205-06 (explaining the payment-calculation process). These payments are calculated by private healthcare insurers, known as Medicare Administrative Contractors ("MACs"), under contract with CMS. *See* 42 U.S.C. § 1395h(a).

Congress recognized, however, that in some circumstances, treatment for patients would be extraordinarily costly. *See Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1009 (D.C. Cir. 1999). Congress thus authorized HHS to make supplemental "outlier payments" to hospitals to account for these disparate costs. 42 U.S.C. § 1395ww(d)(5)(A). Under the statute, a hospital is eligible for an outlier payment "in any case where charges, adjusted to cost, exceed . . . the sum of the applicable [adjusted standardized prospective rate] plus a fixed dollar amount determined by the Secretary." *Id.* § 1395ww(d)(5)(A)(ii). This case deals with the manner in which CMS calculates such payments.

1. Outlier Payment Formula

The Medicare Act and HHS's implementing regulations establish the general formula for outlier payment calculations. First, CMS instructs MACs to calculate the hospital's "cost-to-charge ratio," which represents the amount the hospital on average incurs in costs for every dollar that it bills. 42 C.F.R. § 412.84(i)(2). The MAC then multiplies the total amount billed by the cost-to-charge ratio to determine the hospital's actual costs. *Id.* § 412.84(g). If the difference between this number and the amount that the hospital received as a prospective payment exceeds the "fixed-loss threshold" set by the Secretary, the hospital can request an outlier payment. *Id.* § 412.84(k). The amount of the payment is calculated using the amount by which the actual costs exceed the prospective payment plus the fixed-loss threshold. That number is multiplied by the "marginal cost factor," which is set by regulation at 80%. *Id.* Under this process, a hospital may ultimately recover 80% of the difference between its cost-adjusted charges and the outlier threshold. *Id.*; *see also Dist. Hosp. Partners*, 786 F.3d at 49-51 (providing an example calculation).

In the 2000s, HHS determined that hospitals were manipulating their charges in order to inflate their cost-to-charge ratios. *See Proposed Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Under the Acute Care Hospital Inpatient Prospective Payment System*, 68 Fed. Reg. 10,420, 10,423 (Mar. 5, 2003). This process of "turbocharging" was made possible by the temporal disconnect between the time when the costs were incurred and the time period used to determine the hospital's cost-to-charge ratio. *See id.* For many years, MACs calculated the cost-to-charge ratio using the hospital's most recently settled cost report, which was typically three years old.

Id. By rapidly increasing the amount it charged for services, a hospital could take advantage of the higher out-of-date cost-to-charge ratio which, when multiplied by the inflated charges, would result in a higher outlier payment divorced from any increase in actual cost of care. *See id.*

2. The 2003 Rule

In 2003, HHS responded to the "turbocharging" problem by promulgating a rule, after notice-and-comment rule making, which included several changes to the methodology for determining outlier payments. 68 Fed. Reg. 34,494. For example, the rule permitted MACs to consider "the most recent tentative settled cost report" to determine the applicable cost-to-charge ratio, moderately reducing the lag time. *Id.* at 34,499; 42 C.F.R. § 412.84(i)(2).

Most relevant to this case, the 2003 rule also provided for "reconciliation" of outlier payments. Reconciliation authorizes MACs to revisit outlier payments for a specific year using the cost report for the year in which the service was actually provided once it has been finalized. 68 Fed. Reg. at 34,501; 42 C.F.R. § 412.84(i)(4). HHS indicated that reconciliation would be done only on a limited basis, but the agency declined to prescribe the precise circumstances when reconciliation would be appropriate. 68 Fed. Reg. at 34,503.

3. The 2010 Guidance

In 2010, HHS adopted a policy for MACs to use when administering the reconciliation process. The policy appeared in published instructions in a CMS Manual that covers Medicare claims processing. *See* CMS Manual, Ch. 3 § 20.1.2.5, J.A. 129-30. According to the Manual,

> Subject to the approval of the CMS Central Office, a hospital's outlier claims will be reconciled at the time of cost report final settlement if they meet the following criteria:
>
> 1. The actual operating [cost-to-charge ratio] is found to be plus or minus 10 percentage points from the [ratio] used during that time period to make outlier payments, and
>
> 2. Total outlier payments in that cost reporting period exceed $500,000.

Id., J.A. 129. The Manual instructs MACs to calculate a revised cost-to-charge ratio for the hospital. "If the criteria for reconciliation are not met, the cost report shall be finalized. If the criteria for reconciliation are met, [MACs] shall follow [the procedures to perform and record outlier reconciliation adjustments]." *Id.* It also provides that "[e]ven if a hospital does not meet the criteria for reconciliation, subject to approval of the Regional and Central Office, the [MAC] has the discretion to request that a hospital's outlier payments . . . be reconciled if the hospital's most recent cost and charge data indicate that the outlier payments to the hospital were significantly inaccurate." *Id.*, J.A. 129-30.

HHS did not engage in notice-and-comment rule making procedures before issuing the instructions in the Manual.

B. Facts and Procedural History

Clarian West Medical Center is a hospital located in Avon, Indiana that began operating in December 2004. Because Clarian treated relatively few patients in its first years, its outlier payments from 2007 were based on a 92.2% cost-to-charge ratio from 2005 that differed significantly from its final ratio of 50.5% for 2007. As a result, Clarian's MAC determined upon a retrospective evaluation that the hospital was eligible for reconciliation under the 2010 Manual instructions. The MAC concluded that although Clarian had received approximately $2.8 million in outlier payments for that period, it was actually owed less than $700,000. Following approval from CMS, the MAC issued a Notice of Program Reimbursement stating that Clarian was required to repay $2.4 million (including $200,000 for the time value of the money).

Clarian filed a petition for review with HHS's Provider Reimbursement Review Board ("Board"). Clarian alleged, *inter alia*, the reconciliation was unlawful because the Manual instructions were procedurally invalid. Although the Board has authority to affirm, modify, or reverse a MAC's reimbursement decision, it lacks authority to declare statutes or regulations invalid. 42 C.F.R. § 405.1842(f)(1)(ii), (g)(1)(iii). However, a provision of the Medicare Act permits a provider to bring suit in district court without proceeding through the full Board review process when the Board certifies that it does not have authority to resolve a provider's challenge. 42 U.S.C. § 1395oo(f)(1). Clarian thus sought certification for expedited judicial review of the reconciliation decision. The Board granted Clarian's request for expedited review, concluding that it lacked authority to grant the relief sought "with respect to those issues involving the validity of 42 C.F.R. § 412.84(h)." Dep't of Health & Human Servs., Provider Reimbursement

Review Board, Case No. 12-0629, J.A. 31 [hereinafter P.R.R.B. Decision].

On March 3, 2014, Clarian filed suit in the District Court, alleging, *inter alia*, that "the Secretary's 2012 [reconciliation] determination, and the agency rules governing that determination, are invalid and should be set aside" because they violate the APA and the Medicare statute's procedural requirements. Complaint ¶¶ 58, 60, J.A. 20-21. As is relevant on appeal, Clarian sought recoupment of the $2.4 million and invalidation of the 2010 Manual instructions. *Id.* ¶ 64, J.A. 23-24. The parties filed cross-motions for summary judgment.

The District Court concluded that, under the Medicare Act, HHS was required to promulgate the 2010 instructions through notice-and-comment rule making. *Clarian Health West, LLC*, 206 F. Supp. 3d at 420. It granted Clarian's summary judgment motion, denied the Secretary's, and remanded the matter to HHS for further proceedings. *Id.* The Government then filed an appeal with this court.

The parties' initial briefs to this Court addressed only whether the 2010 Manual instructions were procedurally invalid. In its reply brief, the Government for the first time raised a potential jurisdictional issue. It asserted that the Board's expedited judicial review certification did not cover the question Clarian had ultimately pressed before the District Court, and that as a result the District Court lacked jurisdiction to hear the case. Clarian then filed an unopposed motion for leave to file a supplemental brief addressing the court's jurisdiction, which the court granted on September 15, 2017. While the case was pending, this court resolved a similar jurisdictional issue in *Allina Health Servs. v. Price*, 863 F.3d 937, 941 (D.C. Cir. 2017), on July 25, 2017.

II. Discussion

A. Standard of Review

This Court reviews the District Court's grant of summary judgment *de novo*. *See Southeast Alabama Med. Ctr. v. Sebelius*, 572 F.3d 912, 916 (D.C. Cir. 2009). In determining what procedures an agency was required to employ in adopting a specific policy, we may consider the agency's characterization of its own rule or statement, but we are not compelled to defer on this question. *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1056 (D.C. Cir. 1987).

B. Jurisdiction

Before we address Clarian's procedural challenge to the Manual instructions, we must determine whether this court and the District Court may properly assert jurisdiction over the matter. Clarian asserted jurisdiction under 28 U.S.C. § 1331 and the expedited judicial review provision of the Medicare Act, 42 U.S.C. § 1395oo(f)(1). *See* Complaint ¶ 12, J.A. 9. However, the Medicare Act expressly forecloses jurisdiction under § 1331. *Your Home Visiting Nurse Servs., Inc. v. Shalala*, 525 U.S. 449, 456 (1999) ("42 U.S.C. § 405(h) [is] applicable to the Medicare Act by operation of § 1395ii, which provides that '[n]o action against . . . the [Secretary] or any officer or employee thereof shall be brought under section 1331 . . . ."). The Government contends that the expedited judicial review provision is equally inapplicable to Clarian's claims. We disagree.

The Medicare Act's expedited judicial review provision states, in relevant part, that,

> 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[.] . . . The Board shall render such determination in writing within thirty days after the Board receives the request . . . . 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. § 1395oo(f)(1). In the motion that Clarian submitted to the Board pursuant to this provision, it requested expedited judicial review over "Question 2." Question 2 asked:

> Whether the reconciliation process established under outlier regulation, 42 C.F.R. § 412.84(h), is procedurally and substantively invalid because the regulation establishes no standards governing the exceptions process and related program instructions were not adopted in accordance with the notice and comment rulemaking requirements mandated by the Administrative Procedure Act and Medicare Act.

Provider's Petition for Expedited Review at 14 (Dec. 5, 2013), J.A. 48. In its decision, the Board concluded that "questions 1, 2 and 4, regarding the validity of 42 C.F.R. § 412.84(h)

properly fall[] within" the Medicare Act's expedited review provision, and it "grant[ed] the Provider's request for expedited judicial review with respect to those matter[s]." P.R.R.B. Decision at 7, J.A. 32.

The Government's first argument focuses on its interpretation of the Board's decision. It reads the decision to grant review over only the validity of the 2003 regulation itself, not the 2010 Manual instructions. Because Clarian's challenge before this court and the court below asserted the illegality of the latter, the Government argues that the challenge falls outside of the "specific legal question" covered by the Board's limited grant of expedited judicial review. The Government next argues, in the alternative, that even if the court understands the Board's decision to have granted review over Clarian's challenge to the Manual instructions, the court still lacks jurisdiction on the ground that the "the Board's decision was erroneous because the Board did have authority to decide that challenge." Gov't Reply Br. 6. Under both theories, the Government asserts that the District Court should have dismissed Clarian's claim for lack of subject-matter jurisdiction and that we must now vacate that court's decision and dismiss.

As Clarian notes in its supplemental brief, the Government's second argument is squarely foreclosed by this court's recent decision in *Allina Health Servs.*, 863 F.3d at 941. There, the court held that the Medicare Act does not permit courts to revisit the Board's decision to grant expedited judicial review, or to question the Board's determination that it lacked authority over a question or claim. *See id.* It is thus irrelevant whether the Board correctly determined that it lacked authority over Clarian's challenge to the Manual instructions.

Furthermore, it is apparent from the face of the Medicare Act that the Government's primary jurisdictional argument is similarly unavailing. The expedited judicial review provision makes it clear that "if the Board fails to render [a] determination" on its authority within 30 days, "the provider may bring a civil action . . . with respect to the matter in controversy contained in such request for a hearing." 42 U.S.C. § 1395oo(f)(1). Because the Government does not contend that Clarian failed to raise its argument that the 2010 Manual instructions were procedurally invalid in its motion before the Board, and the Board has not since held a hearing on that question, there is no reading of the Board's Order that could deprive this court, or the District Court of jurisdiction. Either the Board granted expedited review over the question presented, or it failed to decide Clarian's request for expedited judicial review of the question within thirty days. In either event, Clarian had a right to seek review in the District Court, and we have appellate jurisdiction over that court's decision pursuant to 28 U.S.C. § 1291. We accordingly may proceed to the merits of Clarian's challenge.

C. Clarian's Claim Under the Medicare Act

The Medicare Act provides that "[n]o rule, requirement or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . the payment for services . . . shall take effect unless it is promulgated by the Secretary by regulation." 42 U.S.C. § 1395hh(a)(2). Regulations become final only after the Secretary provides an opportunity for public notice and comment. *Id.* § 1395hh(b)(1). The District Court concluded that the Manual instructions were invalid under this provision because HHS did not issue them by regulation after providing opportunity for notice and comment. *Clarian Health West, LLC*, 206 F. Supp. 3d at 420. As it did before that court, the Government argues on appeal

that the instructions fall outside of § 1395hh(a)(2)'s procedural requirement. It does not dispute that the Manual instructions constitute a "rule, requirement, or other statement of policy" governing "the payment of services." Rather, it argues only that the instructions do not "establish[] or change[] a substantive legal standard."

This court has defined a "substantive legal standard" under the Act to include "at [] minimum . . . a standard that creates, defines, and regulates the rights, duties, and powers of parties." *Allina Health Servs.*, 863 F.3d at 943. The Government asserts two reasons that HHS's Manual instructions do not qualify under that standard: First, it argues that the instructions "do not alter the substantive legal standard for determining whether an outlier payment is warranted or the amount of an outlier payment" because the 2003 regulation subjected all outlier payments to reconciliation and set forth the formula for calculating payments during the reconciliation process. Gov't Br. 14. On this theory, the Manual instructions "merely instruct Medicare contractors to identify hospitals whose outlier payments in a given year meet certain criteria . . . [and] seek approval from the agency to recalculate those payments," therefore "reflect[ing] the agency's policy about how best to deploy its contractors' limited resources." *Id.* at 14-15. Second, the Government argues that "the [M]anual instructions do not compel the agency to order reconciliation in any particular case" and, thus, "are not binding on the agency." *Id.* at 15. Both assertions cast the instructions as guidelines that amplify the agency's enforcement discretion—discretion that stems from the statute, the 2003 legislative rule, and 42 C.F.R. § 412.84(i)(4).

Clarian, in turn, responds that the 2003 rule merely set forth the data that should be used in a reconciliation, but it failed to determine which outlier payments would be subjected

to retroactive adjustment. In its view, only the 2010 instructions make that determination and, thus, they establish the substantive legal standard that determines the amount that the providers will ultimately be reimbursed. This type of "gap-filling" in the reconciliation scheme, Clarian urges, is covered by § 1395hh(a)(2). Further, Clarian argues that the Manual instructions are mandatory and binding, as they employ the words "will" and "shall."

It cannot be seriously disputed that HHS's authority to reconcile outlier payments alters providers' legal rights. As in this case, the decision to recalculate a provider's reimbursement pursuant to the reconciliation method may mean that a hospital receives millions of dollars less in payments than it otherwise would. But this change in providers' rights results from the Medicare Act and its implementing regulations—not the 2010 Manual instructions.

Together, the Act and the regulations establish the standard that governs hospitals' eligibility for outlier payments: The Act authorizes hospitals to request outlier payments in cases where "charges, adjusted to cost" exceed certain specified amounts. 42 U.S.C. § 1395ww(d)(5)(A)(ii). It also authorizes the Secretary to determine the amount of such payments, and establishes that they shall "approximate the marginal cost of care beyond the [applicable] cutoff point." *Id.* § 1395ww(d)(5)(A)(iii). The regulations, in turn, set forth the criteria for calculating those payments. *See* 42 C.F.R. §§ 412.80(a)(1), 412.84. The 2003 rule specifically authorizes the agency to adjust the payments pursuant to the reconciliation calculation procedures set forth at 42 C.F.R. 412.84(i)(4). *See* 68 Fed. Reg. at 34,504 ("We are adding § 412.84(i)([4]) to provide that, effective 60 calendar days after the date of publication of this final rule, outlier payments will become subject to adjustment when hospitals' cost reports coinciding

with the discharge are settled."). As Clarian's counsel agreed, *see* Recording of Oral Arg. 27:30-29:12, these statutory and regulatory provisions, of their own force, provide the agency with authority to engage in reconciliation for any outlier payment. Therefore these provisions establish the substantive legal standards governing provider reimbursement.

The Manual instructions do not alter the applicable legal standards. This is not to say that they have no practical effect. Rather, the important point is that the agency maintains the same authority to reconcile any outlier payment that it had prior to the adoption of the Manual instructions. The instructions merely set forth an enforcement policy that determines when MACs will report hospitals for reconciliation. They do not change the legal standards that govern the hospitals, and they do not change the legal standards that govern the agency.

Indeed, the instructions bind neither CMS nor the Board in adjudications. In adjudicated cases, CMS and the Board apply the formulas described in the regulations, not the thresholds contained in the Manual instructions, in determining hospitals' outlier-payment totals. *See* CMS Manual at 34-35, J.A. 129-30 ("Even if a hospital does not meet the criteria . . . the Medicare contractor has the discretion to request that a hospital's outlier payments in a cost reporting period be reconciled . . . ."); *id.* at 34, J.A. 129 ("Subject to the approval of the CMS Central Office, a hospital's outlier claims will be reconciled . . . if they meet the . . . criteria."); 42 C.F.R. § 405.1867 (explaining that the Board must "afford great weight" to CMS policy statements, but is not bound by such statements as it is by regulations).

To put it simply, reconciliation can be initiated in any situation in which CMS deems it appropriate, irrespective of whether the criteria in the Manual instructions are met. When

read in context, it is clear that the Manual's use of the words "will" and "shall" does not indicate otherwise. *See* CMS Manual at 34-35, J.A. 129-30. The agency's authority is accordingly exactly as it would be if the Manual instructions did not exist. The hospitals' legal entitlement to outlier payments is likewise unchanged. A hospital may pursue an action with the Board to challenge an agency decision to subject it to reconciliation without regard to whether it allegedly satisfied the criteria in the 2010 Manual instructions. The instructions thus did not alter or establish a substantive legal standard and the Medicare Act did not require HHS to promulgate the instructions by regulation.

D. Clarian's Claim Under the Administrative Procedure Act

Clarian also argues that the Manual instructions are procedurally invalid because they fail to comply with the APA's independent notice-and-comment procedural requirements. *See* 5 U.S.C. § 553. The APA mandates that substantive, legislative rules be promulgated only after public notice and comment, but it does not extend that requirement to "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice." *Id.* § 553(b)(3)(A). The Government argues that the Manual instructions fall within each of those exempted categories and so were not subject to the APA's constraint. Clarian responds that the instructions fall within none of them.

In addition to arguing that HHS's instructions are encompassed by § 553(b)(3)(A)'s non-legislative rule exemptions, the Government appears to make an additional threshold argument that the APA's procedural requirements do not apply to this case at all. For this assertion, it points to a separate exception for "matter[s] relating to . . . benefits," 5

U.S.C. § 553(a)(2), which has been interpreted to cover Medicare reimbursement determinations, *see Humana of S. Carolina v. Califano*, 590 F.2d 1070, 1082 (D.C. Cir. 1978). The Government recognizes that, in 1971, the Secretary voluntarily waived the § 553(a)(2) exception and subjected itself to the statute's procedural requirements. *Public Participation in Rule Making*, 36 Fed. Reg. 2532 (Feb. 5, 1971). Yet, it appears to contest the assertion that this waiver binds the agency. *See* Gov't Reply Br. 8 & n.3. The Government provides no basis for this argument, however, and it fails to address this court's and the Supreme Court's cases treating this or other such waivers as binding. *See Samaritan Health Serv. v. Bowen*, 811 F.2d 1524, 1529 & n.14 (D.C. Cir. 1987); *Humana of S. Carolina*, 590 F.2d at 1084; *Rodway v. U.S. Dep't of Agric.*, 514 F.2d 809, 814 (D.C. Cir. 1975) ("[T]he regulation fully bound the Secretary to comply thereafter with the procedural demands of the APA."); *see also Service v. Dulles*, 354 U.S. 363, 388 (1957).

Nonetheless, to the extent that, and in whatever form the APA's procedural rulemaking requirements bind HHS, they did not require that the Manual instructions be promulgated after notice and comment. As noted above, the instructions constitute a general statement of policy setting forth the agency's enforcement priorities that binds neither CMS nor the Board. They are accordingly exempt from § 553's notice-and-comment requirement.

The distinguishing line between legislative rules and general statements of policy has long been described as "fuzzy." *See Pac. Gas & Elec. Co.*, 506 F.2d at 37 (quoting 1 K. Davis, Administrative Law Treatise § 5.01, at 290 (1958)). Indeed, we have noted that "know[ing] how to classify an agency action as a legislative rule, interpretive rule, or general statement of policy . . . turns out to be quite difficult and

confused" and that, "given all of the consequences that flow" from that determination, "[i]t should not be that way." *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014). Here, however, it is clear that the Manual instructions constitute a policy statement for the same reason that they do not create or amend a substantive legal standard—they have no binding legal effect.

Our case law sets out "two lines of inquiry" to guide the determination of whether an action constitutes a legislative rule or a general statement of policy. *Wilderness Soc'y v. Norton*, 434 F.3d 584, 595 (D.C. Cir. 2006). "One line of analysis considers the effects of an agency's action, inquiring whether the agency has '(1) impose[d] any rights and obligations, or (2) genuinely [left] the agency and its decisionmakers free to exercise discretion.'" *Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 452 F.3d 798, 806 (D.C. Cir. 2006) (quoting *CropLife Am. v. EPA*, 329 F.3d 876, 883 (D.C. Cir. 2003)). The second "looks to the agency's expressed intentions," including "consideration of three factors: '(1) the [a]gency's own characterization of the action; (2) whether the action was published in the Federal Register or the Code of Federal Regulations; and (3) whether the action has binding effects on private parties or on the agency.'" *Id*. at 806-07 (quoting *Molycorp, Inc. v. EPA*, 197 F.3d 543, 545 (D.C. Cir. 1999)). As we have noted, the two lines of analysis overlap at the inquiry into whether the action has binding effect, *see General Elec. Co. v. EPA*, 290 F.3d 377, 382 (D.C. Cir. 2002), and we have consistently emphasized that this factor is the most important, *see Nat'l Mining Ass'n*, 758 F.3d at 252 (collecting cases).

Applying these criteria, it is clear that the Manual instructions are a general statement of policy. Under the first line of inquiry, the Manual instructions "impose[] [no] rights

[or] obligations" on providers. *CropLife Am.*, 329 F.3d at 883. As explained above, the legal effects on providers stem from the Medicare Act and its implementing regulations as well as the reconciliation actions taken pursuant to those authorities. Under the second line of inquiry, it is noteworthy that HHS has characterized its instructions as mere guidance, *see* 68 Fed. Reg. at 34,504. The instructions were not published in either the Federal Register or the Code of Federal Regulations. And, finally, critical under both lines of analysis, the instructions have no binding effect on either CMS or the Board. The agency is free to determine that reconciliation is or is not appropriate regardless of whether the criteria in the instructions are met. CMS Manual at 34-35, J.A. 129-30. The agency is "genuinely le[ft] . . . free to exercise discretion." *CropLife Am.*, 329 F.3d at 883.

Put simply, the Manual instructions "merely explain[] how the agency will enforce a statute or regulation—in other words, how it will exercise its broad enforcement discretion." *Nat'l Mining Ass'n*, 758 F.3d at 252. Namely, they describe the way in which CMS, through its MACs, will implement the reconciliation authority from the 2003 rule. They provide that, as a general matter, the agency believes that it will best accomplish its goal of ensuring that outlier payments "approximate the marginal cost of care," 42 U.S.C. § 1395ww(d)(5)(A)(iii), by focusing its limited resources on reconciling payments for hospitals whose actual cost-to-charge ratio for the period of service is at least 10% higher or lower than its cost-to-charge ratio for the time period used to calculate the outlier payment, and whose total outlier payments for that period exceed $500,000. But HHS has expressly retained discretion to deviate from these criteria where it determines that doing so would further the aims of the statute. *See* CMS Manual at 34-35, J.A. 129-30.

Clarian argues that the instructions cannot qualify as a policy statement because they "do not invite the Secretary's exercise of informed discretion as to a subset of otherwise retroactively adjustable outlier payments; they define the scope of outlier payments that are subject to retroactive adjustment in theory and in practice." Appellee Br. 45. But, as we have already explained, Clarian acknowledges that the Act and regulations provided CMS with authority to reconcile payments prior to the Manual instructions' issuance, and the Manual itself makes clear that the agency retains the discretion to deviate from the criteria that it set forth. Thus, the instructions are not, as Clarian asserts, "a so-called policy statement [that] in purpose or likely effect . . . narrowly limits administrative discretion, [which must] be taken for what it is—a binding rule of substantive law." *Guardian Fed. Sav. & Loan Ass'n v. Fed. Sav. & Loan Ins. Corp.*, 589 F.2d 658, 666-67 (D.C. Cir. 1978). To the contrary, they do not cabin the agency's discretion.

Finally, Clarian argues that HHS has forfeited the argument that the instructions are merely a policy statement because it relied only on the interpretive and procedural rule exceptions under § 553(b)(3)(A) in its arguments before the District Court. However, the Government argued below that its instructions were "guidance" that "need not go through [] notice-and-comment rulemaking." Gov't Memo. in Supp. of Mot. Summ. J. at 25. The District Court rejected that argument. *See Clarian Health West, LLC*, 206 F. Supp. 3d at 420. A litigant may "adduce[] additional support for [its] side of an issue upon which the district court did rule." *Koch v. Cox*, 489 F.3d 384, 391 (D.C. Cir. 2007); *see Yee v. City of Escondido*, 503 U.S. 519, 534 (1992) ("Once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below."). The Government's reliance on the general

policy statement exception is within the scope of the argument it made below that the instructions were procedurally valid under § 553. The claim was therefore preserved for our review.

The APA leaves to agencies the decision of how to establish policy. If the agency so chooses, it may forego notice-and-comment procedures and announce through a policy statement its intentions for future adjudications. It is not up to the court to second-guess the agency's decision to proceed in that manner, so long as the policy statement is not, in truth, a legislative rule. Because we conclude that the Manual instructions are not, the APA, like the Medicare Act, poses no procedural barrier to the course that HHS took here.

E. This Appeal Does Not Present a Challenge to the Validity of the Manual Instructions on Substantive Grounds

Lest there be any confusion on this point, we want to make it clear that this appeal merely involves a challenge to the agency's failure to follow notice-and-comment procedures when it adopted its Manual instructions. The Government has appealed the District Court's determination that the instructions were *procedurally* invalid. The District Court did not assess the validity of the Manual instructions or the agency's reconciliation determination on substantive grounds. Therefore, these matters are not in issue on this appeal.

The adoption of the Manual instructions without notice-and-comment rule making did not pretermit any possibility of judicial scrutiny of the disputed criteria. An agency election to adopt a policy statement rather than promulgate a legislative rule simply determines how, when, and under what standard the criteria might be reviewed. *See* M. Elizabeth Magill, *Agency Choice of Policymaking Form*, 71 U. CHI. L. REV.

1383, 1395-97 (2004); *see also Christensen v. Harris Cty.*, 529 U.S. 576, 587-88 (2000). When an agency adopts a legislative rule after notice-and-comment rule making, it may be subject to challenge for only a specified period of time. *See, e.g.*, *Sierra Club de Puerto Rico v. EPA*, 815 F.3d 22, 26-28 (D.C. Cir. 2016); *Mendoza v. Perez*, 754 F.3d 1002, 1018 (D.C. Cir. 2014); *Harris v. FAA*, 353 F.3d 1006, 1009-10 (D.C. Cir. 2004). In contrast, although a policy statement is not subject to review upon adoption, it may be challenged if it is applied in an enforcement action against a regulated party. *Nat'l Mining Ass'n*, 758 F.3d at 253 (quoting *Pac. Gas & Elec. Co*, 506 F.2d at 38). If this appeal had concerned a claim by Clarian that the agency's reconciliation determination was invalid on substantive grounds, we might have been required to determine whether HHS's criteria and their application were arbitrary and capricious. *See, e.g.*, *ExxonMobil Oil Corp. v. FERC*, 487 F.3d 945, 950-51 (D.C. Cir. 2007); *U.S. Telephone Ass'n v. FCC*, 28 F.3d 1232, 1235 (D.C. Cir. 2004); *Bechtel v. FCC*, 10 F.3d 875, 878 (D.C. Cir. 1993) ("Sooner or later, the agency must meet its obligation to respond to criticisms.").

This appeal presents only the procedural claim, however. And because neither the APA nor the Medicare Act mandated that HHS promulgate the reconciliation selection criteria in the 2010 Manual instructions through regulation after notice and comment, the agency's decision not to go that route was permissible.

III. Conclusion

For the reasons stated above, we reverse the decision of the District Court and remand for further proceedings consistent with this opinion.

So ordered.