ARGUMENT SCHEDULED FOR MAY 11, 2017
No. 16-5255

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ALLINA HEALTH SERVICES *ET AL.*,

Appellants,

v.

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

Appellee.

On Appeal from the U.S. District Court for the District of Columbia

Appellants' Reply Brief

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GLOSSARY

APA	Administrative Procedure Act
Board	Provider Reimbursement Review Board
DSH	Disproportionate Share Hospital
M+C	Medicare+Choice
Secretary	Thomas E. Price, M.D., Secretary, United States Department of Health and Human Services

INTRODUCTION

The government wrongly equates the Medicare Act's broader notice-and-comment requirement with the Administrative Procedure Act ("APA"). As a result, the government's entire case—on the merits *and* jurisdiction—rests on the contention that the agency's 2014 issuance, changing course from the pre-2004 disproportionate share hospital ("DSH") payment standard reinstated by the vacatur of the 2004 rule, was not a "legislative rule" requiring notice-and-comment rulemaking. But whether the abrupt 2014 issuance can be labeled a legislative rule is irrelevant to the questions presented. Medicare's notice-and-comment requirement is broader than the APA's, and even under the APA, the agency cannot contradict the reinstated regulation by any method. The government's defense cannot excuse the agency's notice-and-comment lapse implicating hundreds of millions of dollars meant to compensate hospitals for services to low-income patients.

SUMMARY OF ARGUMENT

The government's broad-brush brief is largely unresponsive to the Hospitals' primary argument that, whether or not the 2014 issuance is deemed a "legislative rule" under the APA (or a rule at all), the Medicare Act requires notice-and-comment rulemaking to change the substantive legal standard for determining DSH payments. When it finally gets to the Medicare Act, the government mostly

avoids the relevant textual inquiry—whether the 2014 issuance is a "rule, requirement, or other statement of policy" that "changes a substantive legal standard governing . . . the payment for services." 42 U.S.C. § 1395hh(a)(2). But the plain terms of the Medicare Act, reinforced by its structure and legislative history, demonstrate that its separate notice-and-comment requirement is not limited to APA legislative rules.

On the APA, the government says the 2014 issuance is a "first step" in an adjudication it can complete sometime later because there is no binding legislative rule on this issue. But the agency was not writing on a clean slate after the vacatur of the 2004 rule; under the reinstated, pre-2004 regulation, part C patient days do not count as "covered" because they are not paid under the Medicare part A program. Regardless of the procedural vehicle (legislative or interpretative rule, or some future adjudication), the APA required the Secretary to undertake notice-and-comment rulemaking to change the pre-2004 standard on part C patient days in the DSH payment calculation. Under APA precedents, whatever an agency does by notice-and-comment rulemaking (like the pre-2004 rule) can only be undone the same way.

As to jurisdiction, the plain language of the governing statute shows the Hospitals' action for expedited judicial review was proper. The Hospitals "shall have the right to obtain judicial review . . . whenever the Board determines" it

lacks authority to decide a question of "law or regulations." 42 U.S.C. § 1395oo(f)(1). The Board made the requisite determination, so jurisdiction lies. This is especially so as the Hospitals' claim—that the 2014 issuance is a (procedurally invalid) regulation—is the type of claim over which the Board lacks authority. That the government would have this Court deny that claim on the *merits* does not defeat *jurisdiction*. And, as the Secretary seems to understand (even if not his counsel), the Board was bound by the vacated 2004 rule even after the vacatur.

This Court's review is imperative given the government's persistent denial of a major change in payment standard (already recognized in *Northeast Hospital* and *Allina I*)[1] and the unaddressed, enormous fiscal implications for hospitals trying hard to plan for the healthcare needs of their entire communities, including low-income patients, despite limited budgets. Neither the Medicare Act nor the APA countenances the agency's repeated and irregular attempts to change course without adequate notice.

[1] *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1106 (D.C. Cir. 2014); *Northeast Hosp. v. Sebelius*, 657 F.3d 1, 15 (D.C. Cir. 2011).

ARGUMENT

I. The Hospitals' Action for Expedited Judicial Review Was Proper

The government's jurisdictional objection assumes, as a predicate matter, the correctness of its merits argument that the 2014 issuance was not a rule. That is the first clue the government's theory is wrong. The statutory review right is triggered "whenever" the Board determines that it lacks authority to decide a legal issue or fails to timely make such a determination, irrespective of how that determination is viewed in hindsight. Moreover, the Hospitals have more than a colorable claim challenging the validity of a rule; the Board and the district court agree that the validity of the 2014 issuance presents "a question of law or regulations" the Board lacks authority to decide. In second-guessing the Board, the government also ignores the Secretary's longstanding policy that even *vacated* rules continue to bind the Board until the Secretary affirmatively acquiesces in court rulings, which he has not done as to *Allina I*.

A. The Expedited Judicial Review Statute Confers Jurisdiction "Whenever" the Board Determines It Lacks Authority

The government's jurisdiction theory fails because judicial review turns only on the Board's determination (or lack of timely determination) regarding whether it has authority to decide a legal issue.

1. The statute plainly provides that hospitals "shall" have the right to expedited judicial review of payment-related issues "whenever" the Board decides

it lacks authority to decide "a question of law or regulations" relevant to the matter in controversy. 42 U.S.C. § 1395oo(f)(1); *see also Affinity Healthcare Servs., Inc. v. Sebelius*, 746 F. Supp. 2d 106, 115 (D.D.C. 2010) (quoting Oxford English Dictionary (2d ed. 1989) and explaining that "whenever" means "[a]t any time when; every time that, as often as"). The genesis of the expedited review provision was Congress's concern that preexisting law "require[d] providers to pursue a time-consuming and irrelevant administrative review" before filing suit. H.R. Rep. No. 96-1167, at 394 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526, 5757.

The jurisdiction-conferring force of the Board's no-authority determination is confirmed by the availability of judicial review on the merits when the Board simply fails to make a timely determination of its authority. 42 U.S.C. § 1395oo(f)(1). 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. *See Methodist Hosps. of Memphis v. Sullivan*, 799 F. Supp. 1210, 1215 (D.D.C. 1992), *rev'd on other grounds, Adm'rs of Tulane Educ. Fund v. Shalala*, 987 F.2d 790 (D.C. Cir. 1993) (holding the statute conferred subject matter jurisdiction when the Board did not timely determine its authority, without any consideration of whether the Board actually lacked authority). The statute works differently. *Lion Health Servs., Inc. v. Sebelius*, 689 F. Supp. 2d 849, 856 n.6 (N.D. Tex. 2010), *rev'd in*

part on other grounds, 635 F.3d 693 (5th Cir. 2011) ("[S]ubject matter jurisdiction is based on a determination by the [Board] that it lacks authority to decide the question presented," and because "[s]uch determinations were rendered," the "court sees no reason why it should review the [Board]'s determination of its own authority at this time.").

2. At the least, jurisdiction cannot depend on whether the Hospitals are right that the 2014 issuance is an invalid rule. The Hospitals are challenging its validity for failure to satisfy Medicare and APA procedural requirements. *See* AR 5–6, JA___-___ (Board finding it lacks authority to decide validity of 2014 rule). That is precisely the type of legal question the Board lacks authority to decide. *See* 42 C.F.R. § 405.1842(f)(1) (requiring the Board to grant expedited judicial review for challenges to, *inter alia*, "the substantive or procedural validity of a regulation or CMS Ruling").

Subject matter jurisdiction does not turn on the ultimate merits, but whether—taking the Hospitals' allegations as true—they have asserted the *type* of claim the court is authorized to consider. *See Am. Freedom Law Ctr. v. Obama*, 821 F.3d 44, 49 (D.C. Cir. 2016) ("In considering a motion to dismiss for lack of subject matter jurisdiction, courts are required to 'accept as true all of the factual allegations contained in the complaint.'") (citation omitted); *Smith v. Horner*, 846 F.2d 1521, 1523 (D.C. Cir. 1988) (federal question jurisdiction requires only a non-

frivolous federal claim). The Hospitals have asserted the kind of claim the Board lacks authority to decide, so they easily clear the jurisdictional bar.

3. The cases the government invokes are not to the contrary. *Edgewater* did not involve review of a no-authority determination. Rather, it followed from a Board determination that it lacked "jurisdiction" over a Medicare reimbursement claim because it was untimely filed after the statute's 180-day deadline. *Edgewater Hosp., Inc. v. Bowen*, 857 F.2d 1123, 1125, 1130–32 (7th Cir. 1988). The Secretary argued the Board's dismissal of the appeal was not a "final decision" subject to judicial review under section 1395oo(f)(1). *Id.* at 1130. The court disagreed, finding that a Board decision on its own jurisdiction under section 1395oo(a)(1) is a final agency decision. *Id*. at 1131.

In arriving there, the *Edgewater* court first noted the statute expressly designated a no-authority determination as a "final decision." *Id*. It quoted the regulation providing that such a determination "'is a final decision permitting a provider to seek judicial review *with respect to the matter or matters in controversy*'" and deemed it therefore "clear" that section 1395oo(f)(1) "establishes a right to judicial review of the Board's determination that it lacks the authority to decide a question of law or regulations." *Id.* at 1130 (citation omitted) (emphasis added). The context indicates the court was simply noting that the "final decision" prerequisite to judicial review was satisfied by a no-authority

determination. *Id.* The court did not hold a court must agree with the correctness of the Board's no-authority determination in order to reach the merits, a question not at issue in *Edgewater*.

The Ninth Circuit's per curiam decision in *Yakima* seized on the *Edgewater* dictum. *Providence Yakima Med. Ctr. v. Sebelius*, 611 F.3d 1181, 1187 n.7 (9th Cir. 2010). It did not, however, consider the context of the sentence, so it misinterpreted *Edgewater* to mean that the court can examine a Board no-authority decision for correctness. *Id.* In any event, *Yakima* did not go as far as the Secretary would have the Court go here and require that a court decide the merits of the dispute to resolve jurisdiction. Rather, the administrative issuance in *Yakima* could not be a "regulation," meaning a "rule or order, having legal force," because it was a letter from the Medicare contractor that applied to a few specific hospitals, would be applied "on a case-by-case basis," and "did not affect the rights of a broad class of people." *Id.* at 1187-88 (internal quotation marks and citation omitted). In contrast, the 2014 determination in this case was issued by the agency (not one of its contractors), applies to every hospital across the country, and was found by the district court to be a "rule." Mem. Op. 17, JA ___. Because that action is a rule, or *at least* colorably a rule, the Hospitals' claim falls within the class of claims for which expedited judicial review is authorized.

B. The Board's Review Would Have Been Futile Because It Lacks Authority To Decide the Legal Questions Presented

The Secretary's jurisdictional gambit fails also because the Board cannot ignore Medicare rules like the 2004 rule vacated in *Allina I*.

Under the Secretary's regulations, the Board is bound by agency rules and rulings, not court decisions. 42 C.F.R. § 405.1867; *see* AR 6, JA ___ ("The Board finds that . . . it is bound by the regulation."). The Board, therefore, must apply even a vacated regulation unless the agency acquiesces to the court's vacatur in a binding ruling. *See, e.g.*, Centers for Medicare & Medicaid Services, Ruling No. 1355-R (Apr. 14, 2011) (announcing the agency's "determination to grant relief to any hospice provider" with an appeal challenging a regulation only after several district courts and two courts of appeals had invalidated it);[2] *Tranquility Hospice LLC*, Case No. 11-0547 (PRRB Mar. 29, 2011) (Board granting expedited judicial review because it could not depart from a binding regulation despite multiple courts invalidating the regulation), *filed in Tranquility Hospice, LLC v. Sebelius*, Case No. 4:11-cv-00324, ECF No. 2 (N.D. Okla. May 25, 2011); Health Care Fin. Admin., Ruling No. 97-2 (Feb. 27, 1997) (announcing agency's change in interpretation "to follow the holdings of the United States Courts of Appeals for the

[2] *Available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/downloads/cms1355r.pdf.

Fourth, Sixth, Eighth, and Ninth Circuits");[3] Health Care Fin. Admin., Ruling No. 89-1 (Jan. 26, 1989), *reprinted in* Medicare & Medicaid Guide (CCH) ¶ 37,614 ("acquiesce[ing] on a nationwide basis in the D.C. Circuit's decision").

The agency's nonacquiescence in adverse court decisions comports with its "right to refuse to acquiesce in one (or more) court of appeals[]" decisions, *AT&T v. FCC*, 978 F.2d 727, 737 (D.C. Cir. 1992), grounded in the lack of nonmutual collateral estoppel against the federal government, *see United States v. Mendoza*, 464 U.S. 154, 162 (1984). Remand to the Board would only lead to the exact type of futile delay the expedited review provision was meant to end.

II. Notice-and-Comment Rulemaking Is Required

A. The Medicare Act Required Notice-and-Comment Rulemaking

The government narrows the question under the Medicare Act's notice-and-comment provision to whether the 2014 issuance was an APA "legislative rule," disregarding that Medicare's independent and broader notice-and-comment mandate applies to any "rule, requirement, or other statement of policy," that "establishes or changes a substantive legal standard governing . . . the payment for services." 42 U.S.C. § 1395hh(a)(2). The government's lack of engagement on the textual differences between the APA and the Medicare Act only underscores them.

[3] *Available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/downloads/hcfar972.pdf.

It is implausible that Congress adopted a differently worded and structured Medicare notice-and-comment requirement just to restate APA requirements.

1. The 2014 Issuance Changed a Substantive Legal Standard Governing Payment

The Medicare statute requires notice-and-comment rulemaking for any "rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . the payment for services." *See id.*; Hosp. Br. 23-38. Unlike the APA, 5 U.S.C. § 553(b)(A), the Medicare statute does *not* incorporate a categorical notice-and-comment exemption for interpretive rules. 42 U.S.C. § 1395hh(b); *see* Hosp. Br. 9, 30-31. The government all but ignores these key Medicare provisions.

The 2014 issuance is unquestionably a "rule," as the district court correctly found. *See* Mem. Op. 17, JA ___. But Medicare's notice-and-comment requirements apply not only to "rule[s]," but also to "requirement[s]" or "other statement[s] of policy," 42 U.S.C. § 1395hh(a)(2). The government does not dispute that—even if it were the "first step in an adjudication" (Gov't Br. 30)—the 2014 issuance is a "requirement" or "other statement of policy" that part C days must be treated as part A days in hospitals' DSH payment determinations.

The 2014 issuance, moreover, "changes" the substantive legal standard by altering hospitals' legal rights to DSH payments of hundreds of millions of dollars meant to compensate them for services to low-income patients. *See Northeast*

Hosp., 657 F.3d at 17 ("Any rule that alters the method for calculating [DSH] fractions . . . changes the legal consequences of treating low-income patients."); *see also* Hosp. Br. 25-26. Unlike the 2014 issuance, the pre-2004 legal regime reinstated by the *Allina I* vacatur treated part C days as not part-A-entitled days. *Northeast Hosp.*, 657 F.3d at 16-17.[4]

Finally, it "govern[s] . . . payment for services," 42 U.S.C. § 1395hh(a)(2), because it is binding on the agency, its contractors, and hospitals for final DSH payment determinations. 42 C.F.R. § 412.106(b)(2). The government does not and cannot dispute this. The 2014 rule is thus not "Draft Guidance," Gov't Br. 41, but a final payment standard.

2. Medicare Requires Notice-and-Comment Rulemaking Beyond Legislative Rules

Faced with that straightforward application of Medicare's notice-and-comment requirements, the government's response collapses into a single proposition: Medicare notice-and-comment requirements are the same as the APA. But to the extent "the Medicare statute is similar to the APA hardly means it is identical, and the government has presented no reason to depart from the plain meaning of the text." *Allina I*, 746 F.3d at 1109.

[4] Even if there were any doubt that the Secretary effected a "change" in the DSH payment standard (*see* Gov't Br. 46), the 2014 issuance certainly "established" such a standard triggering Medicare's notice-and-comment requirement. *See* 42 U.S.C. § 1395hh(a)(2).

The government asserts the 2014 issuance did not "establish or change" a "substantive legal standard," but offers no analysis for why. *See* Gov't Br. 42. The government just posits that an interpretive rule cannot be a "substantive legal standard." *Id*. The definition of a "legislative rule" exempt from APA's notice-and-comment requirement, however, arises from a distinct body of case law interpreting the APA (cited elsewhere in the government's brief, at 39-40).[5] There is no reason to accept the government's *ipse dixit* that only a legislative rule is a "substantive legal standard" governing payment within the meaning of the Medicare Act.

To the contrary, the plain terms of the Medicare Act, reinforced by the context and legislative history of the statute, make clear that Medicare's notice-and-comment mandate is not limited to APA legislative rules. Hosp. Br. 28-38. Moreover, the government does not address at all Medicare's unique requirement under section 1395hh(a)(4) that a rule vacated for failure of logical outgrowth must

[5] The government invokes *American Hospital Association* to suggest the terms "legislative" and "substantive" synonymously describe rules requiring notice-and-comment rulemaking under the APA. That makes sense in the APA context because those terms are antonyms of the terms "interpretive" and "procedural" used to describe exempt rules. *See Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987). The government does not, and cannot, argue that the 2014 issuance is procedural. And the APA itself uses the term "substantive rule" in a manner showing that "interpretative rules and statements of policy" can be substantive. *See* 5 U.S.C. § 553(d). If interpretative and substantive rules were mutually exclusive, then there would have been no need to specifically exempt interpretive rules from the 30-day notice requirement for substantive rules. *See id*.

be "treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and publication of the provision again as a final regulation." That silence is telling.

The government makes only two textual arguments, both relating to Medicare "manual instructions, interpretative rules, statements of policy, or guidelines of general applicability." 42 U.S.C. § 1395hh(c)(1), (e)(1). Section 1395hh(c)(1)(B) requires the Secretary to publish in the Federal Register a list of such issuances that "are not published pursuant to subsection (a)(1)" rulemaking, and section 1395hh(e)(1)(A) authorizes limited retroactive application of "substantive changes" made through these agency issuances. These provisions underscore that while the agency may attempt to make policy through a variety of methods, notice and comment is required regardless of the form if the issuance changes a substantive legal standard governing payment. Hosp. Br. 31-32. The Secretary highlights that these sections apply both to certain "manual instructions" and to "guidelines of general applicability" in addition to "interpretative rules," and asserts (in circular fashion) that none of the items listed could thus ever be subject to the Medicare Act's notice-and-comment mandate. But any of those could be or include a "rule, requirement, or other statement of policy" changing a substantive legal standard under the plain terms of section 1395hh(a)(2).

The government apparently recognizes that section 1395hh(c)(1)(B) presupposes that some interpretive rules are subject to notice-and-comment rulemaking under the Medicare Act in arguing (at 43) that the Hospitals' interpretation ignores voluntary rulemaking. But the statutory text does not make that distinction, and the legislative history (which the government ignores on this point) says otherwise. *See* H.R. Rep. No. 100-495, at 563 (1987) (Conf. Rep.), *reprinted in* 1987 U.S.C.C.A.N. 2313-1245, 2313-1309 (describing provision as requiring publication of list of "interpretative rules" "which . . . are not published *as required by* [§ 1395hh(a)(2)] above") (emphasis added).

Further, the legislative history that the government addresses (at 45-46) does not further its case. Different from the APA, the initial House bill would have required notice-and-comment rulemaking for any Medicare "rule, requirement, or other statement of policy" that has a "significant effect on . . . the payment for services." *See* H.R. Rep. No. 100-495, at 563, *reprinted in* 1987 U.S.C.C.A.N. at 2313-1309. Although the Conference Committee amended the notice-and-comment rulemaking trigger to "substantive legal standard," the final statutory language was still very different from the APA. The legislative history thus indicates intent to require notice-and-comment rulemaking for more Medicare policy changes than would be required under the APA. *See* Hosp. Br. 35-36.

Indeed, by eliminating the requirement for a "significant effect on . . . the payment for services," *see* H.R. Rep. No. 100-495, at 563, *reprinted in* 1987 U.S.C.C.A.N. at 2313-1309, Congress made Medicare's notice and-comment requirement more stringent than it would have been under the original bill. As enacted, the requirement applies anytime there is a change or establishment of a "substantive legal standard" governing "payment," regardless of whether it has a "significant effect" on payment. *See* 42 U.S.C. § 1395hh(a)(2).

The cited cases provide no support to the government's argument. *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87 (1995), involved an entirely different rulemaking provision and did not consider section 1395hh. And, as the government ultimately acknowledges (Br. 44), this Court *expressly declined* "to explore the possibility of a distinction" between the Medicare Act and the APA in *Monmouth Medical Center v. Thompson*, 257 F.3d 807, 814 (D.C. Cir. 2001). *Monmouth* therefore cannot bear the weight the government places on it. *See* Hosp. Br. 32-33.

Via Christi Regional Medical Center, Inc. v. Leavitt, 509 F.3d 1259 (10th Cir. 2007), is no more persuasive than the other out-of-circuit cases (*Baptist, Erringer* and *Warder*). *See* Hosp. Br. 33 n.14. The government (at 44) relies on a single footnote in *Via Christi* from that court's standard of review section for the proposition that courts generally interpret the Medicare Act to impose similar

requirements to the APA. But the footnote cites to *Baptist Health v. Thompson*, 458 F.3d 768 (8th Cir. 2006), where the court engaged in no analysis of the Medicare Act and relied on a case that actually did not address the question. Hosp. Br. 33 n.14. This issue of first impression cries out for the Court's considered resolution.

B. The APA Required Notice-and-Comment Rulemaking

APA precedents require the Secretary to employ notice and comment to depart, whether through a rule (legislative or interpretive) or adjudication, from any rule previously adopted that way. Accordingly, the Secretary's 2014 issuance violated the APA because it conflicts with the pre-existing rule, adopted through notice-and-comment rulemaking, providing that only days "covered" (*i.e.*, paid) under part A are included as part-A-entitled days.

1. Regardless of the Procedural Vehicle, an Agency Cannot Depart from Its Notice-and-Comment Regulation Without Notice and Comment

Under the APA, the Secretary can take a position inconsistent with the reinstated pre-2004 regulation only if he first undertakes notice-and-comment rulemaking to amend the regulation. *See, e.g., Nat'l Fam. Plan. & Reprod. Health Ass'n, Inc. v. Sullivan*, 979 F.2d 227, 241 (D.C. Cir. 1992) ("Once a regulation is adopted by notice-and-comment rulemaking . . . its text may be changed only in that fashion.") (citation omitted); Hosp. Br. 38-41. This requirement was not

disturbed by *Perez v. Mortgage Bankers Association*, 135 S. Ct. 1199 (2015). The Secretary spills much ink arguing that the 2014 issuance was not a rule, he can eventually proceed through adjudication (sometime after this "first step"), and this Court so held. This Court did not hold that, but more fundamentally, the Secretary fails to recognize that whether the 2014 issuance is a rule or something else, it is invalid for lack of notice-and-comment rulemaking if it contradicts the restored pre-2004 regulation, which it does.

First, as the district court found, Mem. Op. 17, JA ___, the Secretary issued a rule. The Secretary promulgated it simultaneously for all DSH hospitals nationwide, and it reflects a principle of general applicability: the universal policy of including part C days as part A-entitled days. Further, it has "future effect," because the agency used it for interim payments to hospitals until May 2015 (when it was superseded by a new issuance embodying the same part C days policy). *See* 42 C.F.R. § 413.64(e) (requiring contractors to use latest-available part A/SSI fractions for interim payments when the agency has not yet published fractions for the relevant year).

The Secretary responds that, even if the 2014 issuance constituted a "rule," it "would be [an] interpretive rule[] exempt" from notice-and-comment rulemaking. Gov't Br. 38. But under binding precedent, the statute that the government claims the Secretary was merely interpreting contains "two inconsistent sets of statutory

provisions." *Northeast Hosp.*, 657 F.3d at 11. The agency's resolution of that inconsistency is necessarily legislative. *See Citizens to Save Spencer Cty. v. EPA*, 600 F.2d 844, 879 (D.C. Cir. 1979) ("'[I]nterpretation' could only go so far as to spot the dilemma posed by the statutory inconsistency, while legislative-type action was required to carry the agency the rest of the way toward a compromise solution."). Moreover, the Secretary's prior six rulemakings on the exact same issue (including the 2013 prospective rule) are indeed relevant to whether a new rule on the same issue is legislative, *see United States v. Picciotto*, 875 F.2d 345, 348 (D.C. Cir. 1989), even acknowledging that the Secretary might—although not ordinarily always—undertake rulemaking voluntarily.

Regardless, an agency may not issue even an interpretive rule or an adjudicative decision without first amending a conflicting notice-and-comment regulation already on the books. *Guernsey* recognized that the Secretary may not act inconsistently with a regulation without first amending the regulation through notice and comment. 514 U.S. at 99-100 (noting that if the agency "adopt[s] a new position inconsistent with any of the Secretary's existing regulations," then "APA rulemaking would still be required" even for a "prototypical example of an interpretive rule"); *see also Mortg. Bankers*, 135 S. Ct. at 1209 (restating *Guernsey*'s rule); Hosp. Br. 38-39 (collecting circuit precedent).

The other cases cited by the government are not to the contrary. The government first asserts that *Allina I* already decided there was no disabling inconsistency between the pre-2004 regulation and any attempt to include part C days as part A days, and therefore adjudication is proper. *See, e.g.*, Gov't Br. 32-33 (stating this Court "recognized" that "the Secretary should be able to decide how to treat Part C days in plaintiffs' DSH calculations by adjudication"); *id.* 35. The *Allina I* decision said no such thing. Instead, this Court declined to rule on the scope of the pre-2004 regulation, explained that the "question whether the Secretary could reach the same result" on remand through an adjudication "was not before the district court," and held that the district court therefore should simply have "remand[ed] after identifying the error." *Allina I*, 746 F.3d at 1111.

Indeed, *Heartland Regional Medical Center v. Leavitt*, 415 F.3d 24 (D.C. Cir. 2005) (*Heartland I*), which the government invokes, illuminates *why* this Court did not decide the validity of the agency's post-remand actions in *Allina I*. It held that whether the agency's post-remand action was procedurally improper was an issue to be decided in an APA suit subsequent to the post-remand action. *Id.* at 30. This is the post-remand suit required by *Heartland I*.

In *Catholic Health Initiatives Iowa Corp. v. Sebelius*, 718 F.3d 914, 920-21 (D.C. Cir. 2013), this Court found that the agency had not retroactively applied a rule changing policy on one component of the DSH calculation, the Medicaid

fraction, because the agency had previously set that policy through an earlier adjudication. That has not occurred here. As the district court found, the 2007 adjudicative decision in *St. Joseph* is irrelevant because it was reached for pre-2004 years governed by *Northeast Hospital* "with reference to the now vacated 2004 Final Rule," which undermines its validity. *See* Mem. Op. at 22-23, JA __(citing *St. Joseph's Hosp. v. BlueCross BlueShield Ass'n*, PRRB Dec. No. 2007-D68 (Aug. 27, 2004)).[6]

2. The 2014 Issuance Is Inconsistent with the Reinstated Pre-2004 Regulation

The DSH regulation in effect prior to the 2004 vacated rule treated part C days as *not* part-A-entitled because those days were not "covered" (meaning paid) under Medicare part A. Hosp. Br. 41-45. The government cannot now reinterpret the pre-2004 regulation to permit what that regulation in fact prohibited.

The government's assertion (Br. 10) that the pre-2004 regulation "simply parroted" the statute is patently untrue. The pre-2004 regulation included only those days "covered" under the part A program. *See* 42 C.F.R. § 412.106(b)(2)(i) (2003). That term is not found in the Medicare DSH statute. *See* 42 U.S.C. § 1395ww(d)(5)(F)(vi).

[6] *Available at* https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/Downloads/2007d68.pdf.

The government agrees the term "covered" required payment of the days (Br. 36), but argues that it required only "Medicare payment"—not payment under part the A fee-for-service program—or alternatively that per-capita payments to insurance companies for their part C enrollees *is* payment for inpatient days under part A. Neither defense works.

The government's argument that any Medicare payment would suffice under the pre-2004 regulation ignores the regulation's preamble. 51 Fed. Reg. 16,772, 16,777 (May 6, 1986) (including only "covered Medicare Part A inpatient days" as part A days). It also ignores *Catholic Health*, which concluded that the pre-2004 regulation limited the part A/SSI fraction to "covered Medicare Part A inpatient days." 718 F.3d at 921 n.5. And it misunderstands the agency's interpretation of the regulation as excluding inpatient days partially paid under Medicare *part B* for patients who were *enrolled in* the part A fee-for-service program. *See* 42 U.S.C. § 1395*l*(t)(1)(B)(ii); Hosp. Br. 44-45. The government's rejoinder, that some people are eligible only for part B (Br. 37), is a non-sequitur; the part B days addressed in our opening brief are days for patients who met the statutory criteria for, and enrolled in, part A. Moreover, the government unpersuasively discounts the agency's consistent inclusion of only covered part A days and exclusion of part C days as evidence of the pre-2004 regulation's meaning. *See* Hosp. Br. 14-15 & n.7 (collecting citations to transmittals explaining fractions included only part A

"covered" days). This Court found this represented not only a practice, but a policy. *Northeast Hosp.*, 657 F.3d at 16.

Moreover, the 2004 rule (vacated in *Allina I*) made a singular amendment to include two new categories of days as part-A-entitled—days for patients enrolled in part C, and days for Medicaid-eligible patients enrolled in part A but for which part A benefits had been exhausted. 69 Fed. Reg. 48,916, 49,098-99 (Aug. 11, 2004). The *only* change made to the regulation in 2004 to effectuate this change for both categories was to delete "covered" from the regulation. *Compare* 42 C.F.R. § 412.106(b)(2)(i) (2003) *with* § 412.106(b)(2)(i) (2004); *see also* 69 Fed. Reg. at 49,246.

The government contends (Br. 37) the term "covered" was deleted from the regulation *solely* to reverse the treatment of "dual eligible" exhausted-benefits days. This contention is contradicted by the pages of the rulemaking cited by the government, which reflect made only a single regulation change to address *both* types of days. The preamble to the Secretary's 2004 rulemaking states that the Secretary is "revising [his] regulations at § 412.106(b)(2)(i) to include the days associated with dual eligible beneficiaries in the Medicare fraction of the DSH calculation." *See* 69 Fed. Reg. at 49,099, col. 1. Then, in *nearly identical language* on the same page of the *Federal Register*, the preamble states that the Secretary is also "revising [his] regulations at § 412.106(b)(2)(i) to include the

days associated with M+C beneficiaries in the Medicare fraction of the DSH calculation." *Id.* at 49,099, col 2. The only difference is terminology describing the category of days—"dual eligible" versus "M+C [part C]" beneficiaries. Because the only regulatory change was to delete the word "covered" from the regulation, it necessarily applied to *both* exhausted *and* part C days.

The government adds (Br. 35-36) that the agency was interpreting the parenthetical phrase "for such days," as opposed to "entitled to benefits under part A," when it established the "covered" requirement. But what statutory term allegedly prompted the requirement is irrelevant to the regulation's plain meaning. The important thing is that "covered Medicare Part A inpatient days," 51 Fed. Reg. 16,777, excludes part C days.

In any event, the Secretary construed "for such days" "to modify" the terms "eligible for medical assistance" and "entitled to benefits under part A" and restrict both fractions to days for which the relevant programs (part A and Medicaid) paid for the days. 51 Fed. Reg. 31,454, 31,460-61 (Sept. 3, 1986). Thus, "covered" required assignment of days to each fraction based on the "primary payor." *Id*. And under that test, part C days were (and now are again, after *Allina I*) excluded from part A days because payment by private part C Medicare Advantage plans for services to their patients is *not* made under the Medicare part A fee-for-service

program. *See* 42 U.S.C. § 1395w-21(a)(1), (i)(1) (payment of part C benefits is "in lieu of" benefits otherwise payable under part A); *Northeast Hosp.*, 657 F.3d at 6.

The government gets no further arguing part C days are paid under part A. There is no such thing as the "Part A Trust Fund" (Gov't Br. 37). The Federal Hospital Insurance Trust Fund pays for several things, including part A benefits. *See* 42 U.S.C. § 1395i. Payments to plans for part C enrollees also come, but only in part, from that trust fund, *id.* § 1395w-23(f), and in any event those per-capita payments made directly to plans (Gov't Br. 36) are not payments to hospitals for inpatient days. Likewise unavailing is the Secretary's oft-repeated analogy to part A HMO days based on a 1990 Federal Register issuance that did not address part C days at all, which this Court has already rejected. *See Northeast Hosp.*, 657 F.3d at 16.

Finally, the government misses the mark in asserting (Br. 34) that *Northeast Hospital* and *Allina I* "preclude" the argument that the regulation binds the agency. This Court determined in *Northeast Hospital* that the Secretary's 2004 rule altered "the HHS regulation that governs calculation of DSH fractions, to state *expressly* that [part C] patient days should be counted in the Medicare [part A/SSI] fraction," and that "[p]rior to 2004, the regulation did not specify where [part C] enrollees should be counted." 657 F.3d at 14 (emphasis added). These statements mean in context that the pre-existing regulation did not expressly mention part C days. *See*

id; Hosp. Br. 42 n.16. In holding the 2004 rule impermissibly retroactive because it was "'substantively' inconsistent with a prior agency practice," 657 F.3d at 14 (citation omitted), *Northeast Hospital* had no need to decide whether that prior practice was embodied in the pre-2004 regulation.[7] And, because it expressly declined to rule on the propriety of any post-vacatur action by the agency, *Allina I* likewise had no reason to decide that question. *See* p. 20, *supra*.

Neither *Northeast Hospital* nor *Allina I* decided the question now before the Court: whether including part C days as part A days conflicts with the pre-2004 regulation reinstated by the *Allina I* vacatur. Because the answer is yes, notice-and-comment rulemaking is required.

[7] Indeed, *Northeast Hospital* involved a challenge only to retroactive application of the 2004 rule to the Medicaid fraction. 657 F.3d at 4. Nonetheless, based on evidence regarding the exclusion of part C days from the *part A/SSI* fraction, the Court determined the Secretary could not retroactively apply the 2004 rule change to exclude part C days from the *Medicaid* fraction. *Id.* at 14, 17. As confirmed by *Allina I*, *Northeast Hospital* necessarily held that a singular pre-2004 policy dictated the exclusion of part C days from one fraction and their inclusion in another. *Allina I*, 746 F.3d at 1108 ("Granted, we did not say [in *Northeast Hospital*] the Secretary counted the Part C days in the Medicaid fraction, but the statute unambiguously requires that Part C days be counted in one fraction or the other (a Part C-enrolled individual is either eligible for Medicare Part A, or not), so the necessary implication of our opinion is obvious.").

III. The Secretary's Unexplained Rule Is Not the Product of Reasoned Decision-Making

The government's brief only further demonstrates that the Secretary's sudden 2014 determination to treat part C days as part A days does not reflect reasoned decision-making.

As this Court found in *Northeast Hospital*, 657 F.3d 1, even a "brief look" at the Secretary's treatment of part C days prior to 2004 "belies h[is] claim that" his new treatment of those days merely "codified a longstanding policy." *Id.* at 15; *see also Allina I*, 746 F.3d at 1106 ("Prior to 2003, the Secretary treated Part C patients as *not* entitled to benefits under Part A.") (emphasis in original); Hosp. Br. 3–5, 15–17, 46–49. None of the non-contemporaneous rationales offered by the government (Gov't Br. 48–49) admits a policy change on part C days. The "cursory" discussion in the vacated 2004 rule did not. *Allina Health Servs. v. Sebelius*, 904 F. Supp. 2d 75, 93 (D.D.C. 2012), *aff'd in part, rev'd in part*, 746 F.3d 1102 (D.C. Cir. 2014). The 2013 prospective rulemaking and the 2015 *Allina I* remand decision perpetuated the false premise that the Secretary was continuing pre-2004 policy. 78 Fed. Reg. 50,496, 50,615, 50,619-20 (Aug. 19, 2013); Def.'s Mot. for Summ. J. Attach. No. 4 at 34-35, *Allina II*, ECF No. 29-4 (D.D.C. Dec. 15, 2015). This across-the-board refusal to acknowledge the payment standard change confirms that the 2014 issuance is arbitrary and capricious. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

The government dismisses the enormous financial impacts of the change by merely repeating (Br. 52-54) what the 2013 rulemaking and the remand decision claimed about part C patient incomes yielding no dilution of DSH payments. That assertion flies in the face of this Court's prior decisions in *Northeast Hospital* and *Allina I*, as well as the record evidence in this case. *See Northeast Hosp.*, 657 F.3d at 5, 15 ("[T]he practical consequences of this dispute number in the hundreds of millions of dollars."); *Allina I*, 746 F.3d at 1105, 1107 (2004 rule, "costing the hospitals hundreds of millions of dollars," had "enormous financial consequences"); AR 7-9, JA ___-___ (showing impact of nearly $50 million for the Appellant hospitals).

Ironically, the government contends that "a remand for a reasoned explanation would serve no purpose," Gov't Br. 49, thereby *admitting* that the agency has dug in its heels and "become so committed to [its] result as to resist engaging in any genuine reconsideration of the issues." *Food Mktg. Inst. v. ICC*, 587 F.2d 1285, 1290 (D.C. Cir. 1978). This attitude epitomizes the danger of post-hoc rationalizations for no-notice rules changing Medicare payment standards to the detriment of safety-net hospitals needing to plan for serving their communities with dwindling and uncertain budgets.

CONCLUSION

The judgment of the district court should be reversed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The foregoing brief is in 14-point Times New Roman proportional font and contains 6,484 words, and thus complies with the type-volume limitation set forth in Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure.

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March 22, 2017

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I hereby certify that, on March 22, 2017, I served the foregoing brief upon the following counsel of record by filing a copy of the document with the Clerk through the Court's electronic docketing system:

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