No. 17-1484

# In The Supreme Court of the United States

ALEX M. AZAR, II, SECRETARY OF HEALTH AND HUMAN SERVICES,

*Petitioner*,

v.

ALLINA HEALTH SERVICES, ET AL.

*On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit*

## BRIEF IN OPPOSITION


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## QUESTION PRESENTED

This case concerns the Government's decision to forgo notice-and-comment rulemaking in a unique circumstance: when readopting a change in a substantive legal standard governing payment to hospitals nationwide after the D.C. Circuit had vacated a final rule attempting to adopt the same change for a logical outgrowth failure.

The Government frames the Question Presented as follows:

> Whether Section 1395hh(a)(2) requires HHS to conduct notice-and-comment rulemaking before providing instructions to a Medicare Administrative Contractor that makes initial determinations of payments due under Medicare, when those instructions rest on a non-legally-binding administrative interpretation of a relevant statutory provision.

Pet. (I).

The Government does not present any question with respect to 42 U.S.C. 1395hh(a)(4), an independent ground for the D.C. Circuit's judgment that requires notice-and-comment rulemaking before a Medicare rule vacated for a logical outgrowth failure can take effect.

## PARTIES TO THE PROCEEDING

Respondents are the private non-profit hospitals identified below, who were plaintiffs in the district court and appellants in the court of appeals:

1. Allina Health System d/b/a Abbott Northwestern Hospital

2. Allina Health System d/b/a United Hospital

3. Allina Health System d/b/a Unity Hospital

4. Florida Health Sciences Center, Inc. d/b/a Tampa General Hospital

5. Montefiore Medical Center

6. Mount Sinai Medical Center of Florida, Inc. d/b/a Mount Sinai Medical Center

7. New York - Presbyterian / Queens

8. New York Presbyterian Brooklyn Methodist Hospital

9. The New York and Presbyterian Hospital

Petitioner Alex M. Azar II, Secretary of Health and Human Services, was defendant in the district court and appellee in the court of appeals.

## RULE 29.6 DISCLOSURE

Montefiore Health System and Montefiore Medicine Academic Health System, Inc. are parent companies of Montefiore Medical Center. There are no other parent companies, and no publicly held corporation owns 10 percent or more of any respondents' stock.

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## BRIEF IN OPPOSITION

The Government's Question Presented (and the bulk of its petition) suggests that the D.C. Circuit's application of 42 U.S.C. 1395hh(a)(2) to the unique facts here was the sole basis for its judgment that notice-and-comment rulemaking was required. Not so. The D.C. Circuit explicitly found that "even if" section 1395hh(a)(2) did not require notice and comment, a distinct provision of the Medicare Act, 42 U.S.C. § 1395hh(a)(4), did. That is because the D.C. Circuit previously vacated the prior rule on the same issue for a logical outgrowth failure. The independent section 1395hh(a)(4) holding, on a matter of first impression, means the D.C. Circuit's

judgment would stand however this Court resolved the Question Presented. For that and other reasons, the petition should be denied.

## STATEMENT

### I. THE MEDICARE PROGRAM

#### A. Payment for Inpatient Hospital Services

Petitioner Secretary of Health and Human Services ("Secretary") administers the federal Medicare program, which furnishes benefits to elderly and disabled individuals. Two parts of the Medicare Act are pertinent here.

The first is Medicare part A, which covers inpatient hospital services and provides for payment to hospitals on a fee-for-service basis. 42 U.S.C. §§ 426(c), 1395d(a)(1), 1395f(a)-(b), 1395x(u). Part A payments to hospitals generally are made under a prospective payment system at predetermined, standardized rates per inpatient discharge. *Id.* § 1395ww(d); *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 205 (D.C. Cir. 2011). Those standard, per-case rates are subject to further adjustments to account for factors that may cause a hospital to incur greater than average costs to treat Medicare patients. 42 U.S.C. § 1395ww(d)(5). One such adjustment, reflecting the additional costs of providing services to low-income patients, is called the "disproportionate share hospital," or "DSH," payment. *Id.* § 1395ww(d)(5)(F).

The Secretary undertakes yearly notice-and-comment rulemaking on changes to the part A

prospective payment system. 42 U.S.C. § 1395ww(d)(6) (requiring Secretary to publish an annual update of the methodology and payment rates by August 1); 42 C.F.R. § 412.8 (same). This annual rulemaking takes an average of 102 days to complete. Add. 1a-3a.

The second part of the Medicare statute pertinent here is part C, created in 1997. Part C established a managed care program (currently called "Medicare Advantage," formerly "Medicare+Choice" or "M+C") that is an alternative to the part A fee-for-service program. 42 U.S.C. § 1395w-21(a). An eligible beneficiary can elect to receive benefits through enrollment in a managed care plan under part C in lieu of benefits under the part A fee-for-service program. *Id.* § 1395w-21(a)(1), (i)(1); *Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 6 (D.C. Cir. 2011).

**B. The Part A DSH Payment**

This case concerns the treatment of Medicare part C patients in the DSH payment calculation under the part A prospective payment system.

The part A DSH payment turns on a "disproportionate patient percentage" that is the sum of two fractions representing inpatient care furnished to low-income individuals. 42 U.S.C. § 1395ww(d)(5)(F)(v), (vi). The two fractions depend, in inverse fashion, on the number of days spent in the hospital by patients who are "entitled to benefits under [Medicare] part A." *Id.* § 1395ww(d)(5)(F)(vi)(I)-(II).

The first fraction, which the D.C. Circuit called the "Medicare fraction," measures the proportion of all patients "entitled to benefits under [Medicare] part A" who are also "entitled to supplementary security income [("SSI")] benefits." 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I). The Secretary issues Medicare fractions for each fiscal year for all hospitals nationwide that are binding on the agency, its contractors, and hospitals. *See* 42 C.F.R. § 412.106(b)(2), (5).

The second fraction, the "Medicaid" fraction, measures the proportion of the total of all patients who were Medicaid-eligible but "*not* entitled to benefits under part A." 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II) (emphasis added).

Patients are either part-A-entitled or not. Accordingly, a given patient can be counted in the numerator of one fraction or the other, but not both. *Allina Health Servs. v. Sebelius*,, 746 F.3d 1102, 1108 (D.C. Cir. 2014) (*Allina I*).

### C. Medicare Payment Appeals

Medicare Administrative Contractors (formerly called "fiscal intermediaries") perform part A audit and payment functions. Pet. App. 3a. A hospital must file an annual "cost report" with its contractor. 42 C.F.R. §§ 413.20, 413.24. The contractor then issues notice of the final amount of Medicare program reimbursement due the hospital for that period. *See* 42 C.F.R. § 405.1803; *see also id*. § 405.1807.

A hospital may appeal that final determination, or the contractor's failure to issue a timely final determination, to the Provider Reimbursement

Review Board ("Board"), an administrative tribunal appointed by the Secretary. 42 U.S.C. § 1395oo(a)(1), (h); 42 C.F.R. §§ 405.1835-405.1877. When the Board determines that it lacks authority to decide a question of law or regulations relevant to an appeal, hospitals have the right to immediate judicial review of the underlying agency decision. 42 U.S.C. § 1395oo(f)(1).

### D. The Medicare Act's Special Notice-and-Comment Rulemaking Requirements

When it enacted the Medicare program in 1965, Congress authorized the Secretary to prescribe regulations for administering the program. Social Security Amendments of 1965, Pub. L. No. 89-97, Title I, § 102(a), 79 Stat. 286, 331 (codified at 42 U.S.C. § 1395hh(a)(1)).

In 1986, Congress mandated a 60-day notice-and-comment period for Medicare regulations subject to three limited exceptions. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9321(e)(1), 100 Stat. 1874, 2017 (codified at 42 U.S.C. §§ 1395hh(a)(1), 1395hh(b)). The exceptions are: (1) where a statute specifically permits no prior public comment or a shorter comment period; (2) where a statute specifies a rulemaking deadline that falls within 150 days of its enactment; or (3) where the good cause exemption of the Administrative Procedure Act (APA) (5 U.S.C § 553(b)(B)) is satisfied. 42 U.S.C. § 1395hh(b).

A year later, still concerned that "important policies [were] being developed without benefit of the public notice and comment period," H.R. Rep. No.

100-391(I), at 430 (1987), reprinted in 1987 U.S.C.C.A.N. 2313-1, Congress further amended the Medicare statute to establish additional, particularized notice-and-comment rulemaking requirements. Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, § 4035, 101 Stat. 1330, 1330-78. As amended, the statute mandates 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), through notice-and-comment rulemaking, *id.* § 1395hh(a)(1). When "manual instructions, interpretative rules, statements of policy, and guidelines of general applicability" are not required to be promulgated through notice-and-comment rulemaking, then the Secretary must list them in the Federal Register. *Id.* § 1395hh(c)(1). *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)

In 2003, Congress modified the Medicare Act further to provide that "[i]f the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice," that provision "shall not take effect until there is the further opportunity for public comment and publication of the provision again as a final regulation." Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L.

No. 108-173, § 902, 117 Stat. 2066, 2375 (codified at 42 U.S.C. § 1395hh(a)(4)).

In addition, "[a] substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability *** shall not be applied *** retroactively to items and services furnished before the effective date of the change" except under circumstances not relevant here. 42 U.S.C. § 1395hh(e)(1).

## II. THE SECRETARY'S NEW STANDARD ON PART C PATIENTS IN THE DSH PAYMENT AND LITIGATION CHALLENGING IT

### A. The Pre-2004 Rule

This litigation stems from a 2004 rulemaking. Before 2004, the Secretary treated part C patients as *not* entitled to benefits under part A in calculating the DSH payment. *See* Pet. App. 4a ("Before 2004, HHS had *not* treated Part C enrollees as 'entitled to benefits under Part A.'") (citation omitted); *Allina I*, 746 F.3d at 1106, 1108 (Secretary "treated Part C patients as *not* entitled to benefits under Part A," "excluding Part C days from the Medicare fraction and including them in the Medicaid fraction") (citation omitted); *Northeast Hosp.*, 657 F.3d at 16-17 (2004 rule "contradicts [the Secretary's] former practice of excluding [part C] days from the Medicare fraction" as well as written agency guidance).

Specifically, the Secretary's policy and practice before 2004 reflected the original 1986 DSH regulation, which counted as Medicare part-A-entitled days only patient days that were covered and

paid under the part A fee-for-service system. *See* 42 C.F.R. § 412.106(b)(2)(i) (2003) (defining Medicare fraction to include only "the number of *covered* patient days") (emphasis added); *see also id.* § 409.3 (defining "covered" as services for which payment is authorized); 51 Fed. Reg. 16,772, 16,777 (May 6, 1986) (explaining the Secretary's intent when regulation adopted to include only "covered Medicare Part A inpatient days"). Although the 1986 regulation did not expressly mention part C patient days (as noted above, part C came later), it unambiguously excluded them as days not covered and paid under part A. *See Catholic Health Initiatives Iowa Corp. v. Sebelius*, 718 F.3d 914, 921 n.5 (D.C. Cir. 2013) (noting that the pre-2004 regulation limited the fraction to "covered Medicare Part A inpatient days").

**B. The 2004 Rule Change**

In 2003, the Secretary published a proposed rule "to clarify" the longstanding standard under the 1986 regulation of excluding part C days from the Medicare fraction, and including them in the Medicaid fraction, because "once a beneficiary has elected to join [a part C] plan, that beneficiary's benefits are no longer administered under Part A." 68 Fed. Reg. 27,154, 27,208 (May 19, 2003).

In a final rule published a year later, however, the Secretary engaged in a "volte-face," *Allina I*, 746 F.3d at 1109, adopting the exact opposite standard. The 2004 final rule provided that the Secretary would count days not paid by part A, including part C days, as part-A-entitled days. 69 Fed. Reg. 48,916,

49,099 (Aug. 11, 2004); *see also Allina Health Servs. v. Sebelius*, 904 F. Supp. 2d 75, 81 (D.D.C. 2012), *aff'd in part and rev'd in part*, 746 F.3d 1102 (D.C. Cir. 2014).[1] The Secretary's only explanation for the about-face was that part C patients "are still, in some sense, entitled to benefits under Medicare [p]art A." 69 Fed. Reg. at 49,099.

In an impact analysis accompanying the 2004 final rule, the Secretary predicted that the part C days standard change would not "have a significant impact on payments." 69 Fed. Reg. at 49,770. The agency said its estimate was "[b]ased on an analysis from our actuarial staff," and the impact of the new part C days policy would not exceed $50 million for one year even when combined with three other changes that were all expected to reduce DSH payments. *Id.*

### C. Earlier Cases Challenging The 2004 Rule

The Secretary initially attempted to apply the new 2004 rule to DSH payments for services rendered in prior periods. The D.C. Circuit rejected that maneuver, finding the rule "change[d] the legal consequences of treating low-income patients" and

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[1] The final rule deleted the requirement that days must be "covered" by Medicare part A to be included as part-A-entitled days. *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.

thus could not be applied retroactively. *Northeast Hosp.*, 657 F.3d at 13-17.[2]

In 2009, while that case was pending, the Secretary began to apply the 2004 rule to later periods. The Secretary first applied the rule in issuing Medicare fractions for federal fiscal year 2007. A group of hospitals, including Respondents, brought a challenge alleging, *inter alia*, that the 2004 rule was not the "logical outgrowth" of the 2003 proposed rule, and was arbitrary and capricious because the agency's "cursory explanation in the 2004 Final Rule" failed to acknowledge its departure from past policy, or the "financial impact" of that change. *Allina I*, 904 F. Supp. 2d at 92-94. The Secretary's defense of the rule denied any significant economic impact of the 2004 policy change, arguing that the hospitals proffered an "outsized estimate" standing on a "faulty assumption." Def's Mot. Summ. J. at 33-34 & n.13, *Allina I*, No. 1:10-cv-1463, (D.D.C. Mar. 5, 2012), ECF No. 35. The district court agreed with the hospitals, however, and vacated the 2004 rule on both grounds. *Allina I*, 904 F. Supp. 2d at 89-93, 95.

The Secretary appealed. The hospitals again raised the Secretary's "woefully inadequate"

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[2] The hospitals there also argued that the 2004 rule was inconsistent with the DSH statute's plain terms. A divided panel disagreed. *Northeast Hosp.*, 657 F.3d at 5-13, 18-24. Concurring in the judgment, Judge Kavanaugh agreed with the hospitals that a patient who "receives Medicare benefits under Medicare Part C for a particular 'patient day'" is not "also 'entitled' for that same 'patient day' to Medicare benefits under Medicare Part A." *Id.* at 18.

consideration of the impact of the 2004 rule. Br. for Pls.-Appellees at 40, *Allina I*, No. 13-5011 (D.C. Cir. Aug. 1, 2013). This time around, the Secretary contended "this is not a case where the financial impact is readily apparent." Br. for Def.-Appellant at 44 n.6, *Allina I*, No. 13-5011 (D.C. Cir. July 1, 2013).

The D.C. Circuit affirmed on the ground that "the Secretary's final rule was not a logical outgrowth of the proposed rule." *Allina I*, 746 F.3d at 1109. The D.C. Circuit explained that "[t]he Secretary's estimated financial impact of its proposal—that there should not be a major impact associated with this proposed change—supports [the] conclusion" that the 2004 rule was not a logical outgrowth of the 2003 proposed rule. *Id*. at 1108. The D.C. Circuit did not reach the reasonableness of the Secretary's decision-making in adopting the 2004 rule. *Id.* at 1111.

The D.C. Circuit affirmed the vacatur of the rule and remanded the case to the agency, holding that "[t]he question whether the Secretary could reach the same result" on remand was not yet before it. *Id.*

More than a year and a half after the D.C. Circuit decision became final (and the agency summarily promulgated the 2012 Medicare fractions at stake here), the Secretary issued a decision on the remand in *Allina I*. *See* Def.'s Mot. For Summ. J. at Attach. No. 4, *Allina II*, No. 1:14-cv-1415 (D.D.C. Dec. 15, 2015), ECF No. 29-4. The remand decision concluded, again, that part C days should be treated as part-A-entitled days. *Id.* at 41-46. The remand decision rested on the false premise, contrary to D.C. Circuit rulings in *Northeast Hospital* and *Allina I*,

that the Secretary was continuing the same standard that was in effect before the 2004 rule change. *Id.* at 30-35. The remand decision also disclaimed that the treatment of part C patients in the DSH payment calculation had any significant financial impact. *Id.* at 43-44 & nn.93 & 94.

The hospitals in *Allina I* challenged the remand decision in a suit pending before the district court, *Allina Health Sys. v. Burwell*, No. 16-cv-00150 (D.D.C. Jan. 29, 2016). That case is stayed pending the outcome of the petition here.

**D. The 2013 Prospective Rule**

In 2013, while the Secretary's appeal in *Allina I* was pending before the D.C. Circuit, the agency engaged in a new, prospective rulemaking on part C days in the DSH payment as part of the annual inpatient prospective payment system rulemaking for federal fiscal year 2014. 78 Fed. Reg. 50,496, 50,615 (Aug. 19, 2013). Effective October 1, 2013, the standard governing part C days in the DSH calculation reverted to the policy articulated in the now vacated 2004 rule. *See id.* at 50,619 (rule "readopt[ion]" applies to "FY 2014 and subsequent years" only). The Secretary refused again to consider the financial impact of this change from the pre-2004 standard, asserting that the agency did "not believe that there will be additional savings or costs to the Medicare program, and by inference, to hospitals, as a result of this policy." *Id.* at 50,620.

**E. This Case (*Allina II*)**

**1.** In June 2014, the Secretary published Medicare fractions for federal fiscal year 2012

applying the same standard that was adopted in the 2004 rule that the D.C. Circuit had just vacated sixteen days earlier. That issuance, which applied to every hospital nationwide, offered only a cursory note stating that the Medicare fractions included part C days. Pet. App. 5a-6a. The Secretary proceeded without notice, comment opportunity, or explanation for the departure from the reinstated pre-2004 standard under the 1986 regulation.

Respondents filed appeals to the Secretary's Board and requested expedited judicial review. C.A. Joint App. at 89-167, 178-248. The Board granted that request under 42 U.S.C. § 1395oo(f), concluding that it lacked authority to decide the legality of the part C standard embodied in the issuance of the fractions after *Allina I*. Pet. App. 56a-58a, 71a-73a.

Respondents brought suit and, in briefing at the district court, the Secretary again disavowed any clear financial impact of the part C policy. The Secretary argued it "is wrong" to think that including part C days as part A-entitled reduces DSH payments to hospitals. Gov't Reply at 12-13, 15, *Allina II*, No. 1:14-cv-1415 (D.D.C. Feb. 4, 2016), ECF No. 33.

The district court granted summary judgment to the Secretary. It found that the issuance of Medicare fractions treating part C patients as part-A entitled was an interpretative rule exempt from the APA's notice-and-comment requirement, and that Medicare Act section 1395hh(a)(2) incorporated the APA's exemption. Pet. App. 34a, 36a, 44a. The district court did not address Respondents' arguments about

the independent notice-and-comment requirement of section 1395hh(a)(4) triggered by the 2004 rule's logical outgrowth failure. Pet. App. 19a-44a.

**2.** The D.C. Circuit unanimously reversed.

**a.** The D.C. Circuit explained that the text of section 1395hh(a)(2) "describes in fairly straightforward language when notice and comment is necessary"—namely, "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.'" Pet. App. 12a (citation omitted). The D.C. Circuit found that test "readily met here." *Id.*

First, "HHS's inclusion of Part C days in the fiscal year 2012 Medicare fractions," the D.C. Circuit reasoned, "is, at the very least, a 'requirement'" because those fractions, which must be used for DSH payment determinations, "treat Part C enrollees as 'entitled to benefits under Part A.'" Pet. App. 12a-13a (citing 42 C.F.R. § 412.106(b)(2), (5)).

Second, the 2012 issuance constituted a "change" because HHS's "baseline practice" before the invalidated 2004 rule "was to *exclude* Part C days from Medicare fractions." Pet. App. 13a (citing *Northeast Hosp.*, 657 F.3d at 15).

Third, the D.C. Circuit found that the issuance promulgated a "substantive legal standard" because the fractions "define the scope of hospitals' legal rights to payment for treating low-income patients." Pet. App. 13a-14a.

Fourth, because "[t]he 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 "governs 'payment for services.'" Pet. App. 14a. Consequently, "[t]he inclusion of Part C days means that the providers will now receive lower payments." *Id.*

The D.C. Circuit did not decide whether the "decision to include Part C days in the 2012 Medicare fractions was in fact an interpretive rule." Pet. App. 15a. But it nonetheless rejected the Secretary's argument that the Medicare Act incorporates the APA's exception for interpretive rules. Pet. App. 17a. The D.C. Circuit "respectfully disagree[d]" with decisions from other circuits on that specific point. *Id.* "Unlike the APA, the text of the Medicare Act does not exempt interpretive rules from notice-and-comment rulemaking." Pet. App. 15a. "On the contrary," the court explained, "the text expressly *requires* notice-and-comment rulemaking. *** 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." Pet. App. 15a-16a.

**b.** The D.C. Circuit ruled, in the alternative, that "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" based on another provision of the Medicare statute, section 1395hh(a)(4), that "expressly required notice and comment in this case." Pet. App. 17a. In particular, the D.C. Circuit held that section 1395hh(a)(4) precludes a regulation from "becom[ing]

legally operative until it has gone through notice-and-comment rulemaking" if it includes "a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking." Pet. App. 17a-18a (internal quotation marks and citation omitted). Further, the D.C. Circuit confirmed that "HHS could not circumvent this [Section 1395hh(a)(4)] requirement by claiming that it was acting by way of adjudication rather than rulemaking" because "[t]he statutory text says that the vacated rule may not 'take effect' at all until there has been notice and comment." Pet. App. 18a.

The D.C. Circuit denied the Secretary's rehearing petition, with no member of the court calling for a vote. Pet. App. 77a-78a, 79a-80a.

## REASONS FOR DENYING THE PETITION

The Government asks this Court to review the D.C. Circuit's holding that section 1395hh(a)(2) required notice-and-comment rulemaking on the unique facts presented here. But a decision on that issue would not change the outcome in this case. That is because, in an alternate holding that the Government does not ask this Court to review, the D.C. Circuit found that section 1395hh(a)(4) *independently* required notice and comment due to the failure in prior rulemaking on the same underlying Medicare payment policy. The Government's afterthought that section 1395hh(a)(4) somehow depends on the section 1395hh(a)(2) inquiry does not import that independent holding into the Question Presented, resolution of which would be purely academic.

Even apart from that glaring vehicle problem, there is no circuit split warranting review. No other decision, court of appeals or otherwise, comes close to contradicting the D.C. Circuit's holding that section 1395hh(a)(4) required notice-and-comment rulemaking here. There is also no conflict with the D.C. Circuit's application of the text of section 1395hh(a)(2) to the unusual circumstances here—the only issue the petition presents for review. And because the D.C. Circuit did not decide whether the decision at issue was in fact an interpretive rule, it is far from clear that any distinction drawn between the Medicare Act and the APA would be dispositive in this or any other case. At most, the D.C. Circuit departs in the abstract from other courts of appeals that did not grapple with the marked differences between the Medicare Act and the APA. The D.C. Circuit's thorough and straightforward analysis of section 1395hh(a)(2)'s notice-and-comment requirement yielded a faithful application of the text to the facts here. Other circuits might very well adopt that analysis if presented with a need to engage on the question. For those reasons, this Court's intervention would be premature.

The Government's assertion that the D.C. Circuit's decision impairs its ability to administer the Medicare program is not grounded in reality. Requiring notice-and-comment rulemaking for the unique agency issuance at issue here—the byproduct of years of litigation stemming from the Secretary's perpetual denial of a policy change and significant financial impact on hospitals (which the Government now embraces)—would have little to no impact on the

agency's operations. Indeed, as the Government acknowledges, the D.C. Circuit's opinion addressed a transitional problem: HHS engaged in notice-and-comment rulemaking and issued a new final rule applying to fiscal year 2014 and beyond. And to the extent the government's hypothetical concerns ever materialize in other Medicare contexts, the Court can grant review at that time—in a case where resolution of the question presented would actually matter.

## I. REVIEW HERE WOULD BE ACADEMIC IN LIGHT OF THE D.C. CIRCUIT'S INDEPENDENT SECTION 1395hh(a)(4) HOLDING.

**1.** The D.C. Circuit explicitly found two independent bases for invalidating HHS's decision to include part C days in the Medicare fractions, sections 1395hh(a)(2) and 1395hh(a)(4). "[*E*]*ven if* HHS were correct that the Medicare Act somehow incorporated the APA's notice-and-comment exception for interpretive rules," the Court held, "*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." Pet. App. 17a (emphasis added).

Unlike section 1395hh(a)(2), which mandates notice-and-comment rulemaking for setting and changing a specific category of Medicare standard (*i.e.*, "a substantive legal standard *** governing the *** payment for services"), section 1395hh(a)(4) imposes a notice-and-comment requirement for any "provision" of a certain category of invalidly adopted final regulation (*i.e.*, one "not a logical outgrowth of a

previously published notice of proposed rulemaking"). As the D.C. Circuit explained, "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." Pet. App. 17a-18a (citation omitted).

Section 1395hh(a)(4) is tailor-made for this first-of-its-kind case. As the D.C. Circuit reasoned: "HHS's 2004 rule treating Part C enrollees as 'entitled to benefits under Part A' [was vacated] because the 2004 rule 'was not a logical outgrowth of the proposed rule.'" Pet. App. 18a (quoting *Allina I*, 746 F.3d at 1109). Under section 1395hh(a)(4), "HHS therefore had to provide a further opportunity for public comment and a publication of the provision again as a final regulation before [it] could re-impose the rule. HHS did not do so." *Id.* (internal quotation marks and citation omitted). Rejecting HHS's argument that it was excused from notice-and-comment rulemaking because it chose (purportedly) to act through adjudication "rather than rulemaking," the D.C. Circuit found that "[t]he statutory text says that the vacated rule may not 'take effect' at all until there has been notice and comment." *Id.* (quoting section 1395hh(a)(4)).[3]

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[3] The Government revives that merits argument before this Court, asserting that "[a]gency adjudication *** is an established method for resolving interpretive issues" not addressed by regulations. Pet. 22. However true that may be as a general matter under the APA, it ignores section 1395hh(a)(4)'s specific mandate under the Medicare Act in the

**2.** The Government's Question Presented does not expressly raise the section 1395hh(a)(4) holding or fairly include it. The Government frames the Question Presented as follows:

> "The Department of Health and Human Services (HHS) must utilize notice-and-comment rulemaking to promulgate rules, requirements, or statements of policy that "establish[] or change[]" a "substantive legal standard" governing payment for services under the Medicare Act, 42 U.S.C. 1395hh(a)(2). See 42 U.S.C. 1395hh(b)(1). The question presented is:
>
> Whether Section 1395hh(a)(2) requires HHS to conduct notice-and-comment rulemaking before providing instructions to a Medicare Administrative Contractor that makes initial determinations of payments due under Medicare, when those instructions rest on a non-legally-binding administrative interpretation of a relevant statutory provision.

Pet. (I).

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event of a logical outgrowth failure. Tellingly, the cases on which the Government relies, *Shalala v. Guernsey Memorial Hospital,* 514 U.S. 87, 96 (1995), and *SEC v. Chenery Corp.,* 332 U.S. 194, 203 (1947), say nothing about section 1395hh(a)(4) or its application to such an invalidly adopted Medicare rule. Nor could they: the 1995 *Guernsey* decision predated the 2003 enactment of section 1395hh(a)(4) by several years, and *Chenery* (not even a Medicare case) predated it by nearly six decades.

The Government plainly has not asked this Court to review the D.C. Circuit's independent section 1395hh(a)(4) holding. The Question Presented does not mention section 1395hh(a)(4) at all. Pet. (I). And the Government does not even address section 1395hh(a)(4) until the bottom of page 21 of its 23-page petition.

When it finally gets around to it, the Government obliquely suggests that section 1395hh(a)(4)'s notice-and-comment requirement somehow depends on section 1395hh(a)(2). Pet. 22-23. That suggestion is both newly minted and utterly unsupported. The Government did not raise any connection between the provisions in merits briefing before the D.C. Circuit. In fact, until it petitioned for rehearing *en banc*, the Government did not respond *at all* to the hospitals' arguments throughout the litigation that HHS's failure to undertake notice-and-comment rulemaking violated section 1395hh(a)(4). Waiver aside, the lack of any decisions from "other courts" on the issue (Pet. 22), *see* pp. 23-24, *infra*, hardly supports the Government's new intimation that the section 1395hh(a)(4) notice-and-comment requirement depends on the application of the separate and distinct section 1395hh(a)(2) requirement.

This Court has explained that a question not directly mentioned in the question presented (as here) must be "anterior" or a predicate to the question presented to be "fairly included" in it. *Ballard v. Commissioner*, 544 U.S. 40, 46-47 & n.2 (2005); *compare Richlin Sec. Serv. Co. v. Chertoff*, 553 U.S. 571, 579 n.4 (2008) ("Since the question

presented cannot genuinely be answered without addressing the subsidiary question, we have no difficulty concluding that the latter question is 'fairly included' within the former. See this Court's Rule 14.1(a).''). The question whether a prior logical outgrowth failure triggers the mandate to engage in additional notice-and-comment rulemaking under section 1395hh(a)(4) is by no means anterior to, or dependent upon, the independent question whether section 1395hh(a)(2) required that notice-and-comment process for a substantive legal standard governing payment. As the D.C. Circuit made clear below, the Government violated section 1395hh(a)(4) "even if" the Medicare Act "somehow incorporated the APA's notice-and-comment exception for interpretive rules." Pet. App. 17a. The mere fact that the two distinct statutory provisions both address notice-and-comment rulemaking is insufficient to establish that a question presented concerning one provision subsumes the other. *See Yee v. City of Escondido*, 503 U.S. 519, 537 (1992).

Any opinion from this Court resolving the Question Presented would thus be advisory as the judgment would stand regardless. This Court reviews judgments, not opinions, *see e.g., Camreta v. Greene*, 563 U.S. 692, 704 (2011), and should deny review on that basis alone.

## II. THERE IS NO CIRCUIT SPLIT WARRANTING REVIEW.

### A. The D.C. Circuit's Section 1395hh(a)(4) Holding Is One of First Impression

The Government's half-hearted effort to manufacture a circuit conflict with its vague reference to how "other courts" have supposedly ruled on section 1395hh(a)(4) does not withstand any scrutiny. The Government offers that "other courts have not concluded that Section 1395hh(a)(4) *** requires notice-and-comment rulemaking where Section 1395hh would not require such rulemaking for a (non-binding) interpretive action by CMS in the first place." Pet. 22-23. True enough. But as the conspicuous omission of any cases cited to support that statement would suggest, there are no decisions—from any court in any jurisdiction—on that point.

A Westlaw search reveals only six other decisions (two in the prior litigation on part C days) even citing section 1395hh(a)(4) since its enactment in 2003.[4] None comes close to holding, in conflict

[4] *See Allina I*, 746 F.3d at 1109 (citing section 1395hh(a)(4) for the proposition that "the Medicare statute has no harmless error exception"); *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 267 n.9 (D.D.C. 2015) (citing section 1395hh(a)(4) as supplying an exception to the doctrine permitting an unlawfully promulgated rule to stay in place where equity demands it); *Allina Health Servs. v. Sebelius*, 904 F. Supp. 2d 75, 94 n.13 (D.D.C. 2012) (declining to decide whether section 1395hh(a)(4) automatically requires vacatur for notice-and-comment violation because court had already

with the D.C. Circuit, that section 1395hh(a)(4) permits implementation of a Medicare payment policy change, without further notice and comment, when the change was initially adopted through a rulemaking vacated for a logical outgrowth failure. Not surprisingly, the petition also cites no decisions of "other courts of appeals" for the proposition that the Medicare agency should be able to apply its purportedly "non-binding understanding" of the statute "to adjudicate *** Medicare reimbursement" claims here. *See* Pet. 22-23; p. 34, *infra*. It goes without saying that silence on a particular question of first impression does not create a circuit conflict.

### B. There Is No Circuit Split on the Section 1395hh(a)(2) Question Warranting Review.

The undeveloped conflict on the general question whether the Medicare Act incorporates the APA's notice-and-comment exception for interpretive rules does not warrant this Court's review of the specific application of section 1395hh(a)(2) raised here.

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vacated Secretary's action on other grounds), *rev'd in part on other grounds*, 746 F.3d 1102 (D.C. Cir. 2014); *Texas All. for Home Care Servs. v. Sebelius*, 811 F. Supp. 2d 76, 99 n.17 (D.D.C. 2011), *aff'd*, 681 F.3d 402 (D.C. Cir. 2012) (finding no logical outgrowth failure); *National Ass'n for Home Care & Hospice, Inc. v. Sebelius*, No. 08-1765 (RBW), 2009 WL 9057020, *1-2 (D.D.C. Sept. 29, 2009) (dismissing case on jurisdictional grounds without deciding the merits of a challenge under section 1395hh(a)(4)); *Premier Med. Supplies, Inc. v. Leavitt*, No. 1:07cv3809, 2008 WL 11381846, at *5 (N.D. Ohio June 30, 2008) (finding no logical outgrowth failure).

**1**. The Government's Question Presented is narrow and fact-specific: "Whether Section 1395hh(a)(2) requires HHS to conduct notice-and-comment rulemaking before providing instructions to a Medicare Administrative Contractor that makes initial determinations of payments due under Medicare, when those instructions rest on a non-legally-binding administrative interpretation of a relevant statutory provision." Pet. (I). Intimating a circuit conflict on that fact-bound (and misleading, *see* pp. 33-35, *infra*) question, the Government contends: "As the D.C. Circuit acknowledged, the decisions of other courts of appeals reflect the view that instructions from HHS to its [contractors] about Medicare fractions *** do not qualify as a 'substantive legal standard' under Section 1395hh(a)(2)." Pet. 14. That is flatly incorrect. *None* of the cases on which the Government relies concerned the Medicare fractions, let alone found that the agency was exempt from notice-and-comment rulemaking for the change to include part C days as part-A-entitled days. There is thus no circuit split on the particular question presented here.

The issue on which the D.C. Circuit indicated a departure from other circuits was its "holding that the Medicare Act does not incorporate all of the APA's exceptions to the notice-and-comment requirement." Pet. App. 17a. The D.C. Circuit expressly declined, however, to decide whether the decision to include part C days in the Medicare fractions constituted an APA interpretive rule. *Id.* 15a. Respondents vigorously challenged that characterization in the lower courts, and it is far from

obvious that the APA label fits. *See* Pet. App. 34a-35a; *see also* pp. 27-28, *infra*. Absent a decision from the D.C. Circuit on that question, it is unclear whether that court's application of the plain text of the Medicare Act produces an outcome that is any different than it would reach under the APA on the facts presented in this case. That is not a question for this Court to decide in the first instance. *See*, *e.g.*, *McLane Co. v. EEOC*, 137 S. Ct. 1159, 1170 (2017) ("[Ours is] a court of [final] review, not of first view.") (internal quotation marks and citation omitted).[5]

**2.** On the more general interpretive-rule-exception question addressed by the D.C. Circuit, the other circuit decisions the Government cites offer little more than conclusory statements appearing mostly in footnotes and all resting on an unexamined assumption that the Medicare Act incorporates the APA's exceptions. The first cited decision, *Warder v. Shalala*, 149 F.3d 73 (1st Cir. 1998), merely assumed (in a footnote) that the Medicare Act incorporates the

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[5] Review by this Court would also be premature because there are other grounds for invalidating the agency's 2014 action: the Secretary's interpretation is inconsistent with the language and intent of the Medicare DSH statute (*see* note 2, *supra*); the changed standard is arbitrary and capricious for several reasons, including the agency's failure to address the significant economic impact of the change (*see* pp. 36-38, *infra*); under section 1395hh(e)(1)(A), "a substantive change in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied *** retroactively to items and services furnished before the effective date of the change" except under certain circumstances not relevant here (*see* p. 7, *supra*).

APA's exceptions without actually deciding the question. *See id*. at 79 n.4 ("We proceed herein as if the [statute's] exemption for interpretive rules were identical to the APA's. *** [The plaintiff] has not argued that the two standards are materially different."). The second case, *Erringer v. Thompson*, 371 F.3d 625 (9th Cir. 2004), also did not decide the question, as the court "found no reason to explore the possibility of a distinction between the Medicare Act and the APA." *Id.* at 633. And the third (again in a footnote) incorrectly cited *Erringer* as "[holding] that [section 1395hh(a)(2)] imposes no standards greater than those established by the APA," and stated its agreement on that "corollary" issue. *Baptist Health v. Thompson*, 458 F.3d 768, 776 n.8 (8th Cir. 2006). This is not the sort of mature circuit split reflecting the well-considered analysis of the lower courts that would inform and assist this Court's consideration of the matter.

**3.** The strength of the D.C. Circuit's thorough and considered decision makes it all the less likely that a mature conflict will ever emerge. The D.C. Circuit's unanimous application of the plain text of section 1395hh(a)(2) to the facts here is faithful to "Congress's use of different language and its establishment of different notice-and-comment requirements in the Medicare Act and the APA." Pet. App. 16. The Government's latest responses to that analysis are unpersuasive and fail to advance the case for review.

Without actually contending that HHS's determination to include part C days in the Medicare fractions constitutes an "interpretive rule"—an issue

the D.C. Circuit declined to reach (Pet. App. 15a)—the Government explains it has "understood" (Pet. 15) that the Medicare Act's special rulemaking requirements contain the APA's express exception for interpretive rules. Pet. 15-18. But, as the D.C. Circuit observed, section 1395hh(a)(2) states: "'*No* rule, requirement or other statement of policy *** shall take effect *unless* it is promulgated' through notice and comment rulemaking." *Id.* 15a-16a (quoting 42 U.S.C. § 1395hh(a)(2)). Section 1395hh(a)(2) imposes APA-independent criteria that trigger notice-and-comment rulemaking, without any carve-out for interpretive rules. Pet. App. 12a. The plain text speaks for itself. *See* p. 15, *supra*.

The context of section 1395hh(a)(2) also undercuts the Government's position. A neighboring provision, section 1395hh(b), expressly incorporates another APA exception to notice and comment—"[s]pecifically, the *** 'good cause' exception." Pet. App. 16a; *see* 42 U.S.C. § 1395hh(b)(2). The inclusion of the good-cause exception shows that Congress did not incorporate the exemption for interpretive rules *sub silencio*. Pet. App. 16a. ("Congress knew how to incorporate the APA's notice-and-comment exceptions into the Medicare Act when it wanted to.").

Section 1395hh(c) (which the Government does not mention) also cuts against its atextual reading. That provision demands periodic publication of a list of "interpretative rules" when those rules "are not published pursuant to subsection (a)(1)," *i.e.*, by notice-and-comment rulemaking. By requiring publication of a list of interpretative rules that have *not* gone through notice and comment as required by

section 1395hh(a)(2), section 1395hh(c) presupposes that some interpretative rules *are* subject to section 1395hh(a)(2)'s notice-and-comment requirement.

Rather than engage on those textual and structural contours, the government focuses on the "legal landscape" at the time Congress enacted the special Medicare rulemaking provisions. From the premise that Congress would have been familiar with the APA's rulemaking standards, the Government reasons that the D.C. Circuit's decision must be incorrect because "[n]othing in Section 1395hh suggests that Congress intended to apply a new notice-and-comment requirement for subsidiary 'interpretive rules,'" Pet. 17, and "[a]n 'interpretive rule' by its nature does not 'establish[] or change[]' a 'substantive legal standard.'" *Id.* 17-18 (citation omitted).[6] Yet the Government fails to offer any reason why Congress adopted particular requirements in the Medicare Act only to restate there what the APA already required.[7]

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[6] As it did below, the Government here ignores the fact that the APA itself uses the term "substantive rule" in a manner showing that "interpretative rules and statements of policy" can be substantive as opposed to procedural. *See* 5 U.S.C. § 553(d) ("The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except— *** interpretative rules and statements of policy.").

[7] Congress first added a notice-and-comment requirement to the Medicare Act in 1986, long after the agency had itself recognized the need to follow the APA. *See* Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, § 9321(e), 100 Stat. 1874, 2017 (1986); 36 Fed. Reg. 2,531-02, 2,532 (Feb. 5, 1971) (Secretary agreeing to "utilize the public participation

Further, the Government's argument gets the analysis backwards. The section 1395hh(a)(2) inquiry does not begin with the question whether the agency's issuance is an "interpretive rule" within the meaning of the APA.[8] Rather, the analysis sensibly starts with the text of section 1395hh(a)(2), which requires notice and comment for any "rule, requirement, or other statement of policy" that "establishes or changes" a "substantive legal standard" governing "payment for services." Pet. App. 12a. By applying the plain meaning of those terms, the D.C. Circuit determined that HHS's decision to include part C days in Medicare fractions met the section 1395hh(a)(2) test for notice-and-comment rulemaking. *Id.*

The Government also contends that, under the D.C. Circuit's rationale, "CMS could not have properly calculated *any* Medicare fractions for *any* hospital after the 1997 enactment of Medicare Part C, *** [because] fulfilling that obligation required the agency to apply *some* interpretation of the Medicare-fraction statute." Pet. 21. That also is incorrect. As

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procedures of the APA" in issuing "rules and regulations relating to *** benefits").

[8] The Government incorrectly invokes *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199 (2015), to claim that the D.C. Circuit erred. *See* Pet. 21 n.12. To the contrary, this Court recognized there that Congress sometimes drafts special provisions to provide additional procedures or protections, beyond what the APA provides, to address when agencies "alter their views." *Perez,* 135 S. Ct. at 1209.

described above, HHS issued a regulation in 1986 requiring that only days covered and paid under part A were to be treated as part-A-entitled. *See* pp. 7-8, *supra*; *see also Catholic Health Initiatives Iowa Corp.*, 718 F.3d at 921 n.5 ("[In the 1986 regulation], the Secretary interpreted the phrase 'entitled to benefits under part A of [Medicare]' in the Medicare fraction to include only 'covered Medicare Part A inpatient days.'") (second alteration in original). HHS could follow its pre-2004 regulation for the years prior to the 2013 prospective rule change without going through notice-and-comment rulemaking.

As the D.C. Circuit found below, "[w]e must respect Congress's use of different language and its establishment of different notice-and-comment requirements in the Medicare Act and the APA." Pet. App. 16a. The Government's claim that section 1395hh(a)(2) should be interpreted to mirror the APA fails entirely to engage on the Medicare Act's distinct language and the facts presented.

In light of the D.C. Circuit's well-reasoned decision, those few courts with limited treatment of the Medicare Act's notice-and-comment rulemaking requirement might well revise their rudimentary positions. As the Government recognized below, Pet. App. 17a n.4, the D.C. Circuit did exactly that. In *Monmouth Medical Center v. Thompson*, 257 F.3d 807 (D.C. Cir. 2001), the court "s[aw] no reason to explore the possibility of a distinction" between the APA and the Medicare Act. *Id.* at 814. When compelled to "explore th[at] possibility," *id.*, however, the D.C. Circuit concluded that there is in fact a distinction between the two statutes. Pet. App. 17a.

If other courts after thorough consideration aligned their decisions with the D.C. Circuit (or, if further percolation revealed that the D.C. Circuit's departure from other courts is merely semantic and not outcome determinative), there would be no conflict for this Court to resolve. But if not, there would at the very least be more fulsome analysis of the matter for future consideration by this Court.

## III. THE D.C. CIRCUIT'S DECISION HAS NO IMPACT OF NATIONAL IMPORTANCE WARRANTING REVIEW

### A. The Application of the Medicare Act to the Irregular Facts Here Lacks Prospective Importance

The D.C. Circuit's decision in this aberrational litigation on part C days in the DSH payment does not have material future implications for the operation of the Medicare program.

**1.** As Petitioner acknowledges, Pet. 23 n.13, any potential effect of review in this case would be time-limited. In 2013, the Secretary adopted a new, prospectively effective rule on the exact issue—treatment of part C days in the Medicare fractions—in this litigation. *See id.* at 7-8 n.6; *id.* at 23 n.13; 78 Fed. Reg. at 50,614-15. The dispute here relates only to periods from 2004 to 2013.

**2.** The D.C. Circuit's decision here, arising in the context of highly irregular agency proceedings, could not reasonably be expected to disrupt normal agency operations. First, denying that the 2004 rule had made a change in the DSH payment standard, the agency tried to apply it retroactively to pre-2004

years—a gambit the D.C. Circuit rejected. *Northeast Hosp.*, 657 F.3d at 13-17. Second, the 2004 rule was not a logical outgrowth of the proposed rule; after the agency initially attempted to apply it to later years in 2009, the D.C. Circuit vacated the rule. *Allina I*, 746 F.3d at 1109.[9]

Meanwhile, the agency in 2013 undertook the new, prospective-only rulemaking discussed above (while still denying the change and impact). 78 Fed. Reg. at 50,614-15. But for years between 2004 and 2013, the agency abruptly scrapped notice and comment altogether—seemingly to save money it never said was at stake until now. Unless the agency intends to make a habit of the unusual procedural maneuvers associated with the part C days policy change, the D.C. Circuit decision should be of little consequence. Indeed, before *Allina I*, no Medicare rule had ever been invalidated for a logical outgrowth failure.

**3**. The publication of binding fractions reflecting a renewed change in Medicare DSH payment policy also has no bearing on the agency's ordinary use of instructions and manual guidance to its contractors.

The publication of Medicare fractions is not a mere "instruction" to Medicare contractors. The 2012 fractions and the renewed policy they embody are binding on all hospitals when they seek DSH

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[9] The district court in *Allina I* denounced the government's "irregular legal gamesmanship" in denying the policy change after the D.C. Circuit's contrary holding in *Northeast Hospital*. *Allina I*, 904 F. Supp. 2d at 77 n.2.

payments in filing their Medicare cost reports, as well as binding on the agency and its contractors in making payment determinations based on those cost reports. *See* 42 C.F.R. § 412.106(b)(2),(5) (requiring hospitals, the agency, and its contractors to use the agency's published Medicare fraction in calculating DSH payments). The Medicare fractions were also binding on the agency adjudicators in this case. In granting expedited judicial review over the hospitals' challenge here to the fractions and the adoption of the policy reflected in them, the agency's Board found it lacked authority to decide whether those actions "are legal." Pet. App. 57a, 72a.

While attempting to frame them as contractor "instructions," Pet. I, 14, 18, 19, 20, the Government has not actually denied the binding nature of the fractions. Even the petition's Question Presented says only that the fractions "*rest* on a non-legally-binding administrative interpretation of a relevant statutory provision." Pet. I (emphasis added). Elsewhere the petition states that the "agency understanding" of the statute is "non-binding." Pet. 23, not that the issued fractions are non-binding. It is nonsensical to suggest that the "understanding" is non-binding when the fractions themselves are binding on the agency and "hospitals nationwide" as to their Medicare payment determinations. Pet. 8.

The 2014 issuance of the 2012 Medicare fractions is also not a type of manual "guidance" to Medicare contractors for handling, as the Government suggests, "ambiguities that must be resolved" by the contractors in making payment determinations. Pet. 19, 20. The fractions already

reflect the agency's own determination on the binary choice of where to put part C days in the DSH calculation. *See* Pet. 8-9 (Government arguing that the "include[ed] MA [*i.e.,* Part C] Claims Submissions" notation in the 2014 issuance reflected CMS's part C days policy) (alterations in original) (citation omitted); *Allina I*, 746 F.2d at 1108 ("the statute unambiguously requires that Part C days be counted in one fraction or the other"). The 2014 issuance left no "ambiguit[y]" for the contractors to "resolve[]." Pet. 19.

**4.** The Government is also incorrect, Pet. 20, in suggesting that a notice-and-comment requirement for substantive legal payment standards would be unduly constraining and time consuming. Notice-and-comment rulemaking for Medicare payment standards is already the agency's regular practice, and it takes not a few years as the Government suggests, Pet. 20, but a few months. As explained (pp. 2-3, *supra*), the agency undertakes annual notice-and-comment rulemaking for the inpatient hospital prospective payment system that includes the DSH payment. On average, this annual rulemaking takes 102 days. *See* Add. 1a-3a. The agency has repeatedly used notice-and-comment rulemaking to implement new or revised standards on different categories of patient days in the DSH payment—including at least six rulemakings to determine whether patient days not covered or paid under Medicare part A were to be considered part-A-entitled days and ten other times to make changes to the treatment of other categories of days in the DSH payment. *See* Add. 4a-6a.

Regardless, the D.C. Circuit of course did not conclude that the Medicare Act requires notice-and-comment rulemaking for every agency issuance. It simply applied the text of sections 1395hh(a)(2) and 1395hh(a)(4) to the irregular facts here. The D.C. Circuit does not read its decision in this case to require notice-and-comment rulemaking for non-binding manual instructions that do not "establish the substantive legal standards governing provider reimbursement." *Clarian Health West, LLC v. Hargan*, 878 F.3d 346, 355 (D.C. Cir. 2017) (Medicare manual instructions governing reconciliation of special outlier payments "merely set forth an enforcement policy" and "do not change the legal standards that govern the hospitals *** or the agency.").

### B. The Government's New Claim of Financial Impact Undercuts the Petition

The petition is only undermined by the Government's entirely new, unsupported complaint about the financial impact of the underlying issue in this case. Pet. 14, 23. The failure to contend with the impact on hospitals—an important factor the agency must consider as part of any reasoned decision-making—has been among the failures at the core of this entire litigation from the outset. Until now, the agency has never acknowledged—much less rationally considered—in any rulemaking or adjudicatory decision any significant impact of putting the part C days in one DSH fraction versus the other.

In the 2004 final rule the D.C. Circuit vacated in *Allina I*, the agency predicted that the same policy change, even in combination with three other changes expected to reduce the DSH payment, would not "have a significant impact on payments[] [b]ased on an analysis from our actuarial staff." 69 Fed. Reg. at 49,770 (estimating a combined impact for several changes of $50 million). And, as put by the Government in briefing before the D.C. Circuit in this case just last year, "both the 2013 Final Rule and the Administrator's *Allina I* [remand] decision *** refute plaintiffs' concerns about the financial impact of including Part C days in the Medicare/SSI fraction." *See* Gov't C.A. Br. 51. If the impact was not important enough for the agency to recognize in its prior decision-making, *cf. Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (reasoned decision-making requires agency "to consider an important aspect of the problem"), then it hardly constitutes a matter of national importance warranting this Court's review.

In any event, the Government's purportedly new insight as to the financial impact wrought by the policy change only highlights why Congress enacted legislation imposing Medicare-specific notice-and-comment rulemaking requirements. When enacting section 1395hh(a)(2), Congress was concerned in the Medicare context about "important policies being developed without benefit of the public notice and comment period." H.R. Rep. No. 100-391(I), at 430. Because the Medicare program makes $120 billion in expenditures each year just for inpatient hospital services and $675 billion in total, *see*

https://www.cms.gov/fastfacts/, even seemingly small changes in payment standards yield significant changes in reimbursement for hospitals, *see County of Los Angeles v. Shalala*, 192 F.3d 1005, 1010 (D.C. Cir. 1999) ("Given the enormity of the Medicare program, *** seemingly modest percentage differences represent substantial sums of money."). Notice and opportunity for comment are critically important for determining and meaningfully considering the true impact of any payment policy change on hospitals making hard decisions with limited budgets about services, staffing, and other expenditures necessary to meet the health care needs of their communities, including those who lack the means to pay for their care.

## CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted.

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# ADDENDUM

## ADDENDUM

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## Appendix 1 – Annual Inpatient Prospective Payment System Rulemakings (Federal Fiscal Years 2003-2018)

| FFY | Proposed Rule | Final Rule | Number of Days |
|---|---|---|---|
| 2003 | 67 Fed. Reg. 31,404 (May 9, 2002) | 67 Fed. Reg. 49,982 (Aug. 1, 2002) | 84 |
| 2004 | 68 Fed. Reg. 27,154 (May 19, 2003) | 68 Fed. Reg. 45,346 (Aug. 1, 2003) | 74 |
| 2005 | 69 Fed. Reg. 28,196 (May 18, 2004) | 69 Fed. Reg. 48,916 (Aug. 11, 2004) | 85 |
| 2006 | 70 Fed. Reg. 23,306 (May 4, 2005) | 70 Fed. Reg. 47,278 (Aug. 12, 2005) | 100 |
| 2007 | 71 Fed. Reg. 23,996 (Apr. 25, 2006) | 71 Fed. Reg. 47,870 (Aug. 18, 2006) | 115 |
| 2008 | 72 Fed. Reg. 24,680 (May 3, 2007) | 72 Fed. Reg. 47,130 (Aug. 22, 2007) | 111 |

| FFY | Proposed Rule | Final Rule | Number of Days |
|---|---|---|---|
| 2009 | 73 Fed. Reg. 23,528 (Apr. 30, 2008) | 73 Fed. Reg. 48,434 (Aug. 19, 2008) | 111 |
| 2010 | 74 Fed. Reg. 24,080 (May 22, 2009) | 74 Fed. Reg. 43,754 (Aug. 27, 2009) | 97 |
| 2011 | 75 Fed. Reg. 23,852 (May 4, 2010) | 75 Fed. Reg. 50,042 (Aug. 16, 2010) | 104 |
| 2012 | 76 Fed. Reg. 25,788 (May 5, 2011) | 76 Fed. Reg. 51,476 (Aug. 18, 2011) | 105 |
| 2013 | 77 Fed. Reg. 27,870 (May 11, 2012) | 77 Fed. Reg. 53,258 (Aug. 31, 2012) | 112 |
| 2014 | 78 Fed. Reg. 27,486 (May 10, 2013) | 78 Fed. Reg. 50,496 (Aug. 19, 2013) | 101 |
| 2015 | 79 Fed. Reg. 27,978 (May 15, 2014) | 79 Fed. Reg. 49,854 (Aug. 22, 2014) | 99 |
| 2016 | 80 Fed. Reg. 24,324 (Apr. 30, 2015) | 80 Fed. Reg. 49,326 (Aug. 17, 2015) | 109 |

| FFY | Proposed Rule | Final Rule | Number of Days |
|---|---|---|---|
| 2017 | 81 Fed. Reg. 24,946 (Apr. 27, 2016) | 81 Fed. Reg. 56,762 (Aug. 22, 2016) | 117 |
| 2018 | 82 Fed. Reg. 19,796 (Apr. 28, 2017) | 82 Fed. Reg. 37,990 (Aug. 14, 2017) | 108 |
| | | **Average** | **102** |

## Appendix 2 – Notice and Comment Rulemaking on Medicare Part A-Entitled Patient Days in DSH Calculation

| Rule Change | Final Rule |
|---|---|
| Adopting a requirement that days must be covered and paid under part A to be included as part-A-entitled | 51 Fed. Reg. 16,772, 16,777 (May 6, 1986) |
| Attempting to change 1986 rule through rule later vacated in *Allina I* | 69 Fed. Reg. 48,916, 49,098-99 (Aug. 11, 2004) |
| Addressing "days for which Medicare was not the primary payer" | 70 Fed. Reg. 47,278, 47,441 (Aug. 12, 2005) |
| Implementing additional changes to the regulation's text consistent with the 2004 rule | 72 Fed. Reg. 47,130, 47,384 (Aug. 22, 2007) |
| Further amending the regulation text with respect to part C days | 75 Fed. Reg. 50,042, 50,285 (Aug. 16, 2010) |
| Prospectively reinstating the 2004 rule vacated in *Allina I* | 78 Fed. Reg. 50,496, 50,614 (Aug. 19, 2013) |

## Appendix 3 – Notice and Comment Rulemaking on Categories of Patient Days in DSH Calculation Other than Medicare Part A-Entitled

| Rule Change | Final Rule |
|---|---|
| Days for patients who were eligible for Medicaid but for which Medicaid did not make payment | 63 Fed. Reg. 40,954, 40,985 (July 31, 1998) |
| Days for patients eligible for Medicaid expansion waiver programs | 65 Fed. Reg. 3,136, 3,136-39 (Jan. 20, 2000) |
| Patient days in units or wards providing services generally payable under part A | 68 Fed. Reg. 45,346, 45,416-18 (Aug. 1, 2003) |
| Outpatient observation days and patient days in swing beds used to provide skilled nursing services | 68 Fed. Reg. 45,346, 45,418-19 (Aug. 1, 2003) |
| Patient days in labor/delivery rooms | 68 Fed. Reg. 45,346, 45,419-20 (Aug. 1, 2003) |

| Rule Change | Final Rule |
|---|---|
| Days for patients with limited benefits under Medicaid expansion waivers | 68 Fed. Reg. 45,346, 45,420-21 (Aug. 1, 2003) |
| Outpatient observation days for patients ultimately admitted as an inpatients | 69 Fed. Reg. 48,916, 49,096-98 (Aug. 11, 2004) |
| Labor/delivery room patient days | 74 Fed. Reg. 43,754, 43,899-901 (Aug. 27, 2009) |
| Outpatient observation days | 74 Fed. Reg. 43,754, 43,905-08 (Aug. 27, 2009) |
| SSI-entitled days for the Medicare fraction | 75 Fed. Reg. 50,042, 50,275-86 (Aug. 16, 2010) |