No.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

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.

PARTIES TO THE PROCEEDING

Petitioner is Alex M. Azar II, in his official capacity of Secretary of Health and Human Services.

Respondents are Allina Health Services, doing business as United Hospital, Unity Hospital, and Abbott Northwestern Hospital; Florida Health Sciences Center, Inc., doing business as Tampa General Hospital; Montefiore Medical Center; Mount Sinai Medical Center of Florida, Inc., doing business as Mount Sinai Medical Center; New York Hospital Medical Center of Queens; New York Methodist Hospital; and New York and Presbyterian Hospital, doing business as New York Presbyterian Hospital Weill Cornell Medical Center.

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The Solicitor General, on behalf of the Secretary of Health and Human Services (Secretary), respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-18a) is reported at 863 F.3d 937. The opinion of the district court (Pet. App. 19a-44a) is reported at 201 F. Supp. 3d 94. The decisions of the Provider Reimbursement Review Board (Pet. App. 47a-61a, 62a-76a) are unreported.

JURISDICTION

The judgment of the court of appeals was entered on July 25, 2017. A petition for rehearing was denied on November 29, 2017 (Pet. App. 77a-80a). On February 21, 2018, the Chief Justice extended the time within

which to file a petition for a writ of certiorari to and including March 29, 2018. On March 22, 2018, the Chief Justice further extended the time to and including April 27, 2018. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The relevant statutory and regulatory provisions are reproduced in the appendix to this petition. Pet. App. 81a-102a.

STATEMENT

1. This case concerns the scope of the specific notice-and-comment rulemaking requirements that the Department of Health and Human Services (Department or HHS) must follow under the Medicare Act, *i.e.*, Title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq*. The issue arises in the context of the Department's interpretation and calculation of one statutory component (the so-called "Medicare fraction") used to determine the total amount of payment that a hospital should receive under the Medicare program.

a. The Medicare Act, as relevant here, provides an annual payment to certain hospitals for providing inpatient hospital care to Medicare beneficiaries. 42 U.S.C. 1395ww(d); see 42 C.F.R. 412.1(a)(1). The Act provides an "additional payment"—known as a disproportionate share hospital (DSH) adjustment—to certain hospitals that "serve[] a significantly disproportionate number of low-income patients." 42 U.S.C. 1395ww(d)(5)(F)(i)(I). The standard for determining a hospital's eligibility for that payment is defined by the hospital's "disproportionate patient percentage" (DPP). 42 U.S.C. 1395ww(d)(5)(F)(v). A hospital is deemed to "serve[] a significantly disproportionate number of low

income patients" (and is thus entitled to a DSH payment) in a cost-reporting period if it has a DPP that meets or exceeds a specified level. *Ibid.*

The DPP, in turn, is the sum of two fractions expressed as percentages. 42 U.S.C. 1395ww(d)(5)(F)(vi). The first fraction—known as the Medicare fraction—is defined in part by a hospital's number of patient days during the relevant period that were attributable to patients who were both "entitled to benefits under [Medicare] part A" (which provides inpatient hospital insurance coverage) and entitled to supplemental security income (SSI) benefits. 42 U.S.C. 1395ww(d)(5)(F)(vi)(I); see 42 U.S.C. 1395c *et seq.* (Medicare Part A).[1] The second fraction, known as the Medicaid fraction, is separately defined in 42 U.S.C. 1395ww(d)(5)(F)(vi)(II), and includes patient days attributable to persons who, *inter alia*, "were not entitled to benefits under [Medicare] part A," *ibid.*

In 1997, Congress amended the Medicare Act by adding Part C, 42 U.S.C. 1395w-21 *et seq.*, which established the Medicare+Choice (M+C) program, later renamed the Medicare Advantage (MA) program.[2] Part C allows certain individuals to elect to receive benefits available under Part A and Part B through enrollment in a private healthcare plan known as a MA plan.

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[1] SSI benefits are available under Title XVI of the Social Security Act, 42 U.S.C. 1381 *et seq.*, "to financially needy individuals who are aged, blind, or disabled." *Bowen* v. *Galbreath*, 485 U.S. 74, 75 (1988).

[2] See Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (2003 Modernization Act), Pub. L. No. 108-173, § 201(a) and (b), 117 Stat. 2176 (42 U.S.C. 1395w-21 note) (establishing the Medicare Advantage program and providing that "any [Part C] reference to 'Medicare+Choice' is [now] deemed a reference to 'Medicare Advantage' and 'MA'").

42 U.S.C. 1395w-21(a)(1). In order to be enrolled under Medicare Part C, an individual must be "entitled to benefits under [Medicare] part A * * * and enrolled under [Medicare] part B." 42 U.S.C. 1395w-21(a)(3)(A).

The underlying interpretive issue in which the procedural notice-and-comment question presented in this case arises is whether a patient who receives coverage for his or her Medicare Part A benefits through a private healthcare plan under Medicare Part C is a patient "entitled to benefits under [Medicare] part A" for purposes of determining a hospital's Medicare fraction under 42 U.S.C. 1395ww(d)(5)(F)(vi)(I).

b. HHS administers the Medicare program through the Centers for Medicare & Medicaid Services (CMS). CMS, in turn, contracts with private entities known as Medicare Administrative Contractors (MACs)—formerly called fiscal intermediaries—that "act on behalf of CMS in carrying out certain administrative responsibilities." 42 C.F.R. 421.5(b); see 42 U.S.C. 1395kk-1(a)(1).[3] As relevant here, CMS contracts with MACs to determine in the first instance "the amount of the payments required pursuant to [the Medicare Act] to be made to providers of services." 42 U.S.C. 1395kk-1(a)(4)(A). Such contractors, like CMS's own personnel, are "required to follow Federal laws, regulations and [CMS] manual instructions" when performing such functions on behalf of CMS. 74 Fed. Reg. 65,296, 65,312 (Dec. 9, 2009).

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[3] "[A]ny reference to a fiscal intermediary or carrier under * * * [the Medicare Act] (or any regulation, manual instruction, interpretative rule, statement of policy, or guideline issued to carry out such [Act])" is now "deemed a reference to a medicare administrative contractor." 2003 Modernization Act § 911(e), 117 Stat. 2386 (42 U.S.C. 1395kk-1 note).

i. In order to receive payment for providing inpatient hospital services to Medicare beneficiaries, a hospital must submit an annual cost report to its MAC. 42 C.F.R. 405.1801(b)(1). After receiving the cost report, the MAC determines "the total amount of reimbursement due the provider" for the relevant cost-reporting period and issues a Notice of Program Reimbursement containing its determination. 42 C.F.R. 405.1803(a) and (a)(2).

A MAC, however, lacks the information necessary to determine a hospital's Medicare fraction. That is because the Medicare fraction is defined in part by hospital services furnished to patients who were both "entitled to benefits under [Medicare] part A" and "entitled to [SSI] benefits," 42 U.S.C. 1395ww(d)(5)(F)(vi)(I), and data from the Social Security Administration's "SSI file" are needed to make the calculation. 51 Fed. Reg. 16,772, 16,777 (May 6, 1986); see Pet. App. 105a ¶ 7. CMS therefore itself calculates the Medicare fraction for each hospital, 42 C.F.R. 412.106(b)(2); 42 C.F.R. 412.106(b)(2) (2003), and makes the calculated fractions available to the MACs. Each MAC then independently calculates a hospital's Medicaid fraction and adds both fractions to determine the hospital's DPP and its eligibility for (and the proper amount of) a DSH payment as part of the hospital's overall Medicare reimbursement for the cost year. See 42 C.F.R. 412.106(b)(4)-(5), (c), and (d); 42 C.F.R. 412.106(b)(4)-(5), (c), and (d) (2003).

ii. A provider may file an administrative appeal to the Provider Reimbursement Review Board (PRRB) from the MAC's final determination or its failure to render a final determination within 12 months. 42 U.S.C. 1395*oo*(a) and (d); 42 C.F.R. 405.1835(c). In rendering its decision, the Board need only apply the provisions of

the Medicare Act, agency regulations, and formal CMS Rulings issued by the CMS Administrator. 42 C.F.R. 405.1867. Provisions in CMS's manuals and other interpretive rules thus do not bind the Board. *Ibid.*[4]

If the Board determines that it lacks "authority to decide" a relevant "question of law or regulations" (or if it fails to issue a decision within 30 days of a provider's request for such a determination), the provider may seek judicial review of the "action of [the MAC]" that implicates that question. 42 U.S.C. 1395*oo*(f)(1); see 42 C.F.R. 405.1842(a) and (h), 405.1875(a)(2)(iii). Otherwise, after the PRRB issues its final decision on the merits, the Secretary (acting through the CMS Administrator) may within 60 days reverse, affirm, or modify that decision. 42 U.S.C. 1395*oo*(f)(1); see 42 C.F.R. 405.1875.

iii. The final agency decision is then subject to review in district court under the standards for review in the Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.*, 701 *et seq.* See 42 U.S.C. 1395*oo*(f)(1).

c. Before 2004, CMS did not count a hospital's Medicare Part C patient days when calculating the Medicare fraction for each hospital. See *Northeast Hosp. Corp.* v. *Sebelius*, 657 F.3d 1, 15-16 (D.C. Cir. 2011). That practice was not based on notice-and-comment rulemaking or any formal agency guidance. In 2003, after "receiv-[ing] questions whether patients enrolled in an M+C Plan should be counted in the Medicare fraction," CMS chose to address that question through the notice-and-comment process, proposing a rule that would have excluded Part C patient days from that fraction. 68 Fed. Reg. 27,154, 27,208 (May 19, 2003).

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[4] The Board will give great weight to, but need not follow, interpretive rules. 42 C.F.R. 405.1867.

In 2004, after considering public comments—several of which disagreed with its earlier proposal—CMS concluded that Part C patients are "entitled to benefits under [Medicare] part A" within the meaning of the Medicare-fraction provision, 42 U.S.C. 1395ww(d)(5)(F)(vi). See 69 Fed. Reg. 48,916, 49,099 (Aug. 11, 2004). CMS therefore announced that it would count Part C patient days in the Medicare fraction. *Ibid.*[5]

A district court (in a separate case) later vacated that 2004 final rule based on its determination that it was not a logical outgrowth of CMS's 2003 proposal, and it ordered CMS to "affirmatively count Part C days under the Medicaid fraction"—rather than under the Medicare fraction—for the FY2007 cost reports that were at issue in that case. See *Allina Health Servs.* v. *Sebelius*, 746 F.3d 1102, 1105, 1111 (D.C. Cir. 2014) (describing decision). The D.C. Circuit affirmed the district court's holding that the 2004 final rule was not a logical outgrowth of the 2003 proposal, *id.* at 1107-1109, but vacated its requirement that CMS count Part C days in the Medicaid fraction, explaining that "the Secretary might achieve the same result [reached in the vacated rule] through adjudication" of the FY2007 cost reports at issue in that case, *id.* at 1111.[6] On remand, the CMS

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[5] CMS inadvertently did not amend its regulations to reflect the 2004 final rule until 2007. 72 Fed. Reg. 47,130, 47,384, 47,411 (Aug. 22, 2007) (amending 42 C.F.R. 412.106(b)(2)(i)(B) and (iii)(B)).

[6] Despite its disagreement with the district court's view that its final rule was not the logical outgrowth of its proposed rule, cf. *Long Island Care at Home, Ltd.* v. *Coke*, 551 U.S. 158, 174-175 (2007), HHS instituted new notice-and-comment rulemaking "in an abundance of caution" while its appeal of that ruling was pending. 78 Fed. Reg. 50,496, 50,614-50,615 (Aug. 19, 2013). In 2013, HHS promulgated a final rule in which the agency again concluded that Part C patients "are 'entitled to benefits under part A'" within the

Administrator, acting for the Secretary, interpreted the Medicare-fraction statute as part of the agency's adjudication of the plaintiff-hospitals' FY2007 cost reports and concluded that Part C patient days are properly counted in the Medicare fraction. *Allina Health Servs.* v. *Burwell*, No. 2010-D38-R, at 24-46 (CMS Adm'r. 2015), judicial review pending, No. 1:16-cv-150 (D.D.C. filed Jan. 29, 2016).[7]

2. a. Meanwhile, as a result of the D.C. Circuit's decision affirming vacatur of CMS's 2004 final rule, there was no controlling CMS determination whether Part C patient days were to be included in the Medicare fraction. Yet CMS was still obligated to determine annual Medicare fractions for individual hospitals in order to enable MACs to determine each hospital's appropriate Medicare reimbursement. See Pet. App. 105a ¶ 6.

That was the state of affairs in June 2014, when CMS calculated Medicare fractions for FY2012 for hospitals nationwide (including hospitals operated by respondents) and published those fractions in a spreadsheet posted on its website. Pet. App. 5a-6a, 24a. The agency did not calculate those FY2012 Medicare fractions by "rel[ying] on the vacated [2004] rule." *Id.* at 105a ¶ 7; see *id.* at 30a-31a. But the spreadsheet included a note explaining that the "[c]alculations * * * includ[ed] MA

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meaning of the Medicare-fraction statute. *Id.* at 50,614-50,615, 50,620. The 2013 final rule applies prospectively "for FY 2014 and subsequent years." *Id.* at 50,619. Hospitals have challenged the 2013 final rule in a separate civil action that remains pending. See Second Am. Compl. ¶¶ 5, 58-62, *Florida Health Scis. Ctr.* v. *Azar*, No. 17-cv-1751 (D.D.C. Mar. 13, 2018).

[7] The Administrator's decision on remand is available at https://www.cms.gov/Regulations-and-Guidance/Review-Boards/OfficeAttorneyAdvisor/OAA-Decisions-Items/2010-D38-R.html.

[*i.e.*, Part C] Claims Submissions." See CMS, *Disproportionate Share Hospital (DSH)* (providing FY2012 fraction spreadsheet in "DSH Adjustment and 2011-2012 File").[8] That notation reflected CMS's "decision * * * to include Part C days" in calculating the FY2012 Medicare fractions based on the agency's independent "'interpretation of the statute'" as including "'Part C days * * * in the Medicare fraction.'" Pet. App. 33a (citation omitted); see *id.* at 5a-6a.

b. Respondents challenged CMS's calculation of the Medicare fractions by seeking administrative review by the PRRB. See Pet. App. 47a-48a, 62a-63a. The Board concluded that it lacked authority to decide that challenge and granted respondents' request for expedited judicial review. *Id.* at 57a-58a, 72a-73a.

3. a. Respondents accordingly filed this action for judicial review in district court. See Pet. App. 25a-26a. Among other things, respondents argued that the Medicare Act's rulemaking provision in 42 U.S.C. 1395hh required that the agency engage in notice-and-comment rulemaking before it could base its calculations of respondents' FY2012 Medicare fractions on its interpretation of the Act. See Pet. App. 35a-36a.

Section 1395hh grants the Secretary authority to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under [the Medicare Act]." 42 U.S.C. 1395hh(a)(1). Section 1395hh(a)(2) further provides:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard

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[8] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html.

> governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [the Medicare Act] shall take effect unless it is promulgated by the Secretary by regulation under [Section 1395hh(a)(1)].

42 U.S.C. 1395hh(a)(2).

Section 1395hh(b)(1), in turn, provides that before "issuing in final form any regulation under [Section 1395hh(a)]," the Secretary must publish "notice of the proposed regulation in the Federal Register" and provide a public comment period of "not less than 60 days." 42 U.S.C. 1395hh(b)(1). That notice-and-comment requirement is subject to certain exceptions, 42 U.S.C. 1395hh(b)(2), including one for circumstances in which the APA's good-cause exception, 5 U.S.C. 553(b)(B), would not require notice-and-comment rulemaking under the APA. 42 U.S.C. 1395hh(b)(2)(C).

Finally, Section 1395hh(a)(4) provides that "[i]f the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation." 42 U.S.C. 1395hh(a)(4).

b. The district court granted summary judgment to the government. Pet. App. 19a-44a. The court held that CMS's calculation of the FY2012 Medicare fractions by "includ[ing] Part C days," *id.* at 33a, did not require notice-and-comment rulemaking. *Id.* at 34a-36a. The court concluded that Section 1395hh does not apply to

"'interpretive rules'" and that the agency's "interpretation of the DSH statute" in the course of calculating the Medicare fractions to be furnished to MACs "is not a 'rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard'" within the meaning of Section 1395hh(a)(2). *Id.* at 35a-36a (citations omitted).

The district court then rejected respondents' substantive challenge to the agency's interpretation of the Medicare-fraction statute, Pet. App. 39a-44a, holding that the agency had permissibly concluded that "patients enrolled in Part C continue to be 'eligible' for Part A" within the meaning of that provision, *id.* at 44a.

4. The court of appeals reversed and remanded. Pet. App. 1a-18a. As relevant here, the court held that Section 1395hh required HHS to conduct notice-and-comment rulemaking before providing MACs with CMS's calculation of each respondents' FY2012 Medicare fractions reflecting the agency's interpretation of the statute. *Id.* at 11a-18a.

a. The court of appeals first determined that CMS's calculation of the FY2012 Medicare fractions for its MACs was, "at the very least, a 'requirement'" under Section 1395hh(a)(2). Pet. App. 12a-13a. The court reasoned that "[f]iscal intermediaries are *commanded* to use HHS's Medicare fractions in calculating [DSH] adjustment amounts" and "are therefore *required* to include Part C days in their calculations." *Ibid.*

The court of appeals next held that CMS had "established" a "'substantive legal standard'" within the meaning of Section 1395hh(a)(2) by including "Part C days in the fiscal year 2012 Medicare fractions" it furnished to MACs. Pet. App. 13a-14a. The court rested that holding on a dictionary definition of "'[s]ubstantive

law' [as] law that 'creates, defines, and regulates the rights, duties, and powers of parties.'" *Ibid.* (citation omitted). The court concluded that the agency's "2012 Medicare fractions" qualified as a "substantive legal standard" because, in the court's view, they "define the scope of hospitals' legal rights to payment for treating low-income patients." *Id.* at 14a.

The court of appeals also concluded that the inclusion of Medicare Part C days in the FY2012 Medicare fractions "change[d]" a "substantive legal standard" within the meaning of Section 1395hh(a)(2). Pet. App. 13a. The court reasoned that, before 2004, CMS's "practice was to *exclude* Part C days from Medicare fractions," that the pre-2004 practice "remains the baseline practice," and that the agency's inclusion of Part C days for FY2012 was "therefore a change from prior practice." *Ibid.*

b. The court of appeals rejected the government's contention that Section 1395hh's notice-and-comment requirement for regulations establishing or changing a "substantive legal standard," 42 U.S.C. 1395hh(a)(2), does not apply to "interpretive rules." Pet. App. 15a-17a. The court reasoned that Section 1395hh uses "different language" than the APA's rulemaking provision and, unlike the APA, does not expressly "include an exception for interpretive rules." *Id.* at 15a-16a. The court also noted that Section 1395hh(b)(2) "incorporates the APA's 'good-cause' exception" in 5 U.S.C. 553(b)(B), which in the court's view showed that "Congress knew how to incorporate the APA's notice-and-comment exceptions * * * when it wanted to." Pet. App. 16a. The court acknowledged that its holding that Section 1395hh(a)(2) applies to interpretive rules conflicts with decisions of "several other courts of appeals," but stated

that it respectfully disagreed with those decisions. *Id.* at 17a.[9]

c. Finally, the court of appeals held that "even if HHS were correct" that Section 1395hh(a)(2) does not apply to "interpretive rules," Section 1395hh(a)(4) would separately require notice-and-comment rulemaking. Pet. App. 17a-18a. Because the court in an earlier case had vacated HHS's 2004 rule announcing its interpretation of the Medicare fraction on the ground that the final rule was "'not a logical outgrowth of the proposed rule,'" *id.* at 18a (citation omitted); see p. 7, *supra*, the court concluded that Section 1395hh(a)(4) "applies with full force" and requires a "'further opportunity for public comment and a publication of the provision again as a final regulation' before HHS could reimpose the rule," Pet. App. 18a (citation omitted). CMS, the court added, "could not circumvent this requirement by claiming that it was acting by way of adjudication rather than rulemaking," because Section 1395hh(a)(4) "says that the vacated rule may not 'take effect' at all until there has been notice and comment." *Ibid.*

REASONS FOR GRANTING THE PETITION

It is extremely important that agencies rigorously observe applicable procedural requirements, to provide the requisite notice to regulated parties. Within this specific and complex statutory scheme, however, the relevant Medicare rulemaking provision applies only to regulations that establish or change a "substantive legal

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[9] In light of its holding that Section 1395hh requires notice-and-comment rulemaking even for interpretive rules, the court of appeals stated that it "need not decide" if HHS's inclusion of Part C days in the FY2012 Medicare fractions it furnished to MACs was an "interpretive rule." Pet. App. 15a.

standard." 42 U.S.C. 1395hh(a)(2). Interpreting that provision, the D.C. Circuit held that HHS must conduct notice-and-comment rulemaking in order to provide internal instructions (in the form of FY2012 Medicare fractions) to its Medicare Administrative Contractors that are based on an interpretation of the Medicare Act. As the D.C. Circuit acknowledged, the decisions of other courts of appeals reflect the view that instructions from HHS to its Medicare Administrative Contractors about Medicare fractions lack the force and effect of law, and thus do not qualify as a "substantive legal standard" under Section 1395hh(a)(2). See Pet. App. 17a. The D.C. Circuit's contrary decision would significantly impair HHS's ability to administer annual Medicare reimbursements through the MACs that act on its behalf. It would also impose significant costs on the government. Just with respect to the Medicare-fraction issue in this case, the decision below affects between $3 and $4 billion in Medicare funding. This Court's review is therefore warranted.

A. The Decision Below Creates A Circuit Split By Holding That Section 1395hh's Notice-And-Comment Procedures Apply To Interpretive Rules

1. As the D.C. Circuit in this case acknowledged, its holding departs from the decisions of the other courts of appeals that have considered the issue, see Pet. App. 17a, which have held that Section 1395hh(a)(2) does not apply to interpretive rules. The First Circuit, for instance, has determined that, although Section 1395hh(a)(2)'s application to "substantive legal standard[s]" "phrases the distinction between substantive and interpretive rules slightly differently from the APA," Section 1395hh nevertheless exempts "interpretive rules" and is fairly understood to "duplicate the

APA on this score." *Warder* v. *Shalala*, 149 F.3d 73, 79 & n.4 (1998), cert. denied, 526 U.S. 1064 (1999). The Ninth Circuit has similarly held that CMS manual provisions are "interpretive rules" under the APA that do not have the force of law, and that Section 1395hh(a)(2), like the APA, does not require notice-and-comment rulemaking for "interpretive rules." *Erringer* v. *Thompson*, 371 F.3d 625, 632-633 (2004); see *id.* at 630. The Eighth Circuit has adopted the same understanding of Section 1395hh. *Baptist Health* v. *Thompson*, 458 F.3d 768, 776 & n.9 (2006). The Eighth Circuit explained that although Section 1395hh(a)(2) applies to certain changes to a "'substantive legal standard,'" it does not apply to an agency "change [in] interpretation" because the statute does not require rulemaking procedures "greater than those established by the APA." *Ibid.* (citation omitted).

2. Consistent with the decisions of other courts of appeals, HHS has understood that Congress's choice of the phrase "substantive legal standard" reflects its intent to apply rulemaking procedures only to "substantive" regulations that have "legal" force and establish "standards" governing Medicare reimbursement, benefits, and eligibility determinations.

a. The APA's notice-and-comment requirements, 5 U.S.C. 553(b) and (c), apply to what have long been known as "substantive rules." See *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 313, 315 (1979). Well before Congress enacted Section 1395hh's rulemaking requirements for "substantive legal standard[s]" under Medicare, 42 U.S.C. 1395hh(a)(2), it was "well established" that properly promulgated "substantive agency regulations have the 'force and effect of law.'" *Chrysler Corp.*, 441 U.S. at 295. A "substantive rule—or a 'legislative-

type rule'"—has binding legal force because it has been promulgated pursuant to a congressional grant of "quasi-legislative authority" and "conform[s] with [the] procedural requirements" that Congress has provided for its promulgation, which normally include the APA's notice-and-comment requirements. *Id.* at 302-303; see *id.* at 313.

By contrast, the APA provides that, unless "notice or hearing is required by statute," its notice-and-comment provision "does not apply * * * to interpretative rules." 5 U.S.C. 553(b)(A). An "interpretative rule" serves a function significantly different from that of a substantive rule. See *Perez* v. *Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1204 & n.1 (2015). "[I]nterpretive rules" are "'issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers.'" *Ibid.* (quoting *Shalala* v. *Guernsey Mem'l Hosp.*, 514 U.S. 87, 99 (1995)); accord *Chrysler Corp.*, 441 U.S at 302 n.31 (quoting U.S. Dep't of Justice, *Attorney General's Manual on the Administrative Procedure Act* 30 n.3 (1947) (*1947 APA Manual*)). And significantly for present purposes, unlike "substantive" rules, "'interpretive rules' * * * do *not* have the force and effect of *law*," and courts therefore are not required to give them "the binding effect of law." *Chrysler Corp.*, 441 U.S at 302 n.31, 315 (emphases added); accord *Mortgage Bankers Ass'n*, 135 S. Ct. at 1208 (relying on the "longstanding recognition" that "interpretive rules do not have the force and effect of law"); *Guernsey Mem'l Hosp.*, 514 U.S. at 99.

b. Against the backdrop of the APA's governing legal framework, Congress enacted a notice-and-comment procedure, 42 U.S.C. 1395hh(b)(1), that applies to rules, requirements, and other statements of

policy that establish or change certain "substantive legal standard[s]" under the Medicare Act. 42 U.S.C. 1395hh(a)(2). The decisions of other courts of appeals are consistent with the view that, in adding the notice-and-comment rulemaking requirement for "substantive legal standards," Congress would have understood that "[t]he central distinction among agency regulations found in the APA is that between 'substantive rules' on the one hand and 'interpretive rules' * * * on the other." *Chrysler Corp.*, 441 U.S. at 295. And Congress likewise can be presumed to have known the "well established" principle that "substantive agency regulations" carry the "'force and effect of law,'" but that "'interpretive rules' * * * do not." *Id.* at 295, 302 n.31 (citing, *e.g.*, *1947 APA Manual* 30 n.3). A quintessential function of "substantive rules," moreover, has long been recognized to be "defining *standards*" under a governing statute that carry the "force and effect of law." *1947 APA Manual* 13 n.5, 30 n.3 (emphasis added).[10]

Those same principles are embodied in Congress's decision to apply Section 1395hh(a)(2) only to "substantive legal standards" governing benefits, payment, and eligibility under Medicare. Nothing in Section 1395hh suggests that Congress intended to apply a new notice-and-comment requirement for subsidiary "interpretive rules." Indeed, the function played by an interpretive rule is incompatible with the textual scope of Section 1395hh(a)(2). An "interpretive rule" by its nature does

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[10] This Court has repeatedly found the Attorney General's 1947 manual interpreting the APA to be a persuasive construction of the APA. See, *e.g.*, *Norton* v. *Southern Utah Wilderness Alliance*, 542 U.S. 55, 63-64 (2004) (citing cases); *Vermont Yankee Nuclear Power Corp.* v. *NRDC*, 435 U.S. 519, 546 (1978).

not "establish[] or change[]" a "substantive legal standard," 42 U.S.C. 1395hh(a)(2). Such a rule simply announces "the agency's *construction* of the statutes and rules which it administers." *Mortgage Bankers Ass'n*, 135 S. Ct. at 1204 (emphasis added; citation omitted). As such, the view that "an interpretive rule *changes* the [legal provision] it interprets" cannot be "reconcile[d] with the longstanding recognition that interpretive rules do *not* have the force and effect of law." *Id.* at 1208 (emphases added).

3. The court of appeals also held that CMS's calculation of FY2012 Medicare fractions constituted a type of "'requirement'" under Section 1395hh(a)(2) triggering notice-and-comment procedures because the agency directed that MACs "use [those] Medicare fractions in calculating [DSH] adjustment amounts" and thereby "*required* [the MACs] to include Part C days in their calculations." Pet. App. 12a-13a. HHS's practice thus reflects the view that Section 1395hh(a)(2) refers to requirements for providers, not instructions to MACs that make an initial reimbursement determination on CMS's behalf that providers may appeal. The D.C. Circuit has explained that "[i]t is irrelevant whether an HHS directive * * * requir[es] [private entities], as a condition of entering into a contract with HHS" to assist in administering the Medicare program, to follow the agency's instructions when they make determinations on the agency's behalf. *American Hospital Ass'n* v. *Bowen*, 834 F.2d 1037, 1049 (D.C. Cir. 1987). According to that opinion, "focusing on the impact upon [such private entities] of * * * HHS directives" "fail[s] to take heed of the critical difference between [those entities] and hospitals" in this context. *Ibid.*; see *ibid.* (noting the anomaly that would result if "HHS cannot reach

through its contracting agents the same result that it could surely reach itself by using its own employees").

B. The Decision Below Undermines HHS's Ability To Administer The Annual Medicare Reimbursement Process

1. The court of appeals' decision threatens to undermine HHS's ability to administer the Medicare Program in a workable manner. The Medicare program is a "massive, complex health and safety program * * * embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations." *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). Those provisions setting the substantive legal standards for reimbursement and other matters in this extraordinarily complex area of law contain myriad ambiguities that must be resolved, at least as an initial matter, by CMS in its administration of the Medicare program. Agency interpretations such as those in the Provider Reimbursement Manual (PRM) thus set forth CMS's views on questions of Medicare reimbursement for the benefit of providers and promote national uniformity in the administration of the Medicare program by guiding MACs in the initial reimbursement determinations they make on behalf of the agency.

Because MACs are "required to follow * * * [CMS] manual instructions" when performing functions on behalf of CMS, 74 Fed. Reg. at 65,312,[11] the court of ap-

[11] CMS's contracts with MACs also specify that the contractor must comply with "applicable laws, regulations, Medicare manuals, and CMS requirements." See, *e.g.*, Fed. Bus. Opportunities, *Part A/B Medicare Administrative Contractor*, Solicitation 1, No. HHSM-500-2017-RFP-0016, J.01 SOW, § C.1.1, at 19, https://www.fbo.gov/index?s=opportunity&mode=form&id=f7d62fc4ab22c66

peals' decision undermines that longstanding administrative framework by allowing invalidation of Medicare reimbursement determinations that follow such interpretations—not because they are substantively wrong, but because CMS did not go through notice-and-comment rulemaking before issuing such interpretive materials to its own agents. Converting the agency's non-binding manuals and other interpretive materials into regulations requiring notice and comment would jeopardize the flexibility needed in light of Medicare's complex and frequently changing statutory context and administrative developments. The notice-and-comment process can be "long and costly" and "often requires many years and tens of thousands of person hours to complete." Richard J. Pierce, Jr., *Distinguishing Legislative Rules from Interpretative Rules*, 52 Admin. L. Rev. 547, 550-551 (2000); see U.S. Gov't Accountability Office, GAO-09-205, *Federal Rulemaking* 5, 19 (2009) (case study finding average of over four years to complete notice-and-comment rulemaking and that some "rules that were not major took nearly as long or longer to be published").

2. The court of appeals concluded that CMS's inclusion of Part C days in its calculation of the FY2012 Medicare fractions furnished to its MACs "change[d] a substantive legal standard," 42 U.S.C. 1395hh(a)(2), because it reflected a "change from [the agency's] prior practice" of "*exclud[ing]* Part C days from Medicare fractions." Pet. App. 13a. But if the agency's calculation of the FY2012 fractions was invalid because it "change[d]" a substantive legal standard without

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notice-and-comment rulemaking, then the agency's earlier, pre-2004 practice of excluding Part C days was also invalid because that practice "establishe[d] * * * [the] substantive legal standard," 42 U.S.C. 1395hh(a)(2), that the FY2012 fractions purportedly "changed."[12]

Under the D.C. Circuit's rationale, HHS could not now even follow its pre-2004 practice, because that practice would itself establish a "substantive legal standard" and thus could not "take effect," 42 U.S.C. 1395hh(a)(2), without notice-and-comment rulemaking, 42 U.S.C. 1395hh(b)(1). And under that rationale, CMS could not have properly calculated *any* Medicare fractions for *any* hospital after the 1997 enactment of Medicare Part C, notwithstanding its continuing obligation to do so. Fulfilling that obligation required the agency to apply *some* interpretation of the Medicare-fraction statute to decide whether to count Part C days, but no such interpretation could be applied, under the logic of the decision below, without notice-and-comment rulemaking. That anomalous result would prohibit the agency from taking the actions needed for the MACs to process annual Medicare reimbursement requests when faced with any of the myriad statutory or regulatory ambiguities that arise under that program.

3. The court of appeals held that even if Section 1395hh(a)(2) would not have itself required notice-and-comment rulemaking before CMS furnished respondents' Medicare fractions to its MACs for the FY2012

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[12] This Court recently corrected a similar error by the D.C. Circuit in the APA rulemaking context. See *Mortgage Bankers Ass'n*, 135 S. Ct. at 1206 (rejecting conclusion that notice-and-comment rulemaking is required to "change" an agency interpretive rule where the agency could establish the rule without a notice-and-comment process) (citation omitted).

cost year, Section 1395hh(a)(4) would have still "required notice and comment" because HHS's 2004 final rule that would have required inclusion of Part C days in the Medicare fraction "'was not a logical outgrowth of the [2003] proposed rule.'" Pet. App. 17a-18a (citation omitted). But other courts have not concluded that Section 1395hh(a)(4), which addresses the consequences of the invalidation of a binding "substantive" rule, 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.

The court of appeals reasoned that the agency "could not circumvent [Section 1395hh(a)(4)'s] requirement by claiming that it was acting by way of adjudication rather than rulemaking." Pet. App. 18a. Agency adjudication, however, is an established method for resolving interpretive issues. Indeed, HHS has long "relie[d] upon an elaborate adjudicative structure"—which "includes the right to review by the [PRRB], and, in some instances, the Secretary, as well as judicial review in federal district court of final agency action"—to resolve "particular reimbursement details not addressed by [notice-and-comment] regulations." *Guernsey Mem'l Hosp.*, 514 U.S. at 96. Such a "choice made between proceeding by general rule or by individual, *ad hoc* litigation is one that lies primarily in the informed discretion of the administrative agency." *SEC* v. *Chenery Corp.*, 332 U.S. 194, 203 (1947); see *Guernsey Mem'l Hosp.*, 514 U.S. at 96-97 (holding that HHS's mode of addressing Medicare reimbursement determinations "by both rulemaking and adjudication is * * * a proper exercise of [its] statutory mandate"). The decisions of other courts of appeals are consistent with the view that if Section

1395hh(a)(2) does not require notice-and-comment rulemaking for CMS to announce publicly its own non-binding understanding of the Medicare-fraction statute, the agency should not be prohibited from providing calculations to the MACs based on an interpretation of the substantive legal standard in the Medicare-fraction statute when such an interpretation is necessary to adjudicate a provider's claim for Medicare reimbursement. That agency understanding binds neither the administrative bodies that review a MAC's reimbursement decision, see 42 C.F.R. 405.1867, nor the courts on judicial review.

4. The adverse impact of the D.C. Circuit's ruling is particularly significant because universal venue lies in the District of Columbia over Medicare actions by providers. See 42 U.S.C. 1395*oo*(f)(1). Moreover, HHS has informed this Office that the particular issue in this case concerning the proper interpretation of the Medicare-fraction statute alone implicates between $3 and $4 billion in reimbursement for FY2005 through FY2013.[13] The significant financial stakes in this particular context underscore that certiorari is warranted because of the significant and ongoing adverse effect of the court of appeals' decision on the administration of the Medicare program.

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[13] The agency's 2013 final rule, which by its terms applies from FY2014 onwards, should limit the prospective significance of the court of appeals' decision in the particular context of whether to include Part C days in the Medicare fraction if that rule is upheld in the ongoing judicial review. See p. 8 n.6, *supra*.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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APRIL 2018