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 WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE PETITIONER

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QUESTION PRESENTED

The Department of Health and Human Services (HHS) must use notice-and-comment rulemaking to promulgate any rule, requirement, or statement of policy that "establishes or changes a substantive legal standard" governing payment for services under the Medicare Act. 42 U.S.C. 1395hh(a)(2). And if a "final regulation" is not a "logical outgrowth" of the notice of proposed rulemaking, it "shall not take effect" without a further notice-and-comment opportunity. 42 U.S.C. 1395hh(a)(4).

The Centers for Medicare & Medicaid Services (CMS) within HHS instructs private contractors how to determine Medicare payments owed to participating hospitals, including by making available certain intermediate calculations that might affect a hospital's ultimate reimbursement. A hospital dissatisfied with the contractor's payment determination generally can seek both administrative and judicial review, and neither the payment determination nor CMS's intermediate calculation is binding on HHS or the courts. Respondents are hospitals who have challenged CMS's intermediate calculations that it furnished to its contractors to determine respondents' payments for fiscal year 2012. The question presented is:

Whether 42 U.S.C. 1395hh(a)(2) or 1395hh(a)(4) required the Department of Health and Human Services to conduct notice-and-comment rulemaking before providing the challenged instructions to a Medicare Administrator Contractor making initial determinations of payments due under Medicare.

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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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, and the petition was filed on that date. The petition for a writ of certiorari was granted on September 27, 2018. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The relevant statutory and regulatory provisions are reproduced in the appendix to this brief. App., *infra*, 1a-27a.

STATEMENT

This case concerns the scope of the notice-and-comment rulemaking requirements that the Department of Health and Human Services (HHS) must follow in administering the Medicare Act, *i.e.*, Title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq*. "Under the Medicare program, certain qualified providers of health care services are reimbursed" by HHS for "providing covered services to Medicare beneficiaries." *Bethesda Hosp. Ass'n* v. *Bowen*, 485 U.S. 399, 400 (1988) (citation omitted). HHS hires private contractors to make an initial determination of the reimbursement amount to be paid to each provider, which the provider then can generally challenge in an administrative appeal and ultimately on judicial review. *Id.* at 400-401. The issue in this case is whether, under a special rulemaking provision of the Medicare Act, 42 U.S.C. 1395hh, HHS's instructions to its own contractors regarding the calculation of reimbursements, which are not legally binding on either the agency or the courts on subsequent review, must be issued as published regulations after notice-and-comment rulemaking.

1. a. Medicare Part A "covers institutional health costs such as hospital expenses" for certain disabled and 65-and-over persons. *United States* v. *Erika, Inc.*, 456 U.S. 201, 202 (1982); see 42 U.S.C. 1395c *et seq.*[1]

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[1] Medicare Part B, 42 U.S.C. 1395j *et seq.*, not at issue here, "supplements Part A's coverage by insuring against a portion of some

Qualifying hospitals are generally "reimbursed a fixed amount" for covered services they provide to Medicare beneficiaries, "regardless of actual cost." *Good Samaritan Hosp.* v. *Shalala*, 508 U.S. 402, 406 n.3 (1993); see 42 U.S.C. 1395ww(d); 42 C.F.R. 412.1(a)(1). In addition to the fixed amount, hospitals may receive an "additional payment" each year if they "serve[] a significantly disproportionate number of low-income patients." 42 U.S.C. 1395ww(d)(5)(F)(i)(I).

A hospital's eligibility for (and the amount of) the additional payment in a given year is determined in part by a statutorily defined fraction meant to roughly approximate the proportion of Medicare patients the hospital served during that year who are low-income. 42 U.S.C. 1395ww(d)(5)(F)(v) and (vi). The fraction uses a proxy for low-income patients: those entitled to supplemental security income (SSI) benefits under Title XVI of the Social Security Act, 42 U.S.C. 1381 *et seq.*, which are available "to financially needy individuals who are aged, blind, or disabled." *Bowen* v. *Galbreath*, 485 U.S. 74, 75 (1988). The numerator of the fraction is therefore the number of patient days of patients who were *both* "entitled to benefits under part A" *and* "entitled to [SSI] benefits" during the relevant time period. 42 U.S.C. 1395ww(d)(5)(F)(vi)(I). The denominator is the number of patient days of all patients who were "entitled to benefits under part A," whether or not they were entitled to SSI benefits. *Ibid.* This is called the "SSI fraction" or the "Medicare fraction," the term used in this brief.[2]

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medical expenses, such as certain physician services and X-rays, that are excluded from the Part A program." *Erika, Inc.*, 456 U.S. at 202.

[2] A related formula, the "Medicaid fraction," also helps determine a hospital's "additional payment" for serving low-income patients.

In 1997, Congress amended the Medicare Act to add Medicare Part C, 42 U.S.C. 1395w-21 *et seq*., "which gives Medicare beneficiaries an alternative to the traditional Part A fee-for-service system." *Northeast Hosp. Corp.* v. *Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011). Under Part C, an individual enrolls in a private healthcare plan, and HHS generally makes payments to that plan instead of directly paying the healthcare provider (as it does under Part A). *Id.* at 2-3. But payments for covered inpatient hospital services under Part C are still paid from the Part A Trust Fund. 42 U.S.C. 1395w-23(f). And to be eligible to have healthcare benefits administered under Part C, an individual must be "entitled to benefits under part A." 42 U.S.C. 1395w-21(a)(3)(A) (2012).

The underlying interpretive issue in this case is whether a Part C patient, who as just noted must be "entitled to benefits under part A," 42 U.S.C. 1395w-21(a)(3)(A) (2012), is properly regarded as "entitled to benefits under part A" for purposes of calculating the Medicare fraction, 42 U.S.C. 1395ww(d)(5)(F)(vi)(I). If, as the court of appeals assumed, "Part C enrollees [are] wealthier than Part A enrollees," Pet. App. 4a, the inclusion of Part C patients in the Medicare fraction would—if the assumption is true—tend to reduce the value of the fraction (and thus possibly reduce the amount of respondents' "additional payment," 42 U.S.C. 1395ww(d)(5)(F)(i)). But see 78 Fed. Reg. 50,496, 50,615 (Aug. 19, 2013) (noting that recent "research * * * has shown that Part C enrollees tend to

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42 U.S.C. 1395ww(d)(5)(F)(i) and (vi)(II). The numerator of the Medicaid fraction is the number of patient days of patients who are eligible for Medicaid but who are "*not* entitled to benefits under part A." 42 U.S.C. 1395ww(d)(5)(F)(vi)(II) (emphasis added). The denominator is the hospital's total number of patient days for all patients. *Ibid.*

have lower incomes at similar rates as Medicare beneficiaries who are not enrolled in Part C").

b. HHS administers the Medicare program through the Centers for Medicare & Medicaid Services (CMS). CMS, in turn, contracts with private contractors—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). 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). CMS has dozens of manuals, including most notably the Provider Reimbursement Manual, which "provides guidelines and policies to implement Medicare regulations." CMS, Provider Reimbursement Manual—Part 1, Doc. 15-1, at I (Foreword); see *Shalala* v. *Guernsey Mem'l Hosp.*, 514 U.S. 87, 96 (1995).[3] As relevant here, the private contractors 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).

i. To receive payment for providing inpatient hospital services to Medicare beneficiaries, a hospital must submit an annual cost report to the appropriate contractor. *Bethesda Hosp. Ass'n*, 485 U.S. at 400-401; see 42 C.F.R. 405.1801(b)(1). The contractor reviews the cost report and issues a written notice to the hospital specifying the hospital's reimbursement for the year. 42 C.F.R. 405.1803(a) and (2).

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[3] The Medicare Provider Reimbursement Manual is available at www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals.html.

The contractor, however, lacks the information necessary to determine a hospital's Medicare fraction, which requires data from the "SSI file" maintained by the Social Security Administration. 51 Fed. Reg. 16,772, 16,777 (May 6, 1986); see Pet. App. 105a ¶ 7. CMS therefore itself obtains the SSI information from that file and calculates the Medicare fraction for each hospital. 42 C.F.R. 412.106(b)(2); 42 C.F.R. 412.106(b)(2) (2003). CMS then makes those fractions available to the contractor. A contractor in turn uses a given healthcare provider's Medicare fraction as one of several inputs to a series of further calculations to determine that provider'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. Subject to an amount-in-controversy threshold, a provider dissatisfied with a contractor's determination of the total amount of its reimbursement for the year may appeal to the Provider Reimbursement Review Board. 42 U.S.C. 1395*oo*(a) and (d); 42 C.F.R. 405.1835(c). In rendering a decision, the Board must apply the provisions of the Medicare Act, agency regulations, and formal CMS Rulings issued by the CMS Administrator. 42 C.F.R. 405.1867. But interpretive rules and provisions in CMS manuals do not bind the Board, although they receive great weight. *Ibid.*

If the Board determines on appeal 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 immediate judicial review of the "action of [the contractor]" 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, the Board issues its

final decision on the merits. The Secretary (acting through the CMS Administrator) may, within 60 days, reverse, affirm, or modify the Board's 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*. See 42 U.S.C. 1395*oo*(f)(1).

c. Before Part C was enacted in 1997, CMS or its predecessor entity within HHS calculated the Medicare fraction simply "by matching data from the Medicare Part A * * * file with the Social Security Administration's * * * SSI file" to match "individuals who are SSI recipients" with "the Medicare Part A beneficiaries who received inpatient hospital services." 51 Fed. Reg. at 16,777 (1986 interim final rule). "Thus, if a Medicare beneficiary [wa]s eligible for SSI benefits * * * during a month in which the beneficiary [wa]s a patient in the hospital, the covered Medicare Part A inpatient days of hospitalization in that month [were] counted" in the Medicare fraction. *Ibid.*

In 1990, in response to comments, the agency clarified in issuing a final rule that certain Medicare patients "who receive care at a qualified HMO" (health maintenance organization) under 42 U.S.C. 1395mm, a precursor to Part C, were "'entitled to benefits under Part A'" for purposes of the Medicare fraction. 55 Fed. Reg. 35,990, 35,994 (Sept. 4, 1990) (citation omitted) (final rule). That is because, as would later be the case under Part C, individuals could choose this HMO option only if they were "entitled to benefits under part A." 42 U.S.C. 1395mm(d). In promulgating the 1990 regulation, the agency made clear that (once it had resolved some database problems) it "ha[d] been including HMO days in

[the] SSI/Medicare" fraction. 55 Fed. Reg. at 35,994. The agency's decision was based on its interpretation of the Medicare Act: "Based on the language of [42 U.S.C. 1395ww(d)(5)(F)(vi)], which states that that the [Medicare fraction] should include 'patients who were entitled to benefits under Part A', we believe it is appropriate to include the days associated with Medicare patients who receive care at a qualified HMO" under Section 1395mm in the Medicare fraction. 55 Fed. Reg. at 35,994.

When Part C was enacted in 1997, the agency did not immediately address whether to include Part C patient days in the Medicare fraction, as it had done for HMO patient days in 1990. See *Northeast Hosp.*, 657 F.3d at 14-15. Nor did it take any steps to ensure that Part C claims were included in the Medicare databases; as a result, Part C patient days were not included in the Medicare fractions CMS computed. *Id.* at 15. In 2003, however, after "receiv[ing] questions whether patients enrolled in [Part C] 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 the fraction. 68 Fed. Reg. 27,154, 27,208 (May 19, 2003).

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 part A" within the meaning of the statutory 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, consistent with its 1990 final rule regarding HMO patient days, it would count Part C patient days in the Medicare fraction. *Ibid.*; see 42 C.F.R. 412.106(b)(2)(i)(B) and (iii)(B).

In 2012, a district court (in a separate case) 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 "recalculate the [plaintiff] hospitals' reimbursements using the alternate methodology," *i.e.*, to exclude Part C patient days from the Medicare fraction. 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 the court of appeals vacated the district court's directive that CMS exclude Part C days from the Medicare fraction, explaining that "the Secretary might achieve the same result [he originally reached] through adjudication" of the fiscal-year 2007 cost reports at issue in that case. *Id.* at 1111. On remand, the CMS Administrator, acting for the Secretary, did just that: interpreting the Medicare-fraction statute in the course of the agency's adjudication of the plaintiff hospitals' FY2007 cost reports, the CMS Administrator concluded that Part C patient days *are* properly included in the Medicare fraction. *Allina Health Servs.* v. *Burwell*, No. 2010-D38-R, at 24-46 (CMS Adm'r 2015), judicial review pending, No. 16-cv-150 (D.D.C. filed Jan. 29, 2016).[4]

Meanwhile, despite HHS's disagreement with the view that the 2004 final rule was not a logical outgrowth of its proposed rule, cf. *Long Island Care at Home, Ltd.*

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[4] The Administrator's decision is available at www.cms.gov/Regulations-and-Guidance/Review-Boards/OfficeAttorneyAdvisor/OAA-Decisions-Items/2010-D38-R.html. The district court proceedings are stayed pending the disposition of this case. See 10/4/18 Minute Order, *Allina Health Servs.* v. *Burwell*, No. 16-cv-150 (D.D.C.).

v. *Coke*, 551 U.S. 158, 174-175 (2007), the agency instituted new notice-and-comment rulemaking "in an abundance of caution." 78 Fed. Reg. at 50,614-50,615. 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 meaning of the Medicare-fraction provision. *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 Sciences Ctr., Inc.* v. *Azar*, No. 17-cv-1751 (D.D.C. Mar. 13, 2018).

2. a. In the interim, as a result of the vacatur of CMS's 2004 final rule, there was once again no binding CMS regulation governing whether Part C patient days were to be included in the Medicare fraction for fiscal years from 2004 to 2013. Yet CMS remained obligated to calculate annual Medicare fractions to enable the private contractors to make the initial determination of each hospital's appropriate Medicare reimbursement. See Pet. App. 105a ¶ 6.

That was the state of affairs in June 2014, when CMS calculated the FY2012 Medicare fractions 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 the FY2012 Medicare fractions by relying on the vacated 2004 rule. *Id.* at 105a ¶ 7; see *id.* at 30a-31a. Rather, the spreadsheet included a note explaining that the "[c]alculations * * * includ[ed] [Part C] Claims Submissions." CMS, *DSH Adjustment and 2011-2012 File*, www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html. 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'" requiring the inclusion of "'Part C days * * * in the Medicare fraction.'" Pet. App. 33a (citation omitted); see *id.* at 5a-6a.

b. Respondents challenged CMS's calculation of their FY2012 Medicare fractions by seeking administrative review by the Provider Reimbursement Review Board. See Pet. App. 47a-48a, 62a-63a. The Board concluded that it lacked authority to decide that legal challenge and granted respondents' request for expedited judicial review under 42 U.S.C. 1395*oo*(f)(1). Pet. App. 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 governs rulemaking procedures under the Medicare Act. 42 U.S.C. 1395hh. Subsection (a)(1) 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). Subsection (b) describes the procedures such "regulations" must follow, requiring the Secretary to publish "notice of the proposed regulation in the Federal Register" and provide a public comment period of "not less than 60 days" "before issuing in final form any regulation under subsection (a)." 42 U.S.C. 1395hh(b)(1). This 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). And subsection (a)(4) provides that if a provision in a "final regulation" "is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule," the provision "shall not take effect until there is the further opportunity for public comment." 42 U.S.C. 1395hh(a)(4).

But not every Medicare rule or guidance document need be promulgated as a "regulation" under these procedures. Subsection (a)(2) specifies the ones that do:

> No rule, requirement, or other statement of policy (other than a national coverage determination) that *establishes or changes a substantive legal standard* governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under [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) (emphasis added). The italicized text is at issue in this case.

b. The district court granted summary judgment to the Secretary. 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 CMS's "interpretation of the [Medicare] statute" in the course of calculating the

Medicare fractions that it furnished to the private contractors "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 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 the contractors with CMS's calculation of each respondent's FY2012 Medicare fraction based on the agency's interpretation of the statute. *Id.* at 11a-18a.

a. The court of appeals determined that CMS had "establishe[d]" or "change[d]" 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 its contractors. Pet. App. 13a-14a. The court rested that holding on a dictionary definition of "substantive law," which, according to *Black's Law Dictionary* 1658 (10th ed. 2014), is a "law that 'creates, defines, and regulates the rights, duties, and powers of parties.'" Pet. App. 13a-14a. Applying that definition, 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 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's rulemaking provision, 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. In light of its holding that Section 1395hh requires notice-and-comment rulemaking even for interpretive rules, the court stated that it "need not decide" if HHS's inclusion of Part C days in the FY2012 Medicare fractions it furnished to its contractors was an "interpretive rule." *Id.* at 15a.

b. The court of appeals further 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 pp. 8-9, *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 re-impose 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.*

SUMMARY OF ARGUMENT

CMS provides calculations of Medicare fractions for its contractors to use in making one aspect of their initial determinations of payments to be made to providers of Medicare Part A services, subject to further administrative and judicial review. Neither subsection (a)(2) nor subsection (a)(4) of 42 U.S.C. 1395hh required HHS to use notice-and-comment rulemaking procedures in adopting the interpretation of the statute reflected in those payment calculations.

1. Subsection (a)(2) did not require notice-and-comment rulemaking here because the nonbinding interpretation of the Medicare Act reflected in the calculations CMS furnished to its own contractors did not establish or change a substantive legal standard.

a. i. The phrase "establishes or changes a substantive legal standard" in subsection (a)(2) excludes nonbinding interpretations of the Medicare Act. 42 U.S.C. 1395hh(a)(2). Congress enacted subsection (a)(2) against the backdrop of 40 years of administrative law under the APA. A "central distinction" in the APA is between "'substantive rules'" and "'interpretive rules.'" *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 301 (1979) (citation omitted). Substantive rules (sometimes called "legislative rules") are binding and have the force and effect of law. *Id.* at 302-303. Interpretive rules, by contrast, merely reflect "the agency's construction of the statutes and rules which it administers." *Perez* v. *Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1204 & n.1 (2015) (citation omitted). They do not

have the force and effect of law. *Id.* at 1208. It follows that an interpretive rule is, by definition, incapable of "establish[ing] or chang[ing] a substantive legal standard." 42 U.S.C. 1395hh(a)(2). Only a substantive rule can do that. Interpretive rules are therefore outside the scope of subsection (a)(2) and so need not be promulgated through notice-and-comment rulemaking.

It is of no moment that subsection (b)(2) incorporates the APA's exception to the notice-and-comment requirement for "good cause," but not the APA's exception for interpretive rules. Section 1395hh's notice-and-comment provision applies only to "rule[s] * * * that establish[] or change[] a substantive legal standard," which already excludes interpretive rules. 42 U.S.C. 1395hh(a)(2). An additional express exception for interpretive rules would be redundant.

ii. The drafting history of Section 1395hh(a)(2) confirms that it does not apply to interpretive rules. Subsection (a)(2) was enacted in response to a 1982 HHS proposal to do away with a self-imposed undertaking to follow APA notice-and-comment rulemaking for Medicare regulations whenever the costs "outweigh[ed]" the benefits. 47 Fed. Reg. 26,860, 26,860 (June 22, 1982). In enacting subsection (a)(2), there is no indication that Congress intended to import anything other than the established APA rulemaking requirements into the Medicare Act. Indeed, Congress rejected broad language that would have subjected any rule that "may have" a "significant effect" on Medicare payments to notice-and-comment rulemaking, instead choosing to limit the requirement for such rulemaking to rules that "establish[] or change[] a substantive legal standard governing" Medicare payments. 42 U.S.C. 1395hh(a)(2). Congress also drafted the language in subsection (a)(2) to

"reflect[] recent court rulings." H.R. Conf. Rep. No. 495, 100th Cong., 1st Sess. 566 (1987). Those rulings, including a significant opinion from the D.C. Circuit, uniformly applied well-settled law under the APA to hold that "substantive rule[s]" that have "the force of law" and "establish[] a standard of conduct" must go through notice and comment, while interpretive rules need not. *American Hosp. Ass'n* v. *Bowen*, 834 F.2d 1037, 1045-1046 (D.C. Cir. 1987) (citation omitted).

b. Section 1395hh(a)(2) did not require notice-and-comment rulemaking here. The challenged agency action here is, at most, an interpretive rule. It merely reflects "'the agency's construction of the'" Medicare Act and directly "implements the statutory" command to count patient days for patients entitled to benefits under part A in the Medicare fraction. *Shalala* v. *Guernsey Mem'l Hosp.*, 514 U.S. 87, 98-99 (1995). And it does not have the force and effect of law because neither the calculated Medicare fractions nor the contractors' ultimate reimbursement determinations are binding on the agency or on the courts in subsequent review. In fact, the challenged action here is not a "rule, requirement, or other statement of policy" to which Section 1395hh(a)(2) applies in the first place. 42 U.S.C. 1395hh(a)(2). The court of appeals' conclusion that it was a "requirement" because the calculated FY2012 Medicare fractions were binding on the *contractors* is erroneous; in context, "requirement" must mean a requirement imposed on *providers*, not the agency's own contractors. That is the only reading that can be reconciled with Congress's express authorization of the use of private contractors, see 42 U.S.C. 1395kk-1, which therefore act on behalf of the agency itself.

c. The court of appeals' contrary conclusion suffers from additional defects that would substantially undermine the agency's ability to administer the Medicare program. Its holding that the agency can issue instructions to its own contractors only through notice-and-comment rulemaking would, if taken to its logical conclusion, require CMS to promulgate all of its manuals and instructions, including the Provider Reimbursement Manual, through notice and comment. Not only is that at odds with this Court's decision in *Guernsey Memorial Hospital*; it would cripple effective administration of the Medicare program. Also, under the court of appeals' logic, if the agency's calculation of Medicare fractions *including* Part C patients "change[d]" a "substantive legal standard," then the agency's pre-2004 practice of *excluding* Part C patients from the fraction must have "establish[ed]" a "substantive legal standard." But the agency never promulgated its pre-2004 practice through notice-and-comment rulemaking either. This anomaly would mean that the agency was legally prohibited from determining a hospital's additional payment for serving a disproportionate share of low-income patients without notice-and-comment rulemaking—a result that would be entirely at odds with the Medicare Act's directive that "the Secretary *shall* provide * * * for an additional payment" to hospitals using the statutorily defined Medicare fraction, 42 U.S.C. 1395ww(d)(5)(F)(i) (emphasis added).

2. Section 1395hh(a)(4) did not require notice-and-comment rulemaking here either.

a. Subsection (a)(4) did not provide an independent basis for requiring notice-and-comment rulemaking. By its terms, it applies only "[i]f the Secretary publishes

a final regulation." 42 U.S.C. 1395hh(a)(4). But the Secretary did not publish CMS's calculation of respondents' FY2012 Medicare fractions—or the nonbinding statutory interpretation underlying that calculation—as a final regulation. Subsection (a)(4) thus did not apply. And, as the district court determined, the FY2012 calculations were not based on the vacated 2004 rule, and so did not give "effect" to that rule.

b. Even if subsection (a)(4) had independent force, it would not have applied here because the agency chose to proceed by adjudication rather than by rulemaking. Agencies are generally free to choose between rulemaking and adjudication. *SEC* v. *Chenery Corp.*, 332 U.S. 194 (1947). That remains true even if rulemaking would be more efficient, and even if the agency previously had acted (or attempted to act) through rulemaking. *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 292 (1974). Nor did the agency's adjudication of the FY2012 Medicare fractions at issue in this case "circumvent" the vacatur of the 2004 rule, as the court of appeals thought. To the contrary, once the 2004 rule had been vacated, the agency had no choice but to act through adjudication because the Medicare Act imposes a *duty* on the Secretary to compute providers' "additional payment[s]" for serving a disproportionate number of low-income patients. 42 U.S.C. 1395ww(d)(5)(F)(i). And indeed the agency's adjudication of respondents' FY2012 Medicare fractions is consistent with a 1990 final rule that included in the Medicare fraction patient days for analogous patients enrolled in HMOs.

ARGUMENT

I. SECTION 1395hh(a)(2) DID NOT REQUIRE NOTICE-AND-COMMENT RULEMAKING FOR CMS TO FURNISH THE CHALLENGED INSTRUCTIONS TO ITS CONTRACTORS

Section 1395hh(a)(2) requires notice-and-comment rulemaking only for a "rule, requirement, or other statement of policy" that "establishes or changes" certain "substantive legal standard[s]" under the Medicare Act. 42 U.S.C. 1395hh(a)(2). By definition, however, an agency's nonbinding interpretation of a statute cannot "establish[] or change[]" a "substantive legal standard." So it is with the agency action at issue here. CMS's calculation of Medicare fractions for each hospital, based on the agency's interpretation of the Medicare Act (and furnished to the contractor that makes the initial determinations of the reimbursement amounts to be paid to the hospital) does not establish or change any substantive legal standard. The *statute* establishes the governing standard. CMS's calculation of the Medicare fraction is simply one aspect of the contractor's initial determination of the hospital's total reimbursement for the year. And both CMS's calculation and CMS's statutory interpretation on which the calculation is based are subject to administrative review by the Provider Reimbursement Review Board and to judicial review in district court—and both the calculation and the interpretation can be revised at either stage of review. That makes it all the more clear that the calculation does not—indeed cannot—establish or change a substantive legal standard.

To be sure, CMS's calculation of the Medicare fractions is binding on the contractors—both because the contractors do not have access to the necessary data

and to promote uniformity in the contractors' initial determinations of the reimbursement amounts. But the court of appeals' reasoning that CMS was therefore required to conduct notice-and-comment rulemaking before it could furnish that information to its own contractors would, if taken to its logical conclusion, subject the entire panoply of Medicare contractor guidelines and manuals, including the Provider Reimbursement Manual, to Section 1395hh's notice-and-comment requirements. Indeed, in this case, the court of appeals' reasoning would mean that CMS could not instruct its contractors to follow the interpretation of the statute that *respondents* urge without going through notice-and-comment rulemaking. Such a reading of Section 1395hh would cripple effective administration of the vast and complex Medicare program and cannot be what the statutory text effects.

A. The Notice-And-Comment Procedures In Section 1395hh Do Not Apply To Nonbinding Interpretations of the Medicare Act

Section 1395hh requires notice-and-comment rulemaking for "rule[s], requirement[s], or other statement[s] of policy" that "establish[] or change[]" certain "substantive legal standard[s]" under the Medicare Act. 42 U.S.C. 1395hh(a)(2). Congress enacted that provision in 1987 against an established body of administrative law under the APA, and adopted statutory text reflecting APA jurisprudence at that time. Section 1395hh's text, surrounding legal context, and drafting history all demonstrate that the agency's nonbinding interpretation of a statute—which by definition lacks the force and effect of law—does not establish or change a "substantive legal standard" under Section 1395hh(a)(2).

1. The statutory phrase "establishes or changes a substantive legal standard" excludes nonbinding interpretations of the Medicare Act

a. When Congress required rules that "establish[] or change[]" certain "substantive legal standard[s]" to be promulgated through notice-and-comment rulemaking, 42 U.S.C. 1395hh(a)(2), it necessarily excluded the agency's nonbinding interpretations of the Medicare statute. That is because, by definition, an interpretation of a statute cannot establish or change a substantive legal standard. Rather, *the statute* supplies the substantive legal standard. The interpretation simply reflects the understanding on which the agency will base its "implement[ation]" of that standard. *Shalala* v. *Guernsey Mem'l Hosp.*, 514 U.S. 87, 98 (1995). It does not establish or change that standard.[5]

Here, after all, CMS must rely on *some* interpretation of the Medicare Act in instructing the contractors in making their initial determinations. But such an interpretation—whether reflected in the calculation of Medicare fractions as in this case, or contained in the Provider Reimbursement Manual as in other cases—is not binding in final agency review, or in court, or on the hospital or other healthcare provider. A *nonbinding* interpretation by definition "do[es] not have the force and effect of law" and so cannot establish or change any kind of legal standard. *Perez* v. *Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1204 (2015) (citation omitted).

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[5] This case involves action by CMS that rests on an interpretation of the Medicare Act itself, and this brief accordingly discusses the application of Section 1395hh to interpretations of the Act. The same analysis would apply, however, to action by CMS interpreting a regulation that was promulgated to implement the Act.

The fundamental distinction between establishing or changing a substantive legal standard, on the one hand, and nonbinding statutory interpretation, on the other, tracks the "central distinction" in the APA between "'substantive'" and "'interpretive'" rules. *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 301 (1979) (citation omitted); see U.S. Dep't of Justice, *Attorney General's Manual on the Administrative Procedure Act* 30 & n.3 (1947) (1947 APA Manual).[6] Section 1395hh's notice-and-comment provisions were enacted against the backdrop of decades of APA jurisprudence, and so must be interpreted in that light.

Under the APA, only substantive rules must go through notice-and-comment rulemaking. *Chrysler Corp.*, 441 U.S. at 313, 315. Substantive rules are ones that "have the 'force and effect of law.'" *Id.* 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 (citation omitted); see *id.* at 313.

Interpretive rules, by contrast, generally need not go through notice-and-comment rulemaking under the APA. 5 U.S.C. 553(b)(A). "[I]nterpretive rules" reflect "'the agency's construction of the statutes and rules which it administers.'" *Mortgage Bankers Ass'n*, 135 S. Ct. at 1204 (quoting *Guernsey Mem'l Hosp.*, 514 U.S. at 99);

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[6] 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, Inc.*, 435 U.S. 519, 546 (1978).

accord 1947 APA Manual 30 n.3. Unlike "substantive" rules, "'interpretive rules' * * * do *not* have the force and effect of law," and courts are therefore not required to give them "the binding effect of law." *Chrysler Corp.*, 441 U.S at 302 n.31, 315 (citation omitted; emphasis added; citation omitted); accord *Mortgage Bankers Ass'n*, 135 S. Ct. at 1208; *Guernsey Mem'l Hosp.*, 514 U.S. at 99.

The APA had been in effect for some 40 years when Congress added the notice-and-comment requirement for Medicare rules that "establish[] or change[]" certain "substantive legal standard[s]." 42 U.S.C. 1395hh(a)(2); see Omnibus Budget Reconciliation Act of 1987 (1987 OBRA), Pub. L. No. 100-203, Tit. IV, Subtit. A, Pt. 2, Subpt. C, § 4035(b), 101 Stat. 1330-78. Against the longstanding and well settled backdrop of the APA's governing legal framework, including this Court's decision in *Chrysler Corp.*, Congress would have understood the "central distinction * * * in the APA * * * between 'substantive rules' on the one hand and 'interpretive rules' * * * on the other." 441 U.S. at 301 (citation omitted). And Congress likewise would have understood the "well established" principle that "substantive agency regulations" carry the "'force and effect of law,'" while "'interpretive rules' * * * do not." *Id.* at 295, 302 n.31 (quoting, *e.g.*, 1947 APA Manual 30 n.3).

Those principles are embodied in Congress's decision to apply Section 1395hh(a)(2) only to agency actions that "establish[] or change[]" certain "substantive legal standard[s]"—that is, to substantive rules. Indeed a quintessential function of a "*substantive* rule" is "to implement statutory policy" by "defining *standards*" that carry the "force and effect *of law*." 1947 APA Manual 13 n.5, 30 n.3 (emphases added). "[I]f a word is obviously transplanted from another legal source, whether

the common law or other legislation, it brings the old soil with it." *Sekhar* v. *United States*, 570 U.S. 729, 733 (2013) (quoting Felix Frankfurter, *Some Reflections on the Reading of Statutes*, 47 Colum. L. Rev. 527, 537 (1947)). When Congress transplanted the words "substantive," "legal" (*i.e.*, "of law"), and "standard" from decades of APA jurisprudence to the Medicare Act, it brought along their established meaning: a substantive rule that has the force and effect of law.

Nothing in Section 1395hh suggests that Congress, in enacting that provision, intended to jettison decades of administrative law and fashion an unprecedented notice-and-comment requirement for interpretive rules or other interpretive actions by CMS in its administration of the vast and complex Medicare program. To the contrary, the function played by an interpretive rule is incompatible with the text of Section 1395hh(a)(2). An interpretive rule by its very nature does not "establish[] or change[]" a "substantive legal standard," 42 U.S.C. 1395hh(a)(2). Such a rule simply sets forth "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). 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). It follows that by limiting its notice-and-comment requirement to "rule[s] * * * that establish[] or change[] a substantive legal standard," 42 U.S.C. 1395hh(a)(2), the Medicare Act necessarily excludes HHS's nonbinding interpretations of the Act from that requirement.

b. In reaching a contrary conclusion, the court of appeals overlooked these well-established principles of

administrative law—the "old soil"—and instead relied on the definition of "substantive law" in the 10th edition of *Black's Law Dictionary*. Pet. App. 13a-14a. Because that dictionary defines "substantive law" as "law that creates, defines, and regulates the rights, duties, and powers of parties," the court concluded that "substantive legal standard" includes a standard "that creates, defines, and regulates the rights, duties, and powers of parties." *Ibid.* (citation and internal quotation marks omitted). The court further concluded that the quoted definition encompassed the FY2012 Medicare fractions furnished by CMS to the private contractors here. The court's reasoning was erroneous.

As an initial matter, the definition the court of appeals quoted is consistent with the understanding of the term "substantive rule" as used in administrative law, insofar as it refers to *law* that itself establishes binding standards governing the "rights, duties, and powers of parties." Such "substantive law," however, does not include *interpretations* of already existing law, whether announced in the form of an interpretive rule or in the course of an agency adjudication.

In any event, the court of appeals relied on an inapposite definition given the context of this case. As noted, the question in this case turns on the "central distinction" in administrative law between "substantive rules" and "interpretive rules." *Chrysler Corp.*, 441 U.S. at 301. The court of appeals instead relied on a dictionary entry focusing on the distinction between "substantive law" and *procedural* law, as the "Cf." citation and illustrative quotation in the full entry make clear:

> **substantive law** (**səb**-stən-tiv). (18c) The part of the law that creates, defines, and regulates the rights, duties, and powers of parties. Cf. PROCEDURAL LAW.

> "So far as the administration of justice is concerned with the application of remedies to violated rights, we may say that the substantive law defines the remedy and the right, while the law of procedure defines the modes and conditions of the application of the one to the other." John Salmond, *Jurisprudence* 476 (Glanville L. Williams ed., 10th ed. 1947).

Black's Law Dictionary 1658 (10th ed. 2014); see Bryan A. Garner, *Garner's Dictionary of Legal Usage* 713-714 (3d ed. 2011) (making the same distinction). But it is the former distinction, not the latter, that is relevant to the disposition of this case.

Defining "substantive law" in contradistinction to "procedural law" might make sense in some other contexts—but it is inapt to the specialized distinction between "substantive rule" and "interpretive rule" germane to this case. See Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 418 (2012) ("you must use the context in which a given word appears to determine its aptest, most likely sense"). Understanding this specialized distinction requires specialized sources—here, the APA's text and structure, the Attorney General's 1947 APA Manual, and this Court's administrative law cases. As described above, those sources make clear that "interpretive rules"—ones that merely explain "'the agency's construction of the statutes and rules which it administers'" but "do not have the force and effect of law," *Mortgage Bankers Ass'n*, 135 S. Ct. at 1204, 1208 (citation omitted)—are distinct from "substantive rules." Even the dictionary on which the court of appeals relied defines "substantive *rule*" (not "substantive law") by reference to "legislative rule," *Black's Law Dictionary*

1658 (emphasis added; capitalization altered), which in turn is defined as a rule having "the force of law" and is contradistinguished from an "interpretative rule," *id.* at 1040 (capitalization altered). By any relevant definition, therefore, the plain meaning of "rule, requirement, or other statement of policy * * * that establishes or changes a substantive legal standard" necessarily excludes interpretive rules. 42 U.S.C. 1395hh(a)(2). Subsection (a)(2) thus does not apply to interpretive rules, as three other courts of appeals have correctly held. *Baptist Health* v. *Thompson*, 458 F.3d 768, 776 & n.8 (8th Cir. 2006); *Erringer* v. *Thompson*, 371 F.3d 625, 632-633 (9th Cir. 2004); *Warder* v. *Shalala*, 149 F.3d 73, 79 & n.4 (1st Cir. 1998), cert. denied, 526 U.S. 1064 (1999).

Nor was the court of appeals correct to rely (Pet. App. 16a) on the fact that the Medicare Act expressly incorporates the APA's good-cause exception to notice-and-comment rulemaking, see 5 U.S.C. 553(b)(B), but not its exception for interpretive rules, see 5 U.S.C. 553(b)(A). 42 U.S.C. 1395hh(b)(2). The Medicare Act limits its notice-and-comment requirement to "rule[s] * * * that establish[] or change[] a substantive legal standard." 42 U.S.C. 1395hh(a)(2). There is thus no need for an express *exception* from that requirement for interpretive rules, because interpretive rules already are excluded from the scope of notice-and-comment rulemaking in the first place. An express good-cause exception, on the other hand, is necessary because it applies to substantive rules, which *are* covered by Section 1395hh(a)(2)—just as a good-cause exception is necessary for substantive rules under the APA too. Cf. *Reynolds* v. *United States*, 565 U.S. 432, 438 (2012); *Carr* v. *United States*, 560 U.S. 438, 444 n.2 (2010). So the Medicare Act's express incorporation of the APA's good-

cause exception, but not its interpretive-rule exception, does not imply that interpretive rules are subject to a notice-and-comment requirement. To the contrary, it reaffirms that interpretive rules are excluded from the notice-and-comment provision's scope to begin with.

Respondents' suggestion (Br. in Opp. 28-29) that 42 U.S.C. 1395hh(c) "cuts against" the government's reading of the statute also is mistaken. Subsection (c) commands the Secretary to "publish in the Federal Register" at least every three months "a list of all * * * interpretive rules * * * which * * * are not published pursuant to subsection (a)(1) of this section." 42 U.S.C. 1395hh(c)(1) and (B). "By requiring publication of a list of interpretive rules that have *not* gone through notice and comment," respondents assert, subsection (c) "presupposes that some interpretive rules *are* subject to section 1395hh(a)(2)'s notice-and-comment requirement." Br. in Opp. 28-29. Not so. Subsection (c) simply recognizes the possibility that the agency might in some instances *choose* to promulgate a regulation through notice-and-comment rulemaking embodying a statutory interpretation that would otherwise be issued in another form, such as in the Provider Reimbursement Manual. That is what HHS chose to do regarding its interpretation of the Medicare-fraction provision in 2004 and 2013. See 78 Fed. Reg. at 50,614-50,615; 69 Fed. Reg. at 49,099. In that event, the statute simply makes clear that the interpretive rule need not be published a second time in a quarterly list under subsection (c)(1); once is enough. 42 U.S.C. 1395hh(c)(1)(B). It does not imply that interpretive rules must go through notice-and-comment rulemaking.

2. The drafting history of Section 1395hh confirms that it does not apply to nonbinding interpretations of the Medicare Act

Section 1395hh(a)(2)'s drafting history confirms that Congress did not intend a "rule * * * that establishes or changes a substantive legal standard" to encompass an interpretive rule that by definition lacks binding legal force. 42 U.S.C. 1395hh(a)(2). After HHS had taken steps that called into question the continued applicability and enforceability of APA rulemaking procedures under the Medicare program, Congress enacted Section 1395hh's Medicare-specific rulemaking provisions to ensure that Medicare regulations that had long been governed by the APA's rulemaking process would continue to be promulgated through notice-and-comment rulemaking. In doing so, Congress adapted the APA's governing legal framework to the Medicare context.

a. The APA's rulemaking provisions do not apply to any "matter relating to * * * benefits." 5 U.S.C. 553(a)(2). Nevertheless, not long after Medicare's enactment, HHS's predecessor "determined, as a matter of policy, to abide by the APA's notice-and-comment requirements" in its various benefits programs anyway. *Lincoln* v. *Vigil*, 508 U.S. 182, 196 n.5 (1993). Accordingly, in 1971 the Secretary issued a statement of policy directing HHS "to utilize the public participation procedures of the APA." 36 Fed. Reg. 2532, 2532 (Feb. 5, 1971). Throughout the 1970s and into the 1980s, courts held that HHS and its predecessor were bound by that policy, which therefore required the agency to comply with the APA's notice-and-comment requirements, 5 U.S.C. 553(b) and (c). See *Clarian Health W., LLC* v. *Hargan*, 878 F.3d 346, 356-357 (D.C. Cir. 2017) (citing

cases); *Humana of S.C., Inc.* v. *Califano*, 590 F.2d 1070, 1082, 1084 & n.103 (D.C. Cir. 1978).

In 1982, however, HHS published a notice of proposed rulemaking that called into question HHS's continued commitment to conduct APA rulemaking under the Medicare program. See 47 Fed. Reg. at 26,860. The proposal explained that, as a matter of "policy," HHS would "ordinarily * * * use notice and comment procedures," "even though such action is not required by the [APA]" for "rules governing * * * Medicare" and other benefits programs. *Ibid.* Although the notice of proposed rulemaking stated that HHS would generally continue to apply APA rulemaking procedures to benefits programs, HHS could decline to do so if it concluded that the costs of the notice-and-comment process would "outweigh" its benefits in any particular instance. *Ibid.* The proposal further clarified that HHS's "voluntary" policy of conducting notice-and-comment rulemaking was not intended to "create any right or benefit enforceable at law." *Id.* at 26,860-26,861 (proposing 45 C.F.R. 2.2(c)). HHS's proposal "would have [had] the effect of rescinding" its 1971 policy, which courts had held to be judicially enforceable, of complying with APA notice-and-comment rulemaking requirements. See Office of the Chairman, Administrative Conference of the United States, *A Guide to Federal Agency Rulemaking* 27 n.44 (1983).

HHS's proposed rule was met with swift opposition. Less than two months after the published notice, Representative Weiss, joined by 53 of his colleagues, introduced a concurrent resolution resolving that HHS "should withdraw [these] proposed rules * * * that would reduce public notice and comment opportunities." H.R. Con. Res. 401, 97th Cong., 2d Sess. 2 (1982). HHS, the

concurrent resolution stated, "has successfully adhered to Administrative Procedure Act notice and comment period procedures for twelve years." *Ibid.* The agency should thus "affirm current practices." *Ibid.*

HHS never finalized its 1982 proposal, which over the next several years generated criticism from a "broad-based coalition" that expressly wanted HHS "to follow the procedures delineated in the APA (including notice of proposed rule-making) when issuing any regulation or rule relating to Medicare." *Medicare Appeals Provisions: Hearing on S. 1158 Before the Subcomm. on Health of the Senate Comm. on Finance*, 99th Cong., 1st Sess. 25-26 (1985).[7] According to these concerned parties, "the time ha[d] come to make it clear, *by statute*, that Medicare regulations * * * should be subject to the [APA]." *Id.* at 62.

b. In 1986 and 1987, rather than amend the APA to eliminate the exemption for "matter[s] relating to * * * benefits," 5 U.S.C. 553(a)(2), which would have extended to benefit programs generally, Congress prescribed notice-and-comment rulemaking only for the Medicare program, and did so in the Medicare Act itself. It did so

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[7] See, *e.g.*, *Social Security Disability Insurance Program: Hearing Before the Senate Comm. on Finance*, 97th Cong., 2d Sess. 462 (1982) (statement of National Senior Citizens Law Center); *Department of Health and Human Services Oversight: Hearing Before the House Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 97th Cong., 2d Sess. 91 (1982) (August 17, 1982 letter from House Committee Chairmen Dingell, Brooks, and Rodino); H.R. Con. Res. 19, 98th Cong., 1st Sess. (1983) (Rep. Weiss reintroducing his concurrent resolution); *Examination of Quality of Care Under Medicare's Prospective Payment System: Hearing Before the Senate Comm. on Finance*, 99th Cong., 2d Sess. 334, 346 (1986) (statement of American Association of Retired Persons).

by amending 42 U.S.C. 1395hh, which at the time simply authorized the Secretary 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 (1982) (App., *infra*, 6a).

In 1986, Congress added Subsection (b) to Section 1395hh. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, Tit. IX, Subtit. D, Pt. 2, § 9321(e), 100 Stat. 2017-2018; see 42 U.S.C. 1395hh(b) (Supp. IV 1986) (App., *infra*, 7a). That provision, unchanged today, requires the Secretary to "provide for notice of [a] proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon"—twice the 30-day minimum in the APA, 5 U.S.C. 553(d)—"before issuing in final form any regulation under subsection (a)." 42 U.S.C. 1395hh(b)(1). It also exempts regulations from the 60-day notice-and-comment requirement where a statute permits otherwise, where a statute requires (relatively) fast implementation, or in circumstances where the APA's good-cause exception (5 U.S.C. 553(b)(B)) would apply. 42 U.S.C. 1395hh(b)(2). As amended, Section 1395hh did not expressly state which sorts of rulemaking would be covered by the notice-and-comment requirement. The Conference Report for the bill explained, however, that Section 1395hh(b) "does not require the Secretary to [follow notice-and-comment rulemaking] for items (such as interpretive rules * * *) that are not currently subject to that requirement." H.R. Conf. Rep. No. 1012, 99th Cong., 2d Sess. 311 (1986).

The following year, Congress enacted subsection (a)(2), the provision now at issue. 1987 OBRA § 4035(b), 101 Stat. 1330-78; see 42 U.S.C. 1395hh(a)(2) (1988) (App., *infra*, 8a). That provision, unchanged today, states that

"[n]o rule, requirement, or other statement of policy * * * that *establishes or changes* a *substantive legal standard* governing * * * the payment for services * * * 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) (emphasis added).

The House of Representatives initially passed a version of what eventually became subsection (a)(2) in much broader form:

> No rule, requirement, or other statement of policy * * * that *has (or may have) a significant effect on* * * * the payment for services * * * under [the Medicare Act] shall take effect unless it is promulgated by the Secretary by regulation under [Section 1395hh(a)(1)].

133 Cong. Rec. 30,019 (1987) (emphasis added) (reproducing H.R. 3545, 100th Cong., 1st Sess. § 4073(a)(2) (1987)); *id.* at 30,237-30,238 (passage by House of Representatives); see H.R. Rep. No. 391, 100th Cong., 1st Sess. 594-595 (1987). The Senate bill contained no corresponding provision. H.R. Conf. Rep. No. 495, 100th Cong., 1st Sess. 565 (1987) (1987 Conf. Report).

The House and Senate conferees then amended the House provision by replacing the italicized language above with the phrase "establishes or changes a substantive legal standard governing." 1987 Conf. Report 82, 563. "[T]his language," the 1987 Conference Report explained, "reflect[ed] recent court rulings." *Id.* at 566. The amendment "clarif[ied] that only policies establishing or changing a substantive legal standard governing benefits, payment, or eligibility must be promulgated as *regulations*." *Ibid.* (emphasis added). The statutory text

and description in the 1987 Conference Report were consistent with the 1986 amendment, which subjected only "regulation[s]" to notice-and-comment requirements. 42 U.S.C. 1395hh(b)(1).

c. This statutory drafting history embodies three key lessons. First, the 1986 and 1987 amendments were enacted in response to the concerns of lawmakers and citizens who objected to HHS's 1982 proposal and who wanted HHS to comply with *the APA*—which they explicitly identified by name. Nothing in the drafting history so much as hints that Congress had some other, novel administrative rulemaking procedures in mind when it enacted Section 1395hh(a)(2). The most natural reading of that provision, especially when viewed in light of the legal landscape against which it was enacted, is that it simply imports APA principles into the Medicare Act. Under those APA principles, of course, interpretive rules—nonbinding agency interpretations of the statutes and regulations it administers—do not, by definition, "establish[] or change[] a substantive legal standard." 42 U.S.C. 1395hh(a)(2).

Second, Congress significantly narrowed the text of what became Section 1395hh(a)(2). As initially proposed, that provision would have covered rules that "may have" had (not actually have had) a "significant effect" (not a binding legal effect) on Medicare payments. 133 Cong. Rec. at 30,019. But Congress rejected that language. In particular, by restricting subsection (a)(2)'s scope to rules that actually "establish[] or change[] a substantive legal standard," 42 U.S.C. 1395hh(a)(2), Congress deliberately used language reflecting the well-settled administrative-law notice-and-comment framework that excludes interpretive rules, which by definition have no binding legal effect.

Third, the only "recent court rulings" on which Congress could have based Section 1395hh's "substantive legal standard" language were decisions interpreting *the APA*. After all, the APA was the only statute whose rulemaking requirements could have been enforced against the agency at the time.

One of the most significant then-recent court rulings was the D.C. Circuit's decision in *American Hospital Association* v. *Bowen*, 834 F.2d 1037 (1987). That case involved a legal challenge by an association of 6000 member hospitals to HHS's adoption, without notice-and-comment rulemaking, of certain directives, transmittals, and contracts concerning Peer Review Organizations (PROs) under the Medicare program. *Id.* at 1043. Like the private contractors here, PROs contracted with HHS to assist it in deciding "whether Medicare should pay for the services" provided by hospitals. *Id.* at 1042. The court of appeals concluded that the challenged provisions did not require notice-and-comment rulemaking because they had left "unchanged" the "substantive standard for reimbursement under the Medicare statute." *Id.* at 1055. The APA's notice-and-comment requirement, the court said, applies only to "'substantive rules'" that "'create law'" and "'establish[] a standard of conduct which has the force of law,'" and not to "[i]nterpretive rules" that "'merely clarify or explain existing law.'" *Id.* at 1045-1046 (citations omitted). The court made clear that notice-and-comment procedures *would* have been necessary had HHS imposed a "new standard" or "change[d] the standard" for reimbursement. *Id.* at 1051.

American Hospital Association, which applied well-settled principles of administrative law, thus forms the backdrop for the very language ("establishes or changes

a substantive legal standard") that Congress enacted to "reflect[] recent court rulings," 1987 Conf. Report 566. Other examples of then-recent decisions describing in similar terms the types of regulations for which the APA requires notice-and-comment include *National Latino Media Coalition* v. *FCC*, 816 F.2d 785, 788 (D.C. Cir. 1987) ("binding" rules that "make[] law"); *Mada-Luna* v. *Fitzpatrick*, 813 F.2d 1006, 1013-1014 (9th Cir. 1987) ("binding rule of substantive law") (citation omitted); and *Grumman Ohio Corp.* v. *Dole*, 776 F.2d 338, 351 (D.C. Cir. 1985) ("substantive legal effect") (citation omitted). That preexisting jurisprudence confirms that the phrase "changes a substantive legal standard" in Section 1395hh(a)(2) incorporates standard APA principles —and thus excludes from its scope an agency's nonbinding interpretation of the statutes it administers.

B. The Challenged Agency Action Here Is Based On A Nonbinding Interpretation Of The Medicare Act

1. CMS's calculation of respondents' FY2012 Medicare fractions did not "establish[] or change[]" a "substantive legal standard" under 42 U.S.C. 1395hh(a)(2) because it was based on the agency's nonbinding interpretation of the Medicare Act. That underlying statutory interpretation is, at most, an interpretive rule to which subsection (a)(2) does not apply. A rule is interpretive if it merely explains "'the agency's construction of the statutes and rules which it administers'" and "do[es] not have the force and effect of law." *Mortgage Bankers Ass'n*, 135 S. Ct. at 1204, 1208 (citation omitted).

Both are true here. The agency determined that Part C patient days should be included in the Medicare fraction. That was simply a "construction of the statute[]." *Mortgage Bankers Ass'n*, 135 S. Ct. at 1204 (citation omitted). The Medicare Act expressly requires

the fraction to include patient days of patients "entitled to benefits under part A." 42 U.S.C. 1395ww(d)(5)(F)(vi)(I). But the Act also expressly says that Part C patients *must* be "entitled to benefits under part A." 42 U.S.C. 1395w-21(a)(3)(A) (2012). Whether the phrase "entitled to benefits under part A" means the same thing in these two statutory provisions is a quintessential "construction of the statute[]" by the CMS Administrator.

The agency's inclusion of Part C patient days in the Medicare fractions furnished to its contractors also does not have the force and effect of law. Those fractions merely supply one aspect of the contractors' initial reimbursement determinations. Although the contractors, rather than fulltime CMS staff, make those reimbursement determinations, they do so as agents of CMS itself. 42 U.S.C. 1395kk-1(a)(1) and (4)(A). Their reimbursement determinations are therefore just the first step in CMS's own administrative adjudicatory process. Subject to an amount-in-controversy threshold, a hospital may appeal the reimbursement determination to the Provider Reimbursement Review Board. 42 U.S.C. 1395*oo*(f)(1). In that appeal, the contractor's determination of the hospital's total reimbursement (which includes the Medicare fraction, among other calculations) is not binding. Although the Board must apply the statute, regulations, and formal CMS Rulings, it need not follow the Provider Reimbursement Manual or other interpretive materials, including the Medicare fraction or the statutory interpretation on which it is based. 42 C.F.R. 405.1867. Nor are the fractions or reimbursement determinations binding on the CMS Administrator (acting for the Secretary) when she reviews the Board's decision, or on courts in subsequent judicial review. See 42 U.S.C. 1395*oo*(f)(1); 42 C.F.R. 405.1875. It

follows that the FY2012 Medicare fractions here are, at most, interpretive rules outside the scope of Section 1395hh's notice-and-comment requirements.

Indeed the agency's calculations of the FY2012 Medicare fractions based on its interpretation of the Medicare Act, and the contractors' subsequent calculations of respondents' reimbursement amounts, most resemble the reimbursement calculations at issue in *Guernsey Memorial Hospital*. As relevant here, the question in that case was whether an accounting provision in the Provider Reimbursement Manual that specified amortized, rather than immediate, reimbursement of certain provider costs had to be issued through notice-and-comment rulemaking. 514 U.S. at 90. Applying the APA (the 1985 cost year at issue predated the 1986 and 1987 amendments to Section 1395hh), the Court held that it did not. *Id.* at 100. The challenged provision in that case simply "implement[ed] [a] statutory" command. *Id.* at 98. In fact it was just "the first step toward reimbursement," not "the only step." *Id.* at 94. And the resulting calculations did "not have the force and effect of law * * * in the adjudicatory process." *Id.* at 99. Accordingly, this Court held that the challenged manual provision was "a prototypical example of an interpretive rule" that did "not require notice and comment" under APA standards. *Ibid.* Just so here.

2. In fact the challenged action here is not "a rule, requirement, or other statement of policy" to which subsection (a)(2) applies in the first place. 42 U.S.C. 1395hh(a)(2). The agency's calculation of respondents' FY2012 Medicare fractions is not a "rule," for it neither has "future effect" nor involves a "prescription for the future." 5 U.S.C. 551(4) (APA definition of "rule"). To the contrary, the agency in theory would remain free to

calculate the fractions in other years (between 2004 and 2013, at least, when no binding regulation was in effect) based on a different nonbinding interpretation of the statute, if it chose. And not even respondents claim that their FY2012 fractions are "statement[s] of policy."

That leaves "requirement." The court of appeals held that CMS's calculation of respondents' FY2012 Medicare fractions constituted a "'requirement'" to which Section 1395hh(a)(2) applies because the agency directed that its contractors "use [those] Medicare fractions in calculating adjustment amounts" and thereby "*required* [the contractors] to include Part C days in their calculations." Pet. App. 12a-13a. That reasoning is erroneous.

In context, "requirement" in subsection (a)(2) means a "requirement" for *providers*. It does not encompass instructions to the agency's own contractors making initial reimbursement determinations on CMS's behalf. Evaluating a similar challenge to CMS's instructions to its contractors, *American Hospital Association*—one of the "recent court rulings" that inspired Section 1395hh(a)(2), 1987 Conf. Report 566; see pp. 34, 36-37, *supra*—made clear that "[i]t is irrelevant whether an HHS directive * * * requir[es] [private entities], as a condition of entering into a contract with HHS," to follow the agency's instructions when they make determinations on the agency's behalf. 834 F.2d at 1049. Focusing, as the court of appeals in this case did, on the fact that private contractors are bound to follow CMS's instructions "fail[s] to take heed of the critical difference between [private contractors] and hospitals" in this context: namely, that contractors are acting *on behalf of the agency itself*. *Ibid.* In view of "Congress' expressed desire that HHS utilize private [entities]" to administer the Medicare program, HHS must be able to "reach

through its contracting agents the same result that it could surely reach itself by using its own employees." *Ibid.*; see 42 U.S.C. 1395kk-1(a)(1). The court of appeals' holding in this case contravenes these principles.

C. The D.C. Circuit's Interpretation of Section 1395hh Would Substantially Undermine HHS's Ability To Administer The Medicare Program

The court of appeals' interpretation of Section 1395hh, including its holding that CMS interpretive rules—such as the extensive and detailed provisions of the Provider Reimbursement Manual, including the one at issue in *Guernsey Memorial Hospital*—require notice-and-comment rulemaking, would substantially undermine HHS's ability to administer Medicare in a workable manner.

1. 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). In particular, those provisions setting forth the substantive legal standards for reimbursement routinely 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 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 contractors in the initial reimbursement determinations they make on behalf of the agency. Such interpretations, which do not have the force and effect of law and thus are not legally binding on the Provider Reimburse-

ment Review Board or courts that review Medicare decisions, have long been held exempt from notice-and-comment rulemaking. See, *e.g.*, *Guernsey Mem'l Hosp.*, 514 U.S. at 90, 99.

The court of appeals' interpretation of Section 1395hh would substantially undermine this longstanding administrative framework. Converting the agency's nonbinding manuals and other interpretive materials into regulations requiring notice-and-comment rulemaking would jeopardize the flexibility that is essential 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). To be sure, the agency might be able to promulgate *some* regulations relatively quickly. Cf. Br. in Opp. App. 1a-3a. But the court of appeals' rationale, if taken to its logical conclusion, would subject nearly *all* of CMS's nonbinding manuals and interpretive materials to the notice-and-comment process because the agency's contractors are "required to follow" *all* of those instructions when performing functions on behalf of CMS. 74 Fed. Reg. at 65,312. It is difficult even to estimate the disruptive effect that would have on the Medicare program.

2. The court of appeals reasoned that CMS's inclusion of Part C days in its calculation of respondents' FY2012 Medicare fractions "change[d] a substantive legal standard," 42 U.S.C. 1395hh(a)(2), and therefore required notice-and-comment rulemaking, because it reflected a "change from [the agency's] prior practice" of

"excluding Part C days from Medicare fractions." Pet. App. 13a. That reasoning is flawed.

If the agency's calculation of the FY2012 fractions was invalid because it "change[d]" a substantive legal standard without 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." That cannot be right. Cf. *Mortgage Bankers Ass'n*, 135 S. Ct. at 1206 (notice-and-comment rulemaking not required under the APA to "change" an agency interpretive rule when the agency could establish the interpretive rule without notice and comment in the first place).

Yet 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" without notice-and-comment rulemaking. 42 U.S.C. 1395hh(a)(2) and (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 private contractors to apply *some* interpretation of the statutory Medicare-fraction provision 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—which would prohibit the agency from taking the actions needed for the contractors to process annual Medicare reimbursement requests—further underscores the court of appeals' error here.

II. SECTION 1395hh(a)(4) DID NOT REQUIRE NOTICE-AND-COMMENT RULEMAKING FOR CMS TO FURNISH THE CHALLENGED INSTRUCTIONS TO ITS CONTRACTORS

A. Section 1395hh(a)(4) Did Not Provide An Independent Basis To Require Notice-And-Comment Rulemaking

If, as the government maintains, Section 1395hh(a)(2) did not require notice and comment under the circumstances of this case, Section 1395hh(a)(4) does not provide an independent basis to conclude otherwise. Subsection (a)(4) requires a "final regulation" to be "a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule." 42 U.S.C. 1395hh(a)(4). The "logical outgrowth" rule is a familiar one under the APA. See *Long Island Care at Home, Ltd.* v. *Coke*, 551 U.S. 158, 174-175 (2007). But unlike the APA, under which the "unlawfully promulgated regulation" ordinarily "can be left in place while the agency provides the proper procedural remedy," *Fertilizer Inst.* v. *EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991), subsection (a)(4) says that the procedurally defective regulation "shall be treated as a proposed regulation and shall not take effect" without a further notice-and-comment opportunity. 42 U.S.C. 1395hh(a)(4).

Importantly, a "regulation" under subsection (a)(4) is the same type of "regulation" described throughout Section 1395hh, namely, one "promulgated by the Secretary" under subsection (a)(1) that follows the procedural requirements (*i.e.*, notice and comment) described in subsection (b). 42 U.S.C. 1395hh(a)(1) and (b). And by its terms, subsection (a)(4) applies only "[i]f the Secretary publishes a final regulation." 42 U.S.C. 1395hh(a)(4). Subsection (a)(4) thus logically does not apply to agency actions that are *not* published as final regulations. So if subsection (a)(2)—the "substantive legal standard"

provision—does not require an agency action to be "promulgated by the Secretary by regulation under [subsection (a)(1)]," and in fact the agency action is *not* promulgated as a final regulation, subsection (a)(4) has no independent force. 42 U.S.C. 1395hh(a)(2). If a rule need not—and therefore does not—go through notice-and-comment rulemaking, it would be nonsensical to prevent the rule from "tak[ing] effect" under subsection (a)(4) unless it goes through notice-and-comment rulemaking. 42 U.S.C. 1395hh(a)(4). Accordingly, if subsection (a)(2) did not require notice and comment here, subsection (a)(4) does not provide an independent basis to conclude otherwise.

The court of appeals' theory (Pet. App. 17a-18a), echoed by respondents (Br. in Opp. 18-19), appears to be that because the *2004 regulation* was not a "logical outgrowth" of the 2003 proposed rule and thus did not "take effect," 42 U.S.C. 1395hh(a)(4), the agency's *2014 calculation* of respondents' FY2012 Medicare fractions also cannot take effect because it happens to be consistent with the 2004 rule. That reasoning is flawed for two reasons.

First, it overlooks key language in subsection (a)(4): a logical-outgrowth failure means the attempted "final regulation" "*shall be treated as a proposed regulation* and shall not take effect until" a further notice-and-comment period. 42 U.S.C. 1395hh(a)(4) (emphasis added). It would make no sense to "treat[]" CMS's 2014 calculation of respondents' FY2012 Medicare fractions—or the nonbinding statutory interpretation on which it was based—"as a proposed regulation" when the Secretary never attempted to propose it as a regulation in the first place. *Ibid.* And if subsection (a)(2) did not require the Secretary to propose it as a regulation, there is no basis to

conclude that subsection (a)(4) imposed a freestanding requirement to do so anyway.

Second, to the extent the court of appeals thought the 2014 calculation was itself an attempt to give "effect" to the unsuccessful 2004 regulation, it was mistaken. The FY2012 Medicare fractions were not based on the vacated 2004 regulation. The district court found "no convincing evidence that [the agency] relied on the vacated rule in promulgating the 2012" fractions. Pet. App. 31a; see also *id.* at 105a ("[Respondents'] posted 2012 SSI fractions were not calculated in reliance on the vacated rule."). Instead, CMS personnel "appropriately relied on and interpreted the underlying [Medicare] *statute* to calculate" the fractions. *Id.* at 31a (emphasis added). That determination was left undisturbed by the court of appeals, and was unchallenged by respondents in their brief in opposition in this Court. Because the 2012 fractions were not calculated based on the 2004 regulation, they did not give "effect" to that regulation, and subsection (a)(4) is thus inapplicable here.

B. Even If Section 1395hh(a)(4) Had Some Independent Force, It Did Not Apply Here Because The Agency Chose To Proceed By Adjudication

Even if Section 1395hh(a)(4) carried independent force, it would not apply here because the calculation of respondents' FY2012 Medicare fractions, in the absence of a governing regulation, represents the agency's choice to proceed by adjudication rather than by rulemaking. The court of appeals mistakenly rejected this position, reasoning that the agency "could not circumvent [subsection (a)(4)'s] requirement by claiming that it was acting by way of adjudication rather than rulemaking." Pet. App. 18a. But an agency does not "circumvent"

rulemaking when it chooses to proceed by an entirely lawful adjudicative process instead.

Agencies are generally free to choose between rulemaking and adjudication. *SEC* v. *Chenery Corp.*, 332 U.S. 194 (1947). That is true for HHS, too: although the APA exempts "matter[s] relating to * * * benefits" from its rulemaking provision, 5 U.S.C. 553(a)(2)—a gap that 42 U.S.C. 1395hh fills—it contains no prohibition against proceeding by adjudication to establish the amount of reimbursement to be paid to a hospital under Medicare. See *Guernsey Mem'l Hosp.*, 514 U.S. at 96-97. Acting by adjudication, rather than rulemaking, thus does not "circumvent" rulemaking procedures as a matter of law. *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 294 (1974). To be sure, rulemaking in this context might be appropriate to the extent the agency seeks to apply a similar formula to the adjudication of every hospital's ultimate reimbursement calculation on a more permanent basis. Cf. *Heckler* v. *Campbell*, 461 U.S. 458 (1983). But the agency "is not precluded from announcing new principles in an adjudicative proceeding" if it wishes to proceed in that manner instead. *Bell Aerospace*, 416 U.S. at 294.

That is particularly true when, as here, the agency *must* act whether or not a regulation is in place. Once the 2004 rule was set aside, there was no binding agency regulation addressing how to handle Part C patients in the Medicare fraction calculations. Yet HHS still "had a statutory duty to decide the issue at hand," *Bell Aerospace*, 416 U.S. at 292; for under the Medicare Act, "the Secretary *shall* provide * * * for an additional payment" to hospitals using the statutorily defined Medicare fraction, 42 U.S.C. 1395ww(d)(5)(F)(i) (emphasis added); see *Murphy* v. *Smith*, 138 S. Ct. 784, 787 (2018) ("the word 'shall' usually creates a mandate, not

a liberty"). And "this duty remained 'regardless of whether th[e] [Medicare fraction formula] previously had been spelled out in a general rule or regulation.'" *Bell Aerospace*, 416 U.S. at 292 (quoting *Chenery*, 332 U.S. at 201). Once the 2004 rule had been vacated, leaving nothing in its place, HHS had little choice but to address the handling of Part C patients by adjudication. See *Northeast Hosp. Corp.* v. *Sebelius*, 657 F.3d 1, 14 (D.C. Cir. 2011) ("Prior to 2004, the regulation did not specify where [Part C] enrollees should be counted.").

It is no answer (cf. Br. in Opp. 31) that the 1986 interim final rule remained in effect. See p. 7, *supra*. That rule did not address how to handle Part C patients in the Medicare fraction; it could not have done so because Part C was not enacted until 1997. All the interim rule did was set forth the mechanical calculation the agency would undertake to determine a hospital's Medicare fraction: "The number of patient days of those patients entitled to both Medicare Part A and SSI will be determined by matching data [from two databases]." 51 Fed. Reg. at 16,777. Based on that match, "if a Medicare beneficiary is eligible for SSI benefits * * * during a month in which the beneficiary is a patient in the hospital, the *covered* Medicare Part A inpatient days of hospitalization in that month will be counted" in the Medicare fraction. *Ibid.* (emphasis added). Respondents latch onto the word "covered" to suggest that "only days covered and paid under part A were to be treated as part-A-entitled" under the interim rule, and therefore HMO or Part C patient days are excluded. Br. in Opp. 31. But in fact "covered" simply indicates that the days of patients who had *exhausted* their Medicare coverage for an inpatient stay would be excluded from the Medicare fraction. See 42 U.S.C. 1395d(a) and (b); *Catholic*

Health Initiatives Iowa Corp. v. *Sebelius*, 718 F.3d 914, 921 & n.5 (D.C. Cir. 2013). It does not mean that *covered* HMO (or Part C) patient days would also be excluded. Nor did the interim rule even purport to address the question of whether such patients are "entitled to benefits under part A."

By contrast, the agency did address that question in issuing the 1990 final rule on HMO patient days. In a precursor to Part C, the Medicare Act allowed certain individuals "entitled to benefits under part A" to enroll in a qualifying HMO plan and have their healthcare provided by the HMO. 42 U.S.C. 1395mm. HHS made clear in promulgating the 1990 regulation that patient days for those patients *would* be included in the Medicare fraction because, under the statute's plain text, they were "entitled to benefits under Part A." 55 Fed. Reg. at 35,994 (citing 42 U.S.C. 1395ww(d)(5)(F)(vi)). Those HMO patients are obviously quite analogous to Part C patients. Although the benefits of both are administered under provisions outside of Part A, both must be "entitled to benefits under part A," and the covered inpatient benefits of both are paid from the Part A Trust Fund. Compare 42 U.S.C. 1395mm(a) and (d), with 42 U.S.C. 1395w-21(a)(3)(A) (2012) and 42 U.S.C. 1395w-23(f). So if anything, it is the promulgation of the 1990 final rule—and not the earlier interim rule—that would provide the background rule in effect before the 2004 rulemaking attempt. The agency's choice to proceed by adjudication in a manner consistent with the 1990 rule thus did not circumvent any operative regulation at all.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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APPENDIX

1. 5 U.S.C. 551 provides in pertinent part:

Definitions

For the purposes of this subchapter—

* * * * *

(4) "rule" means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing;

(5) "rule making" means agency process for formulating, amending, or repealing a rule;

(6) "order" means the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rule making but including licensing;

(7) "adjudication" means agency process for the formulation of an order;

* * * * *

2. 5 U.S.C. 553 provides:

Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and

public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

3. 42 U.S.C. 1395w-21 (2012) provides in pertinent part:

Eligibility, election, and enrollment

(a) Choice of medicare benefits through Medicare+Choice plans

(1) In general

Subject to the provisions of this section, each Medicare+Choice eligible individual (as defined in paragraph (3)) is entitled to elect to receive benefits (other than qualified prescription drug benefits) under this subchapter—

(A) through the original medicare fee-for-service program under parts A and B of this subchapter, or

(B) through enrollment in a Medicare+Choice plan under this part,

and may elect qualified prescription drug coverage in accordance with section 1395w-101 of this title.

(2) Types of Medicare+Choice plans that may be available

A Medicare+Choice plan may be any of the following types of plans of health insurance:

(A) Coordinated care plans (including regional plans)

(i) In general

Coordinated care plans which provide health care services, including but not limited to health maintenance organization plans (with or without point of service options), plans offered by

provider-sponsored organizations (as defined in section 1395w–25(d) of this title), and regional or local preferred provider organization plans (including MA regional plans).

(ii) Specialized MA plans for special needs individuals

Specialized MA plans for special needs individuals (as defined in section 1395w-28(b)(6) of this title) may be any type of coordinated care plan.

(B) Combination of MSA plan and contributions to Medicare+Choice MSA

An MSA plan, as defined in section 1395w-28(b)(3) of this title, and a contribution into a Medicare+Choice medical savings account (MSA).

(C) Private fee-for-service plans

A Medicare+Choice private fee-for-service plan, as defined in section 1395w-28(b)(2) of this title.

(3) Medicare+Choice eligible individual

(A) In general

In this subchapter, subject to subparagraph (B), the term "Medicare+Choice eligible individual" means an individual who is entitled to benefits under part A of this subchapter and enrolled under part B of this subchapter.

(B) Special rule for end-stage renal disease

Such term shall not include an individual medically determined to have end-stage renal disease, except that—

(i) an individual who develops end-stage renal disease while enrolled in a Medicare+Choice plan may continue to be enrolled in that plan; and

(ii) in the case of such an individual who is enrolled in a Medicare+Choice plan under clause (i) (or subsequently under this clause), if the enrollment is discontinued under circumstances described in subsection (e)(4)(A) of this section, then the individual will be treated as a "Medicare+Choice eligible individual" for purposes of electing to continue enrollment in another Medicare+Choice plan.

* * * * *

4. 42 U.S.C. 1395hh (1982) provides:

Regulations

The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

5. 42 U.S.C. 1395hh (Supp. IV 1986) provides:

Regulations

(a) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means,

unless the context otherwise requires, regulations prescribed by the Secretary.

(b)(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection.

6. 42 U.S.C. 1395hh (1988) provides:

Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection.

(c) Publication of certain rules; public inspection; changes in data collection and retrieval

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list

of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which—

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) of this section and have not been previously published in a list under this subsection.

(2) Effective June 1, 1988, each fiscal intermediary and carrier administering claims for extended care, post-hospital extended care, home health care, and durable medical equipment benefits under this subchapter shall make available to the public all interpretative materials, guidelines, and clarifications of policies which relate to payments for such benefits.

(3) The Secretary shall to the extent feasible make such changes in automated data collection and retrieval by the Secretary and fiscal intermediaries with agreements under section 1395h of this title as are necessary to make easily accessible for the Secretary and other appropriate parties a data base which fairly and accurately reflects the provision of extended care, post-hospital extended care and home health care benefits pursuant to this subchapter, including such categories as benefit denials, results of appeals, and other relevant factors, and selectable by such categories and by fiscal intermediary, service provider, and region.

7. 42 U.S.C. 1395hh provides:

Regulations

(a) Authority to prescribe regulations; ineffectiveness of substantive rules not promulgated by regulation

(1) The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter. When used in this subchapter, the term "regulations" means, unless the context otherwise requires, regulations prescribed by the Secretary.

(2) No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation.

(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice

of the different timeline by not later than the timeline previously established with respect to such regulation. Such notice shall include a brief explanation of the justification for such variation.

(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable regular timeline under this paragraph and that provides an explanation for such failures.

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

(b) Notice of proposed regulations; public comment

(1) Except as provided in paragraph (2), before issuing in final form any regulation under subsection (a) of this section, the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon.

(2) Paragraph (1) shall not apply where—

(A) a statute specifically permits a regulation to be issued in interim final form or otherwise with a shorter period for public comment,

(B) a statute establishes a specific deadline for the implementation of a provision and the deadline is less than 150 days after the date of the enactment of the statute in which the deadline is contained, or

(C) subsection (b) of section 553 of title 5 does not apply pursuant to subparagraph (B) of such subsection.

(c) Publication of certain rules; public inspection; changes in data collection and retrieval

(1) The Secretary shall publish in the Federal Register, not less frequently than every 3 months, a list of all manual instructions, interpretative rules, statements of policy, and guidelines of general applicability which—

(A) are promulgated to carry out this subchapter, but

(B) are not published pursuant to subsection (a)(1) of this section and have not been previously published in a list under this subsection.

(2) Effective June 1, 1988, each fiscal intermediary and carrier administering claims for extended care, post-hospital extended care, home health care, and durable medical equipment benefits under this subchapter shall make available to the public all interpretative materials, guidelines, and clarifications of policies which relate to payments for such benefits.

(3) The Secretary shall to the extent feasible make such changes in automated data collection and retrieval by the Secretary and fiscal intermediaries with agreements under section 1395h of this title as are necessary to make easily accessible for the Secretary and other appropriate parties a data base which fairly and accurately reflects the provision of extended care, post-hospital extended care and home health care benefits pursuant to this subchapter, including such categories as benefit denials, results of appeals, and other relevant factors, and selectable by such categories and by fiscal intermediary, service provider, and region.

(e)[1] Retroactivity of substantive changes; reliance upon written guidance

(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this subchapter shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that—

(i) such retroactive application is necessary to comply with statutory requirements; or

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[1] So in original. No subsec. (d) has been enacted.

(ii) failure to apply the change retroactively would be contrary to the public interest.

(B)(i) Except as provided in clause (ii), a substantive change referred to in subparagraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be, the substantive change.

(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change.

(2)(A) If—

(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1395zz(g) of this title) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim to the contractor in writing; and

(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any penalty or interest under this subchapter or the provisions of subchapter XI of this chapter insofar as they relate to this subchapter (including interest under a repayment plan under section 1395ddd of this title or otherwise) relating to the provision of such items or service or such claim if the provider of services or supplier reasonably relied on such guidance.

(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.

(f) Report on areas of inconsistency or conflict

(1) Not later than 2 years after December 8, 2003, and every 3 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this subchapter and areas of inconsistency or conflict among the various provisions under law and regulation.

(2) In preparing a report under paragraph (1), the Secretary shall collect—

(A) Information from individuals entitled to benefits under part A or enrolled under part B of this subchapter, or both, providers of services, and suppliers and from the Medicare Beneficiary Om-

budsman with respect to such areas of inconsistency and conflict; and

(B) information from medicare contractors that tracks the nature of written and telephone inquiries.

(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts.

8. 42 U.S.C. 1395ww provides in pertinent part:

Payments to hospitals for inpatient hospital services

* * * * *

(d) Inpatient hospital service payments on basis of prospective rates; Medicare Geographical Classification Review Board

* * * * *

(5)(A)(i)

* * * * *

(F)(i) Subject to subsection (r), for discharges occurring on or after May 1, 1986, the Secretary shall provide, in accordance with this subparagraph, for an additional payment amount for each subsection (d) hospital which—

(I) serves a significantly disproportionate number of low-income patients (as defined in clause (v)), or

(II) is located in an urban area, has 100 or more beds, and can demonstrate that its net inpatient care revenues (excluding any of such revenues attributable to this subchapter or State plans approved under subchapter XIX of this chapter), during the cost reporting period in which the discharges occur, for indigent care from State and local government sources exceed 30 percent of its total of such net inpatient care revenues during the period.

* * * * *

(v) In this subparagraph, a hospital "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals, or exceeds—

(I) 15 percent, if the hospital is located in an urban area and has 100 or more beds,

(II) 30 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and has more than 100 beds, or is located in a rural area and is classified as a sole community hospital under subparagraph (D),

(III) 40 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in an urban area and has less than 100 beds, or

(IV) 45 percent (or 15 percent, for discharges occurring on or after April 1, 2001), if the hospital is located in a rural area and is not described in subclause (II).

A hospital located in a rural area and with 500 or more beds also "serves a significantly disproportionate number of low income patients" for a cost reporting period if the hospital has a disproportionate patient percentage (as defined in clause (vi)) for that period which equals or exceeds a percentage specified by the Secretary.

(vi) In this subparagraph, the term "disproportionate patient percentage" means, with respect to a cost reporting period of a hospital, the sum of—

(I) the fraction (expressed as a percentage), the numerator of which is the number of such hospital's patient days for such period which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter and were entitled to supplementary security income benefits (excluding any State supplementation) under subchapter XVI of this chapter, and the denominator of which is the number of such hospital's patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under part A of this subchapter, and

(II) the fraction (expressed as a percentage), the numerator of which is the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX of this chapter, but who were not entitled to benefits under part A of this subchapter, and the denominator of which is the total number of the hospital's patient days for such period.

In determining under subclause (II) the number of the hospital's patient days for such period which consist of

patients who (for such days) were eligible for medical assistance under a State plan approved under subchapter XIX, the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under subchapter XI.

* * * * *

9. 42 C.F.R. 412.106 (2003)[1] provides in pertinent part:

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(b) *Determination of a hospital's disproportionate patient percentage.* (1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year.* For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of covered patient days that—

(A) Are associated with discharges occurring during each month; and

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[1] The version of this provision reproduced in the Petition Appendix contained a typographical error.

(B) Are furnished to patients who during that month were entitled to both Medicare Part A and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of patient days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A.

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(5) *Disproportionate patient percentage*. The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

* * * * *

10. 42 C.F.R. 412.106 (2004) provides in pertinent part:

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(b) *Determination of a hospital's disproportionate patient percentage.* (1) *General rule.* A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year.* For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of patient days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A.

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation*. The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(5) *Disproportionate patient percentage*. The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

* * * * *

11. 42 C.F.R. 412.106 provides in pertinent part:

Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(b) *Determination of a hospital's disproportionate patient percentage*—(1) *General rule*. A hospital's disproportionate patient percentage is determined by adding the results of two computations and expressing that sum as a percentage.

(2) *First computation: Federal fiscal year*. For each month of the Federal fiscal year in which the hospital's cost reporting period begins, CMS—

(i) Determines the number of patient days that—

(A) Are associated with discharges occurring during each month; and

(B) Are furnished to patients who during that month were entitled to both Medicare Part A (including Medicare Advantage (Part C)) and SSI, excluding those patients who received only State supplementation;

(ii) Adds the results for the whole period; and

(iii) Divides the number determined under paragraph (b)(2)(ii) of this section by the total number of days that—

(A) Are associated with discharges that occur during that period; and

(B) Are furnished to patients entitled to Medicare Part A (including Medicare Advantage (Part C)).

(3) *First computation: Cost reporting period.* If a hospital prefers that CMS use its cost reporting period instead of the Federal fiscal year, it must furnish to CMS, through its intermediary, a written request including the hospital's name, provider number, and cost reporting period end date. This exception will be performed once per hospital per cost reporting period, and the resulting percentage becomes the hospital's official Medicare Part A/SSI percentage for that period.

(4) *Second computation*. The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for which patients were eligible for Medicaid but not entitled to Medicare Part A, and divides that number by the total number of patient

days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a waiver authorized under section 1115(a)(2) of the Act on that day, regardless of whether particular items or services were covered or paid under the State plan or the authorized waiver.

(ii) Effective with discharges occurring on or after January 20, 2000, for purposes of counting days under paragraph (b)(4)(i) of this section, hospitals may include all days attributable to populations eligible for Title XIX matching payments through a waiver approved under section 1115 of the Social Security Act.

(iii) The hospital has the burden of furnishing data adequate to prove eligibility for each Medicaid patient day claimed under this paragraph, and of verifying with the State that a patient was eligible for Medicaid during each claimed patient hospital day.

(iv) For cost reporting periods beginning on or after October 1, 2009, the hospital must report the days in the numerator of the fraction in the second computation in a cost reporting period based on the date of discharge, the date of admission, or the dates of service. If a hospital seeks to change its methodology for reporting days in the numerator of the fraction in the second computation, the hospital must notify CMS, through its fiscal intermediary or MAC, in writing at least 30 days before the beginning of the cost reporting period in which the change would apply. The written

notification must specify the methodology the hospital will use, the cost reporting period to which the requested change would apply, and the current methodology being used. Such a change will be effective only on the first day of a cost reporting period. If a hospital changes its methodology for reporting such days, CMS or the fiscal intermediary or MAC may adjust the number of days reported for a cost reporting period if it determines that any of those days have been counted in a prior cost reporting period.

(5) *Disproportionate patient percentage*. The intermediary adds the results of the first computation made under either paragraph (b)(2) or (b)(3) of this section and the second computation made under paragraph (b)(4) of this section and expresses that sum as a percentage. This is the hospital's disproportionate patient percentage, and is used in paragraph (c) of this section.

* * * * *