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.,

Respondents.

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

---

BRIEF FOR *AMICI CURIAE* 77 HOSPITALS AND SOUTHWEST CONSULTING ASSOCIATES IN SUPPORT OF RESPONDENTS

PAUL D. CLEMENT
Counsel of Record
ERIN E. MURPHY
LAUREN N. BEEBE
KIRKLAND & ELLIS LLP
655 Fifteenth Street, NW
Washington, DC 20005
(202) 879-5000
paul.clement@kirkland.com

Counsel for Amici Curiae

December 20, 2018

TABLE OF CONTENTS

TABLE OF AUTHORITIES ii

STATEMENT OF INTEREST 1

SUMMARY OF ARGUMENT 2

ARGUMENT 5

I. Robust Notice-And-Comment Rulemaking Is Critical To The Effective Operation Of The Medicare Act's Prospective Payment System 5

   A. Notice-and-Comment Rulemaking Has Long Been a Fixture of the PPS System 5

   B. Notice and Comment Assures Providers the Predictability and Accountability that Congress Commanded 12

II. The Tortured History Of This Case Underscores The Critical Role That Notice-And-Comment Rulemaking Serves 18

   A. The Secretary Has a Long History of Trying to Subvert the DSH Adjustment.... 19

   B. This Case Arises Out of a Failed Effort to Decrease DSH Adjustments *Sub Silentio* . 24

   C. The Secretary's Failure to Provide *Effective* Notice and Comment in 2004 Does Not Entitle Him to Effectuate His Preferred Payment Policy Unilaterally 27

CONCLUSION 33

APPENDIX

TABLE OF AUTHORITIES

Cases

Alhambra Hosp. v. Thompson,
259 F.3d 1071 (9th Cir. 2001)................................ 20

Allina Health Servs. v. Sebelius,
746 F.3d 1102 (D.C. Cir. 2014)...................... *passim*

Bellevue Hosp. Ctr. v. Leavitt,
443 F.3d 163 (2d Cir. 2006) 8

Cabell Hunting Hosp., Inc. v. Shalala,
101 F.3d 984 (4th Cir. 1996).................................. 23

Cape Cod Hosp. v. Sebelius,
630 F.3d 203 (D.C. Cir. 2011)............................ 8, 17

Cty. of Los Angeles v. Shalala,
192 F.3d 1005 (D.C. Cir. 1999).............................. 14

Deaconess Health Servs. Corp. v. Shalala,
83 F.3d 1041 (8th Cir. 1996).................................. 23

H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Azar,
324 F. Supp. 3d 1 (D.D.C. 2018).............................. 8

Jewish Hosp., Inc. v. Sec'y of Health & Human Servs.,
19 F.3d 270 (6th Cir. 1994).............................. 18, 23

Legacy Emanuel Hosp. & Health Ctr. v. Shalala,
97 F.3d 1261 (9th Cir. 1996).................................. 23

Methodist Hosp. of Sacramento v. Shalala,
38 F.3d 1225 (D.C. Cir. 1994).......................... 5, 6, 7

Ne. Hosp. Corp. v. Sebelius,
657 F.3d 1 (D.C. Cir. 2011)........................... *passim*

Samaritan Health Ctr. v. Bowen,
646 F. Supp. 343 (D.D.C. 1986) 20

Samaritan Health Ctr. v. Heckler,
636 F. Supp. 503 (D.D.C. 1985) 20

Shands Jacksonville Med. Ctr. v. Burwell,
139 F. Supp. 3d 240 (D.D.C. 2015) 8

Statutes

42 U.S.C. §1395 5

42 U.S.C. §§1395c-1395i-5 24

42 U.S.C. §§1395w-21-1395w-29 24

42 U.S.C. §1395hh(a)(2) .... *passim*

42 U.S.C. §1395ww(d)(5)(C)(i) (1983) 19

42 U.S.C. §1395ww(d)(5)(F)(vi) 21

42 U.S.C. §1395ww(d)(6) 7

Deficit Reduction Act of 1984,
Pub. L. No. 98-369, 98 Stat. 494 20

Omnibus Budget Reconciliation Act of 1987,
Pub. L. No. 100-203, 101 Stat. 1330 7

Regulations

42 C.F.R. §412.106(b)(2)(i) (2003) 25

49 Fed. Reg. 234 (Jan. 3, 1984) 20

50 Fed. Reg. 35,646 (Sept. 3, 1985) 9

50 Fed. Reg. 53,398 (Dec. 31, 1985) 20

51 Fed. Reg. 16,772 (May 6, 1986) 9, 23, 25

51 Fed. Reg. 31,454 (Sept. 3, 1986) 9

53 Fed. Reg. 38,476 (Sept. 30, 1988) 9

54 Fed. Reg. 36,452 (Sept. 1, 1989) 9

55 Fed. Reg. 35,990 (Sept. 4, 1990) 9

56 Fed. Reg. 43,196 (Aug. 30, 1991) 9
56 Fed. Reg. 568 (Jan. 7, 1991) 9
58 Fed. Reg. 46,270 (Sept. 1, 1993) 9
59 Fed. Reg. 45,330 (Sept. 1, 1994) 9
60 Fed. Reg. 45,778 (Sept. 1, 1995) 9
61 Fed. Reg. 27,444 (May 31, 1996) 10
61 Fed. Reg. 46,166 (Aug. 30, 1996) 10
62 Fed. Reg. 29,902 (June 2, 1997) 10
62 Fed. Reg. 45,966 (Aug. 29, 1997) 10
63 Fed. Reg. 25,576 (May 8, 1998) 10
63 Fed. Reg. 40,954 (July 31, 1998) 10
64 Fed. Reg. 24,716 (May 7, 1999) 10
64 Fed. Reg. 41,490 (July 30, 1999) 10
65 Fed. Reg. 26,282 (May 5, 2000) 10
65 Fed. Reg. 47,054 (Aug. 1, 2000) 10
66 Fed. Reg. 22,646 (May 4, 2001) 10
66 Fed. Reg. 39,828 (Aug. 1, 2001) 10
67 Fed. Reg. 31,404 (May 9, 2002) 10
67 Fed. Reg. 49,982 (Aug. 1, 2002) 10
68 Fed. Reg. 27,154 (May 19, 2003) 25, 29
68 Fed. Reg. 45,346 (Aug. 1, 2003) 25
69 Fed. Reg. 28,196 (May 18, 2004) 25
69 Fed. Reg. 48,916 (Aug. 11, 2004) 26
70 Fed. Reg. 23,306 (May 4, 2005) 11
70 Fed. Reg. 47,278 (Aug. 12, 2005) 11
71 Fed. Reg. 23,996 (Apr. 25, 2006) 11
71 Fed. Reg. 47,870 (Aug. 18, 2006) 11

72 Fed. Reg. 24,680 (May 3, 2007) 8
72 Fed. Reg. 47,130 (Aug. 22, 2007) 8
74 Fed. Reg. 24,080 (May 22, 2009) 11
74 Fed. Reg. 43,754 (Aug. 27, 2009) 11
75 Fed. Reg. 23,852 (May 4, 2010) 11
75 Fed. Reg. 50,042 (Aug. 16, 2010) 11
76 Fed. Reg. 25,788 (May 5, 2011) 11
76 Fed. Reg. 51,476 (Aug. 18, 2011) 11
77 Fed. Reg. 27,870 (May 11, 2012) 11
77 Fed. Reg. 45,061 (July 30, 2012) 8
77 Fed. Reg. 53,258 (Aug. 31, 2012) 11
77 Fed. Reg. 68,210 (Nov. 15, 2012) 9
78 Fed. Reg. 27,486 (May 10, 2013) 9, 11, 30
78 Fed. Reg. 50,496 (Aug. 19, 2013) 8, 11, 30
78 Fed. Reg. 61,191 (Oct. 3, 2013) 11
79 Fed. Reg. 27,978 (May 15, 2014) 11
79 Fed. Reg. 49,854 (Aug. 22, 2014) 11
80 Fed. Reg. 24,324 (Apr. 30, 2015) 11
80 Fed. Reg. 49,326 (Aug. 17, 2015) 11
81 Fed. Reg. 24,946 (Apr. 27, 2016) 11
81 Fed. Reg. 56,762 (Aug. 22, 2016) 11
82 Fed. Reg. 19,796 (Apr. 28, 2017) 11
82 Fed. Reg. 37,990 (Aug. 14, 2017) 11
83 Fed. Reg. 20,164 (May 7, 2018) 12
83 Fed. Reg. 41,144 (Aug. 17, 2018) 12

Other Authorities

340B Health, *Evaluating 340B Hospital Savings and Their Use in Serving Low-Income and Rural Patients: Results from 340B Health's 2017 Annual Survey* 4 (June 2018), https://bit.ly/2rGVyKK 16

FY 2012 SSI Ratios, CMS, https://go.cms.gov/2CmkPju (last visited Dec. 20, 2018).. 31

H.R. Rep. No. 98-25 (1983), *reprinted in* 1983 U.S.C.C.A.N. 219 6

H.R. Rep. No. 100-391(I) (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313 .... 7, 14

H.R. Rep. No. 99-241(I) (1985), *reprinted in* 1986 U.S.C.C.A.N 579 .... 19, 22

Maryland All-Payer Model, CMS, https://bit.ly/2Bj3XbK (last visited Dec. 20, 2018) 15

Program Memorandum (Intermediaries), HCFA Pub. 60A, Transmittal No. A–98–21 (July 1, 1998).. 28

Prospective Payment Systems - General Information, CMS, https://go.cms.gov/2uIwOE9 (last visited Dec. 20, 2018)... 6

S. Rep. No. 98-237 (1983), *reprinted in* 1983 U.S.C.C.A.N. 143 6

STATEMENT OF INTEREST[1]

Amici are 77 hospitals across the country and Southwest Consulting Associates, a financial consulting group that provides healthcare finance and compliance consulting services to healthcare providers. *Amici* hospitals span urban, suburban, and rural areas across 22 different states and range in size from 20 beds to 1,343 beds. As is common among hospitals, *amici* devote a substantial and disproportionate share of their resources to treating low-income patients, which makes the adjustment Congress provided to Medicare reimbursements for hospitals that do so of critical importance to their continued ability to serve those most in need. *Amici* thus can attest to the substantial impact that (even ostensibly minor) regulatory adjustments have on their Medicare reimbursements and in their internal budgeting, financial forecasting, and management. To take the issue underlying this case as an example, depending on the size of the hospital and a variety of other factors, the impact for any given individual *amicus* hospital of including Part C days in the Medicare fraction ranges anywhere from less than $100,000 to more than $27 million.

---

[1] Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amici curiae*, their members, their consultants, and their counsel, made any monetary contribution toward the preparation or submission of this brief. Pursuant to Supreme Court Rule 37.3, counsel of record for all parties have consented to this filing in letters on file with the Clerk's office.

Because Medicare payment rates and adjustments are so critical to their continued ability to provide care on the front lines, *amici* have, of necessity, become every bit as well versed in the complex regulatory scheme of Medicare and Medicaid as the Secretary and his agencies. As such, *amici* are uniquely well positioned to speak to the importance of agency accountability, predictability, and stability in this context, and to explain how traditional notice-and-comment rulemaking has long served those interests.

A full list of *amici* is set forth in the appendix to this brief.

SUMMARY OF ARGUMENT

Notice-and-comment rulemaking is essential to the effective operation of the modern Medicare system. In 1983, Congress shifted the Medicare system from one in which hospitals were reimbursed after the fact based on the actual costs of serving Medicare patients, to one in which standard reimbursement rates are fixed in advance based on specified categories of patient diagnoses, and a hospital is reimbursed based on those rates regardless of the actual costs of its services. The shift to a prospective payment system reflected an effort to incentivize hospitals to be more efficient and cost-effective in the provision of services. But the success of that effort depends on hospitals actually knowing *in advance* what those fixed payment rates will be, as well as how the myriad adjustments that the Medicare Act establishes to their payments will be calculated. To that end, Congress coupled the shift to a prospective payment system with a specific

requirement that the Secretary of Health and Human Services ("Secretary") must employ notice-and-comment rulemaking for every "rule, requirement, or other statement of policy … that establishes or changes a substantive legal standard governing … the payment for services." 42 U.S.C. §1395hh(a)(2).

Consistent with that and other rulemaking obligations, the Secretary undertakes a comprehensive rulemaking each year, published in the Federal Register under the title "Proposed Rules" or "Rules and Regulations," to explain what the rates will be and how adjustments to hospitals' payments will be calculated in the following fiscal year. And the Secretary has long used that mandatory annual notice-and-comment rulemaking process to propose and promulgate changes to how the disproportionate share hospital ("DSH") adjustment—*i.e.*, the adjustment for hospitals that devote a disproportionate share of their resources to treating low-income patients—will be calculated in the coming year. Indeed, the Secretary employed notice-and-comment rulemaking when the agency first tried to adopt the payment policy underlying this case, and has addressed the calculation of the DSH adjustment in all but four of the 33 rounds of annual proposed and final rulemakings since 1986. The Secretary deviated from that practice in the fiscal year presently at issue only because his effort to alter how the DSH calculation was adjusted through notice-and-comment rulemaking was *rejected*, on account of a failure to provide the notice necessary to allow for meaningful comment.

This case thus is manifestly not about an effort to saddle the Secretary with some onerous new notice-and-comment rulemaking requirement. It is simply about whether the Secretary must continue to use notice and comment in a context in which he has long done so—namely, when changing the substantive standards governing the calculation of prospective payment rates and adjustments. Relieving the Secretary of that obligation not only would be contrary to the plain text and intent of Congress, but would deprive hospitals and the rest of the regulated community of the fair notice and accountability on which the prospective payment system depends.

After all, even seemingly small changes can have enormous financial implications in this context, and those implications are particularly acute for the precise hospitals that the DSH adjustment is designed to assist—*i.e.*, those that spend a disproportionate share of their resources caring for low-income individuals. Notice and comment thus not only ensures that the Secretary will not *inadvertently* make seemingly minor changes with drastic consequences for hospitals, but also gives courts the tools to hold the Secretary accountable when (as here) he tries to deviate from settled practice *sub silentio*, and without regard for the true economic impact that those actions will have on the ability of hospitals to continue serving those most in need. Accordingly, the Court should decline the Secretary's invitation to disrupt the status quo, and instead ensure that the regulated community continues to receive the fair notice, transparency, and accountability that the Medicare Act's notice-and-comment rulemaking requirements command.

ARGUMENT

I. Robust Notice-And-Comment Rulemaking Is Critical To The Effective Operation Of The Medicare Act's Prospective Payment System.

A. Notice-and-Comment Rulemaking Has Long Been a Fixture of the PPS System.

Medicare is a federal health insurance program for the elderly and disabled. *See* 42 U.S.C. §1395 *et seq*. At its inception, Medicare reimbursed hospitals retrospectively on the basis of their "reasonable costs" of treating Medicare patients. But in 1983, Congress shifted to a prospective payment system ("PPS") under which, rather than compensating hospitals retrospectively based on their actual costs, the Secretary prospectively fixes standard reimbursement rates, and a hospital receives those rates regardless of how much its treatments actually cost. *See Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1227 (D.C. Cir. 1994). Congress designed this prospective, fixed reimbursement system to incentivize hospitals to provide more cost-effective care. By giving hospitals advance notice of what reimbursement they will receive, the PPS system allows hospitals to use that information when planning and budgeting for the coming year.

"Indeed, this link between prospectivity and efficiency lay at the heart of Congress' purpose when it created the PPS system[.]" *Id.* As the accompanying House Report explained, the shift to a prospective system was "intended to reform the financial incentives hospitals face, promoting efficiency in the provision of services by rewarding cost/effective

hospital practices." H.R. Rep. No. 98-25, at 132 (1983), *reprinted in* 1983 U.S.C.C.A.N. 219, 351; *see also* S. Rep. No. 98-23, at 47 (1983), *reprinted in* 1983 U.S.C.C.A.N. 143, 188 (prospective system was "intended to create incentives for hospitals to operate in a more efficient manner, since hospitals would be allowed to keep payment amounts in excess of their costs and would be required to absorb any costs in excess of the [fixed] rates"). Over the decades since 1983, the prospective payment approach has been extended far beyond acute inpatient hospitals, to home health agencies, hospice, hospital outpatient, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and skilled nursing facilities. *See Prospective Payment Systems - General Information*, CMS, https://go.cms.gov/2uIwOE9 (last visited Dec. 20, 2018).

It is thus no surprise that Congress has deemed notice-and-comment rulemaking particularly critical to the effective operation of the Medicare Act. After all, a *prospective* system designed to incentivize efficiency and cost-effective practices cannot achieve those ends if hospitals do not have advance notice of the rates Medicare will pay and how adjustments to those rates will be calculated. *See Methodist Hosp.*, 38 F.3d at 1227 ("Congress designed this system to encourage health care providers to improve efficiency and reduce operating costs."). In keeping with that commonsense point, Congress coupled the shift to a PPS system with an obligation that the Secretary must "provide for publication in the Federal Register, on or before the August 1 before each fiscal year …, a description of the methodology and data used in

computing the adjusted [diagnosis-related group ("DRG")] prospective payment rates under this subsection, including any adjustments required under subsection (e)(1)(B)." 42 U.S.C. §1395ww(d)(6).

And Congress did not stop there. Concerned that "important policies [were still] being developed without benefit of the public notice and comment period," H.R. Rep. No. 100-391(I), at 430 (1987), *reprinted in* 1987 U.S.C.C.A.N. 2313-1, 2313-250, Congress imposed additional notice-and-comment rulemaking requirements in 1987, including the requirements at issue here. *See* Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 100-203, §4035, 101 Stat. 1330, 1330-78. Those amendments made clear that the Secretary must use notice-and-comment rulemaking not only to explain how PPS rates and certain adjustments specified in 42 U.S.C. §1395ww(d)(6) would be calculated, but for *every* "rule, requirement, or other statement of policy … that establishes or changes a substantive legal standard governing … the payment for services." 42 U.S.C. §1395hh(a)(2). After all, only if hospitals *actually* "receive advance notice" of how Medicare will reimburse them can they attempt to "improve efficiency and reduce operating costs" based on the prospectively fixed rates and reimbursement methodologies in that notice. *Methodist Hosp.*, 38 F.3d at 1227.

Consistent with those obligations, each year the Secretary undertakes a comprehensive notice-and-comment rulemaking that sets forth on a prospective basis not only the rates that providers can receive for their services in the coming year, but also how the

Medicare Act's myriad adjustments to those rates will be calculated. That annual rulemaking, which typically takes between three and four months, *see* BIO.Add.1a-3a, addresses all manner of issues related to the methodology through which payments and adjustments are calculated.

For example, "in May 2007, [the Secretary] published a proposed rule for fiscal year 2008 that would offset the rural floor by adjusting area wage indexes rather than by adjusting the standardized amount as CMS had done in the past." *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 208 (D.C. Cir. 2011) (citing 72 Fed. Reg. 24,680 (May 3, 2007)); *see also* 72 Fed. Reg. 47,130 (Aug. 22, 2007). The Secretary also has undertaken lengthy notice-and-comment rulemaking efforts with regard to cancer hospitals and potential adjustments for the specialized services they provide, *see H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 7-9 (D.D.C. 2018) (summarizing rulemaking beginning in 2010), *appeal filed*, No. 18-6277 (D.C. Cir. Sept. 19, 2018), as well as decades-long efforts regarding the grouping of hospitals into geographic areas, *see Bellevue Hosp. Ctr. v. Leavitt*, 443 F.3d 163, 169-72 (2d Cir. 2006) (summarizing rulemaking beginning in 1985). And the Secretary has routinely employed notice-and-comment rulemaking to adjust how "inpatient" and "outpatient" services are defined, an issue that has a substantial effect on payments. *See Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 243 (D.D.C. 2015) (citing 78 Fed. Reg. 50,496, 50,965 (Aug. 19, 2013)); *see also* 77 Fed. Reg. 45,061, 45,155 (July 30, 2012); 77 Fed. Reg. 68,210, 68,430-31 (Nov.

15, 2012); 78 Fed. Reg. 27,486, 27,644-50 (May 10, 2013).

The Secretary also has a long and robust history of using notice-and comment in the specific context relevant here—*i.e.*, the DSH adjustment. Indeed, even before Congress codified the DSH adjustment formula, the Secretary used notice and comment to discuss a potential "adjustment … for hospitals that serve a disproportionate share of low income or Medicare patients or both and that a definition of these hospitals be established based on a broader concept of low income than simply percentage of Medicaid patients." 50 Fed. Reg. 35,646, 35,685 (Sept. 3, 1985); *see also id.* at 35,686. And after Congress codified the DSH adjustment formula in 1986, the Secretary routinely used the annual notice-and-comment rulemaking process to address how the DSH adjustment would be calculated. *See, e.g.*, 51 Fed. Reg. 16,772, 16,776-78 (May 6, 1986); 51 Fed. Reg. 31,454, 31,457-61 (Sept. 3, 1986); 53 Fed. Reg. 38,476, 38,480-81, 38,516 (Sept. 30, 1988); 54 Fed. Reg. 36,452, 36,489 (Sept. 1, 1989); 55 Fed. Reg. 35,990, 35,992-94 (Sept. 4, 1990); 56 Fed. Reg. 568, 571 (Jan. 7, 1991); 56 Fed. Reg. 43,196 (Aug. 30, 1991); 58 Fed. Reg. 46,270, 46,313 (Sept. 1, 1993); 59 Fed. Reg. 45,330, 45,374 (Sept. 1, 1994); 60 Fed. Reg. 45,778, 45,811-12 (Sept. 1, 1995).

In addition to providing the regulated community with advance notice of potential changes to how the DSH adjustment would be calculated, notice and comment has promoted valuable dialogue between the Secretary and the regulated community. For example, in the proposed rulemaking for fiscal year ("FY") 1997,

the Secretary sought comments and feedback on alternatives to various aspects of the methods and data used to calculate the DSH fractions and adjustment. *See* 61 Fed. Reg. 27,444, 27,473-74 (May 31, 1996). The Secretary did not enact any changes to the calculation methods in the final rule released later that year, but the Secretary did note that the request for comments had been fruitful in providing feedback on how "to improve the data and the calculation to better target those hospitals that treat a disproportionate share of the indigent population." 61 Fed. Reg. 46,166, 46,206-07 (Aug. 30, 1996).

The Secretary thereafter addressed the DSH adjustment in every single one of the annual proposed and final rulemakings for the next six fiscal years. *See* 62 Fed. Reg. 29,902, 29,933 (June 2, 1997); 62 Fed. Reg. 45,966, 46,001-02 (Aug. 29, 1997); 63 Fed. Reg. 25,576, 25,594-95 (May 8, 1998); 63 Fed. Reg. 40,954, 40,984-85 (July 31, 1998); 64 Fed. Reg. 24,716, 24,745-46 (May 7, 1999); 64 Fed. Reg. 41,490, 41,539 (July 30, 1999); 65 Fed. Reg. 26,282, 26,307-08 (May 5, 2000); 65 Fed. Reg. 47,054, 47,086-87 (Aug. 1, 2000); 66 Fed. Reg. 22,646, 22,690 (May 4, 2001); 66 Fed. Reg. 39,828, 39,882-83 (Aug. 1, 2001); 67 Fed. Reg. 31,404, 31,462-63 (May 9, 2002); 67 Fed. Reg. 49,982, 50,060-61 (Aug. 1, 2002). And the Secretary proceeded to address the precise issue underlying this case (Part C days) in each of the four subsequent proposed and final rules, proposing to "clarify" its policy on that issue in the proposed rulemaking for FY 2004, deferring action on that issue in the final FY 2004 rulemaking, further deferring action in the proposed rulemaking for FY 2005, then attempting to adopt the

position it now presses in the final FY 2005 Rule. *See infra* Part II.B.

Since then, the Secretary has continued to address DSH-related issues in its annual notice-and-comment rulemaking routinely. *See, e.g.*, 70 Fed. Reg. 23,306, 23,434-36 (May 4, 2005); 70 Fed. Reg. 47,278, 47,438-43 (Aug. 12, 2005); 71 Fed. Reg. 23,996, 24,107-08 (Apr. 25, 2006); 71 Fed. Reg. 47,870, 48,066-67 (Aug. 18, 2006); 74 Fed. Reg. 24,080, 24,187-91 (May 22, 2009); 74 Fed. Reg. 43,754, 43,899-908 (Aug. 27, 2009); 75 Fed. Reg. 23,852, 24,002-07 (May 4, 2010); 75 Fed. Reg. 50,042, 50,275-86 (Aug. 16, 2010); 76 Fed. Reg. 25,788, 25,942-44 (May 5, 2011); 76 Fed. Reg. 51,476, 51,681-83 (Aug. 18, 2011); 77 Fed. Reg. 27,870, 27,974-75 (May 11, 2012); 77 Fed. Reg. 53,258, 53,411-13 (Aug. 31, 2012).

Indeed, the Secretary used notice-and-comment rulemaking when the Secretary once again altered the treatment of Part C days in 2013. *See* infra Part II.B; 78 Fed. Reg. 27,486, 27,577-78 (May 10, 2013); 78 Fed. Reg. 50,496, 50,613-47 (Aug. 19, 2013); 78 Fed. Reg. 61,191, 61,191-97 (Oct. 3, 2013). And the Secretary has continued to address DSH-related issues in subsequent rulemakings as well. *See, e.g.*, 79 Fed. Reg. 27,978, 28,094-104 (May 15, 2014); 79 Fed. Reg. 49,854, 50,004-22 (Aug. 22, 2014); 80 Fed. Reg. 24,324, 24,480-88 (Apr. 30, 2015); 80 Fed. Reg. 49,326, 49,512-30 (Aug. 17, 2015); 81 Fed. Reg. 24,946, 25,081-94 (Apr. 27, 2016); 81 Fed. Reg. 56,762, 56,943-73 (Aug. 22, 2016); 82 Fed. Reg. 19,796, 19,940-55 (Apr. 28, 2017); 82 Fed. Reg. 37,990, 38,189-220 (Aug. 14, 2017); 83 Fed. Reg. 20,164, 20,386-401, 20,547-48 (May 7,

2018); 83 Fed. Reg. 41,144, 41,401-28, 41,682-84 (Aug. 17, 2018).

As the foregoing makes clear, affirming the D.C. Circuit's conclusion that a change to how the DSH adjustment will be calculated constitutes a "rule, requirement, or other statement of policy … that establishes or changes a substantive legal standard governing … the payment for services," 42 U.S.C. §1395hh(a)(2), would not "substantially undermine the agency's ability to administer the Medicare program," let alone "cripple effective administration of the Medicare program," Pet'r.Br.18. Not only is the Secretary fully capable of addressing changes to the DSH adjustment through notice-and-comment rulemaking; that is what the Secretary has been doing for decades. The Secretary deviated from that approach in June 2014—when HHS published the Medicare fractions to be used in calculating DSH adjustments for FY 2012, Pet.App.5a-6a—only because the Secretary's first effort to effectuate the policy change through notice-and-comment rulemaking *failed*, on account of the agency's failure to provide the notice necessary to allow the regulated community to comment on that proposed change. *See infra* Part II.B; *Allina Health Servs. v. Sebelius* (*Allina I*), 746 F.3d 1102, 1109 (D.C. Cir. 2014). It is thus the Secretary, not respondents, that is asking this Court to alter the long-settled status quo.

B. Notice and Comment Assures Providers the Predictability and Accountability that Congress Commanded.

The Court should decline the Secretary's invitation to curtail the Medicare Act's notice-and-

comment requirements not only because the statute plainly compels that result, but also because those requirements are essential to the effective administration of the PPS system. As explained, the whole point of the prospective system is to incentivize providers to be more efficient and cost-effective. To achieve that goal, providers must know not just what the annual rate will be, but how the Secretary will calculate the myriad adjustments and alterations the Medicare Act contemplates to those rates. That is precisely why Congress has mandated notice and comment for *every* "rule, requirement, or other statement of policy … that establishes or changes a substantive legal standard governing … the payment for services." 42 U.S.C. §1395hh(a)(2). Without the fair and advance notice that notice-and-comment rulemaking provides on *all* payment policies, providers will not have the ability to fully take into account what "the payment for services" will be when planning for the upcoming fiscal year.

After all, hospitals have to budget for each fiscal year well in advance. Indeed, *amici* begin that process (at least) as soon as the Secretary releases the proposed annual rule for each fiscal year, which typically happens in late April or early May. *See* BIO.Add.1a-3a. While neither the proposed rule nor the final rule can tell hospitals what their actual DSH adjustments will be (those cannot be calculated until after the data from the coming year is available to input), knowing how those adjustments will be calculated allows hospitals to project their DSH adjustments with a fair amount of confidence. And having advance notice of that calculation and other payment information not only ensures that hospitals

can take that data into account *before* their budgets, forecasts, and management for the coming year are finalized; it also ensures that hospitals and other members of the regulated community will have time to provide meaningful feedback on proposed changes to the Secretary's payment methodology before it is too late for the Secretary to reverse course. Congress plainly envisioned this back-and-forth dialogue, *see, e.g.*, H.R. Rep. No. 100-391(I), at 430, and only notice-and-comment rulemaking ensures that it can occur on a timeline consistent with the objectives that a *prospective* payment system is designed to achieve.

That back and forth is particularly critical "[g]iven the enormity of the Medicare program," as even "seemingly modest" tweaks to the Secretary's calculation methodologies can "represent substantial sums of money." *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1010 (D.C. Cir. 1999); *cf. Allina I*, 746 F.3d at 1105 ("Although ostensibly only a detail, the financial impact is apparently substantial, costing the hospitals hundreds of millions of dollars."). This is a case in point: In requesting review here, the Secretary estimated that the issue underlying this case "affects between $3 and $4 billion in Medicare funding." Pet.14. It affects hospitals, moreover, in one of the most critical areas, as the whole point of the DSH adjustment is to enable and incentivize hospitals to serve a "disproportionate share" of low-income patients. *See infra* Part II.A-B. And thousands of hospitals in virtually every state do just that.[2]

---

[2] Because Maryland has a "unique all-payer rate-setting system for hospital services" that operates outside of the PPS system, its hospitals do not receive DSH adjustments. *See*

For example, based on recently filed 2017 Medicare cost reports and excluding managed care, 79.42% of acute care patient days are Medicare and Medicaid days at Lourdes Medical Center of Burlington County in Willingboro, New Jersey (formerly known as Rancocas Hospital; part of the Trinity Health hospital network and an *amicus* here). The numbers for other hospitals across the country reflect a similar commitment to providing services to those in need: 71.40% at Marian Community Hospital in Carbondale, Pennsylvania; 65.64% at North Colorado Medical Center in Greeley, Colorado; 62.63% at Banner University Medical Center Phoenix (formerly Banner Good Samaritan Medical Center) in Phoenix, Arizona; 52.50% at UMass Memorial HealthAlliance-Clinton Hospital with campuses in Clinton, Fitchburg, and Leominster, Massachusetts; 47.55% at Northern Light Mercy Hospital in Portland, Maine; 44.65% at Mercy Hospital in Miami, Florida; and 42.93% at Samaritan Hospital in Troy, New York.

As with many aspects of Medicare, moreover, a hospital's DSH adjustment has consequences beyond the DSH adjustment itself. For instance, the size of its DSH percentage also determines whether a hospital may participate in the 340B Drug Pricing Program under the Public Health Service Act, which provides qualifying hospitals with substantial discounts on outpatient drugs. *See* 42 U.S.C. §256b(a)(4)(L). For many *amici*, how Part C days are treated in calculating the DSH adjustment will make the difference in whether they are eligible for the 340B

Maryland All-Payer Model, CMS, https://bit.ly/2Bj3XbK (last visited Dec. 20, 2018). But hospitals in all other 49 states do.

Program in a given year. Savings under the 340B Program are often substantial: "DSH hospitals … reported saving a median of $5 million to $10 million from 340B discounts in [FY 2017]," and 20 percent of those hospitals "reported more than $25 million in savings." *See* 340B Health, *Evaluating 340B Hospital Savings and Their Use in Serving Low-Income and Rural Patients: Results from 340B Health's 2017 Annual Survey* 4 (June 2018), https://bit.ly/2rGVyKK. Whether those considerable savings will be available is precisely the kind of information that Congress wanted hospitals to know *before* they have to finalize their pricing, cost allocations, and budget projections for the coming fiscal year and make all manner of forward-looking decisions on issues such as personnel recruitment and retention, capital expenditures, and building renovations.

Finally, while the Secretary seeks refuge in the complexity of the Medicare regime, that complexity only underscores the need for the fair notice and transparency that notice-and-comment engenders. The regulated community is by far the best positioned to understand the real-world impact of alterations to the Secretary's payment methodology. Requiring the Secretary not only to explain those changes in advance, but to consider and respond to the comments they prompt, is the best way to ensure that there is at least *some* measure of oversight in this admittedly complex area. That oversight is particularly critical because all too often "[t]he only thing that" seems to explain the Secretary's payment methodologies "is [his] apparent policy of paying out as little money as possible." *Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 20

n.1 (D.C. Cir. 2011) (Kavanaugh, J., concurring). Indeed, the notice-and-comment process once revealed that the Secretary had deprived hospitals of more than $1 billion over the course of a decade due to a simple math error—yet the Secretary would not even correct the error *prospectively* until the D.C. Circuit ordered him to do so. *See Cape Cod Hosp.*, 630 F.3d at 216. Particularly in a world with considerable deference to the Secretary's substantive decisions, meaningful procedural constraints can make all the difference.

* * *

In sum, Congress' decision to impose a more demanding notice-and-comment requirement under the Medicare Act than under the Administrative Procedure Act makes perfect sense. Meaningful advance notice of and dialogue about how payments and adjustments will be calculated is critical to ensuring that the PPS system achieves its intended ends. Moreover, requiring notice and comment for all changes to how payments and adjustments will be calculated imposes little additional administrative burden because the Secretary is already statutorily obligated to undertake a comprehensive notice-and-comment rulemaking addressing comprehensive PPS rates and adjustments each fiscal year. And the Secretary has long used that process, not other less formal tools, to address changes to the DSH adjustment. Thus, to the extent the Secretary now contends that such changes do not have to be done through notice-and-comment rulemaking, that approach is flatly at odds with the Secretary's long history of using notice and comment in precisely that way. Accordingly, this Court should affirm what is

clear on the face of the statute. If the Secretary wants to "establish[] or change[] a substantive legal standard governing … the payment for services," 42 U.S.C. §1395hh(a)(2), then the Secretary must do what he has been doing for decades: use notice-and-comment rulemaking.

II. The Tortured History Of This Case Underscores The Critical Role That Notice-And-Comment Rulemaking Serves.

Notice-and-comment rulemaking is particularly critical in the context of the DSH adjustment because the Secretary has an unfortunate history of trying to subvert Congress' intent and systematically reduce hospitals' DSH adjustments. *See Jewish Hosp., Inc. v. Sec'y of Health & Human Servs.*, 19 F.3d 270, 276 (6th Cir. 1994) (finding "credible and compelling" evidence of the agency's "hostil[ity] to the concept of [the] disproportionate share adjustment"). Indeed, the questions presented in this case arose only because the Secretary's efforts to alter how the DSH fractions would be calculated *sub silentio* failed, leaving the agency with the reinstated baseline standard in effect before 2004, which did not allow the Secretary to employ his now-preferred calculation methodology. While that history explains why the Secretary now finds himself advancing a position that is squarely at odds with how the agency has long administered both the Medicare Act generally and the DSH adjustment specifically, it certainly does not justify his effort to free himself from the constraints of notice-and-comment rulemaking. To the contrary, the tortured history behind this case underscores the critical role that notice-and-comment rulemaking plays in holding

the Secretary accountable in this exceedingly complex area.

A. The Secretary Has a Long History of Trying to Subvert the DSH Adjustment.

When Congress shifted to the prospective payment system in 1983, it recognized that low-income patients are, as a class, more costly to treat. Among other things, many low-income patients lack access to preventative medicine and suffer from poor nutrition, and hospitalization of low-income patients often results in the discovery of (and need to treat) health issues beyond those that prompted hospitalization (and thus beyond the reimbursement that the hospital will receive for treating the patient). As a result, hospitals that (like *amici*) treat a high percentage of low-income patients typically have higher-than-average costs per case for all patients (including patients who are not low-income). *See* H.R. Rep. No. 99-241(I), at 16 (1985), *reprinted in* 1986 U.S.C.C.A.N 579, 594 (finding that hospitals that treat a large proportion of low-income patients overall tend to incur higher costs per case due, in part, to the specialized services that they provide and other structural characteristics of these hospitals).

To ensure that hospitals would be able and incentivized to continue to provide care to those in need, Congress instructed the Secretary to make "exceptions and adjustments" to the new fixed rates "to take into account the special needs … of public or other hospitals that serve a significantly disproportionate number of patients who have low income or are entitled to benefits under part A of" Medicare. 42 U.S.C. §1395ww(d)(5)(C)(i) (1983). "The

'overriding intent' of Congress in establishing the DSH reimbursement was to 'supplement the prospective payment system payments of hospitals serving low-income persons[,]' … 'because those patients historically require comparatively greater resources in their care.'" *Alhambra Hosp. v. Thompson*, 259 F.3d 1071, 1075-76 (9th Cir. 2001).

Notwithstanding that mandate, the Secretary refused to make any such exceptions or adjustments, insisting they were not "warranted." 49 Fed. Reg. 234, 276 (Jan. 3, 1984). The next year, Congress once again attempted to force the Secretary to act, this time mandating that the Secretary at least adopt a definition for determining whether a hospital serves a significantly disproportionate number of low-income patients. *See* Deficit Reduction Act of 1984, Pub. L. No. 98-369, §2315(h), 98 Stat. 494, 1080. The Secretary once again did nothing. A number of hospitals then brought suit to compel the Secretary to comply with Congress' mandates. After the court ordered "the Secretary to publish [a] definition … on or before December 31, 1985," *Samaritan Health Ctr. v. Heckler*, 636 F. Supp. 503, 519 (D.D.C. 1985), the Secretary finally relented but adopted an unreasonably narrow definition of a disproportionate share hospital that would have included "only 1% of the hospital beds in the United States and only a handful of hospitals located in urban areas." *Samaritan Health Ctr. v. Bowen*, 646 F. Supp. 343, 346 (D.D.C. 1986); 50 Fed. Reg. 53,398, 53,398-400 (Dec. 31, 1985).

At that point, Congress took matters into its own hands and established its own statutory formula to

ensure that hospitals are adequately compensated for the services they provide to low-income patients. To that end, Congress instructed the Secretary to increase each qualifying hospital's annual reimbursement based on the extent to which the hospital's "disproportionate patient percentage" exceeds a certain threshold. Congress defined that percentage as the sum of two fractions:

> (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, 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.

42 U.S.C. §1395ww(d)(5)(F)(vi).

In essence, the first fraction (known in the regulated community as the Medicare fraction) asks, out of all days spent treating patients "entitled" to benefits under Part A of Medicare, what proportion is attributable to patients who are also "entitled" to supplemental security income ("SSI") benefits. In other words, the Medicare fraction uses entitlement to SSI benefits as a proxy for whether patients whose services are covered by Part A are low-income patients. The second fraction (known as the Medicaid fraction) asks, out of all patient days *total*, what proportion is attributable to patients who are "eligible" for Medicaid *but not* "entitled" to benefits under Part A. In other words, the Medicaid fraction uses eligibility for Medicaid as a proxy for whether patients are low-income, but excludes days attributable to patients who are both "eligible" for Medicaid and "entitled" to benefits under Part A, thereby ensuring that patient days covered by Part A are not double-counted in the two fractions. Combined, Congress intended this percentage to serve as a "proxy" for the number of low-income patients a hospital serves. *Ne. Hosp.*, 657 F.3d at 3 (citing H.R. Rep. No. 99-241(I), at 17).

Each fiscal year, a hospital's Medicare fraction is calculated by the Secretary, and its Medicaid fraction is calculated by one of the insurance companies that serve as audit agents for the Secretary (now known as "Medicare Administrative Contractors," and formerly known as "fiscal intermediaries"). Because the sum of the fractions is used as a multiplier to calculate a hospital's DSH adjustment, the greater the sum (and the greater each fraction), the greater the DSH adjustment.

The Secretary's reluctance to compensate DSH hospitals as Congress contemplated did not wane with the codification of the DSH adjustment formula. Shortly after Congress enacted that formula, the Secretary promulgated regulations that systematically reduced DSH adjustments by refusing to treat patients as "eligible" for Medicaid unless Medicaid actually paid for the specific services at issue. *See* 51 Fed. Reg. at 16,777. That regulation was challenged throughout the country, and court after court invalidated it as foreclosed by the plain text of the statute. *See, e.g.*, *Cabell Hunting Hosp., Inc. v. Shalala*, 101 F.3d 984, 988 (4th Cir. 1996); *Legacy Emanuel Hosp. & Health Ctr. v. Shalala*, 97 F.3d 1261, 1265 (9th Cir. 1996); *Deaconess Health Servs. Corp. v. Shalala*, 83 F.3d 1041, 1041 (8th Cir. 1996) (per curiam), *aff'g* 912 F. Supp. 438 (E.D. Mo. 1995); *Jewish Hosp. Inc. v. Sec'y of Health & Human Servs.*, 19 F.3d 270, 275 (6th Cir. 1994). Courts likewise concluded that the Secretary's effort to artificially decrease each hospital's Medicaid fraction was inconsistent with Congress' "overarching intent to compensate hospitals for serving low-income people" through the DSH adjustment. *Legacy Emanuel*, 97 F.3d at 1266; *see also, e.g.*, *Jewish Hosp.*, 19 F.3d at 275.

After this string of losses, the Secretary relented. But the Secretary soon began devising other methods of systematically decreasing the DSH adjustment to the financial detriment of hospitals serving those in need.

B. This Case Arises Out of a Failed Effort to Decrease DSH Adjustments *Sub Silentio*.

This case arises out of one such effort, involving beneficiaries of Part C of Medicare. Individuals who are eligible to participate in Medicare can obtain insurance under different "parts" of the program. Medicare Part A provides Medicare enrollees with government-administered health insurance through which the government makes direct payments to hospitals for healthcare services provided. *See* 42 U.S.C. §§1395c-1395i-5. Medicare Part C, by contrast, provides enrollees with government-subsidized enrollment in private insurance plans. *See id.* §§1395w-21-1395w-29.

Because Medicare Part A will not pay for services provided to patients enrolled in Medicare Part C, the Secretary traditionally treated such patients as not "entitled to benefits under Part A." *See Ne. Hosp.*, 657 F.3d at 15-17. This meant that patient days attributable to such patients were *not* included in the Medicare fraction (because both the numerator and the denominator of that fraction include only days for patients "entitled to benefits under Part A"), but *were* included in the numerator of the Medicaid fraction if they were eligible for Medicaid (because the numerator includes days for patients who were eligible for Medicaid benefits but *not* "entitled to benefits under Part A"), as well as in the denominator of the Medicaid fraction (which includes all patients). That practice was consistent with a rule enacted through notice and comment back in 1986 when the DSH adjustment was first codified that expressly included in the Medicare statute only patient days

actually "covered" by Part A. *See* 51 Fed. Reg. at 16,777; 42 C.F.R. §412.106(b)(2)(i) (2003).

In the proposed rulemaking for FY 2004, the Secretary addressed the calculation of the DSH adjustment (as the Secretary had done almost every year since 1986 and would continue to do almost every one of the next 15 years). *See* 68 Fed. Reg. 27,154, 27,201-08 (May 19, 2003). And, as to the treatment of Part C patients (also then known as "M+C patients"), that rulemaking "propos[ed] to clarify that once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary should *not* be included in the *Medicare* fraction of the DSH patient percentage," but "*should* be included in the count of total patient days in the *Medicaid* fraction (the denominator), and the patient's days for the M+C beneficiary who is also eligible for Medicaid would be included in the numerator of the Medicaid fraction." *Id.* at 27,208 (emphases added). In other words, the Secretary proposed to reaffirm his longstanding practice of treating patients who receive coverage under Part C as not "entitled to benefits under Part A."

The Secretary did not end up promulgating this (or any other) rule governing the treatment of Part C patients in the final rule for FY 2004. *See* 68 Fed. Reg. 45,346, 45,422 (Aug. 1, 2003). Instead, the Secretary put the issue off. *See* 69 Fed. Reg. 28,196, 28,286 (May 18, 2004). When the Secretary released the FY 2005 Rule, however, the agency did an about-face. Instead of adopting the position that had been proposed in the FY 2004 rulemaking and followed for years, the Secretary announced that, henceforth, Part C days

"should be *included* in the *Medicare* fraction of the DSH calculation," and *excluded* from the *Medicaid* fraction—*i.e.*, exactly the opposite of what the Secretary had proposed in 2003. 69 Fed. Reg. 48,916, 49,099 (Aug. 11, 2004) (emphases added). In support of this abrupt 180-degree change of course, the Secretary offered only the feeble explanation that even though Part A will not pay for inpatient services provided to someone who has elected coverage under Part C, Part C beneficiaries "are still, in some sense, entitled to benefits under Medicare Part A." *Id.*

The Secretary did not acknowledge the massive consequences of this change in the FY 2005 rulemaking, but its ultimate impact was to "decrease[] the DSH adjustment that hospitals receive" to the tune of "hundreds of millions of dollars." *Ne. Hosp.*, 657 F.3d at 5.[3] Indeed, even that estimate ultimately proved far too conservative, as the government has now estimated that this issue "affects between $3 and $4 billion in Medicare funding." Pet.14.[4]

---

[3] As the D.C. Circuit explained, *including* Part C patient days in the Medicare fraction "dilutes th[at] fraction because M+C enrollees are less likely to qualify for SSI benefits than non-M+C enrollees," meaning their inclusion will increase the denominator far more than the numerator. *Ne. Hosp.*, 657 F.3d at 5. Conversely, *excluding* such days from Medicaid fraction dilutes that fraction because "counting M+C patients among patients 'entitled to benefits under Part A' decreases the numerator of the fraction (all patients 'eligible for [Medicaid]' *but not* 'entitled to benefits under Part A') and has no effect on the denominator ('total number of patient[s]')." *Id.* As a result, each fraction, as well as their sum, is smaller, producing a smaller DSH adjustment.

[4] The government has conveniently re-characterized the financial significance of this litigation based on whether it was

C. The Secretary's Failure to Provide *Effective* Notice and Comment in 2004 Does Not Entitle Him to Effectuate His Preferred Payment Policy Unilaterally.

As then-Judge Kavanaugh explained when the FY 2005 Rule was first challenged in court, the rule should have failed under the plain language of the Medicare Act because a patient cannot "be both enrolled in Part C and entitled to Part A benefits *for the same day*." *Ne. Hosp.*, 657 F.3d at 19 (Kavanaugh, J., concurring). "Medicare beneficiaries must choose between government-subsidized private insurance plans under Part C and government-administered insurance under Part A," and "after they choose, they are obviously not entitled on the same 'patient day' to benefits from both kinds of plans." *Id.* at 18. Nonetheless, a two-judge majority in the *Northeast Hospital* case found that the phrase "entitled to benefits under Part A" left a gap for the Secretary to fill. 657 F.3d at 5, 11-13.

The majority decided not to reach the question of whether the Secretary's new rule could survive, however, as *Northeast Hospital* involved only an effort to apply the rule *retroactively*. And on that question, the judges were unanimous: The Secretary could not

---

trying to get the Court's attention (as in its petition) or trying to minimize the impact of its sudden change in position (as in its merits brief). In reality, the financial impact is and always has been substantial, which only underscores that the Secretary's change in position was indeed a "rule, requirement, or other statement of policy … that establishe[d] or change[d] a substantive legal standard governing … the payment for services," and thus required notice-and-comment rulemaking. 42 U.S.C. §1395hh(a)(2).

apply this new rule to fiscal years past. While the Secretary argued (as he does again here) that the rule "merely confirmed [the Secretary's] longstanding view" that Part C beneficiaries "are still 'entitled to benefits under Part A,'" the court found precisely the opposite: Before 2004, "the Secretary routinely *excluded* M+C days from the Medicare fraction." *Id.* at 14-15; *see also Allina I*, 746 F.3d at 1106 ("Prior to 2003, the Secretary treated Part C patients as *not* entitled to benefits under Part A.").

Indeed, until 2007 (*i.e.*, a decade after Medicare Part C was enacted), the Secretary had not even asked all hospitals to provide the data that would have been needed to include those days in the fraction. In fact, the Secretary affirmatively told hospitals in 1998—*i.e.*, the year after Congress enacted Medicare Part C—"*not* to submit information that [CMS would have] needed to count M+C days in the Medicare fraction." *See Ne. Hosp.*, 657 F.3d at 15 (citing Program Memorandum (Intermediaries), HCFA Pub. 60A, Transmittal No. A–98–21 (July 1, 1998)). As the D.C. Circuit thus concluded, there can be no serious dispute that the Secretary was excluding Part C days from the Medicare fraction before the FY 2005 Rule tried to change course, as the Secretary did not even have the data necessary to include them. Indeed, the Secretary *still* does not have the data for FY 2005 and thus could not apply the FY 2005 Rule consistently across the years in question. Because of this clear prior practice, the court concluded that "the Secretary's present interpretation, which marks a substantive departure from [his] prior practice of excluding M+C days from

the Medicare fraction, may not be retroactively applied to fiscal years 1999-2002." *Id.* at 17.[5]

That left the question of whether the Secretary could apply the FY 2005 Rule going forward. And on that question, the D.C. Circuit said no as well, invalidating the rule on the ground that "the Secretary's final rule was not a logical outgrowth of the proposed rule." *Allina I*, 746 F.3d at 1109. As the court recognized, "[t]here is nothing in the text of the notice[] … to suggest that the Secretary was thinking of reconsidering a longstanding practice." *Id.* at 1108. To the contrary, "the notice indicated that 'there should not be a major impact associated with this change,'" which certainly would not be the case had the Secretary been considering a reversal of course that would cost hospitals billions of dollars. *Id.* (citing 68 Fed. Reg. at 27,416). The court thus concluded that "a reasonable member of the regulated class—even a good lawyer—[would not] anticipate that such a volte-face with enormous financial implications would follow the Secretary's proposed rule." *Id.* at 1109; *see also id.* at 1108 ("[A] party reviewing the Secretary's notice of proposed rulemaking understandably would have assumed that the Secretary was proposing to 'clarify' a then-existing policy, *i.e.*, one of excluding Part C days from the Medicare fraction and including them in the Medicaid fraction.").

---

[5] Contrary to the Secretary's contention that "the agency never promulgated its pre-2004 practice through notice-and-comment rulemaking," as explained, *see supra* pp.24-25, the Secretary had long had in place a rule under which the DSH Medicare fraction included only patient days that were actually "covered" by Medicare Part A.

By now acutely aware that a significant amount of money was at stake (although still not acknowledging that impact—or even the change itself—to the regulated community or the courts), the Secretary insisted on taking another stab at converting patient days for which Medicare Part A will not pay into days on which the patient nonetheless is "entitled to benefits under Part A." And the Secretary did so the same way the Secretary did in 2003: by utilizing the notice-and-comment rulemaking process. In 2013, the Secretary proposed that, in its final rule for FY 2014, it would declare Part C patients "entitled to benefits under Part A." 78 Fed. Reg. at 27,578. And later that same year, the Secretary did indeed promulgate that rule in its final rule for FY 2014. 78 Fed. Reg. at 50,614-15, 50,620. The Secretary chose not even to try to invoke its limited retroactive rulemaking authority under §1395hh(e), leaving him with no rule that allowed him to treat patients whose services were covered by Part C as "entitled to benefits under Part A" when calculating hospitals' Medicare fractions for years pre-dating the FY 2014 Rule.

Of course, there was an easy solution to this conundrum: follow the *true* longstanding practice and policy of *excluding* Part C days from the Part-A-entitled days in the Medicare fraction, just as the Secretary had done for years before trying to abruptly change course in 2004. Indeed, that was the only course consistent with the concerns animating *Northeast Hospital* and *Allina I*, as the whole point of those cases was to prevent the Secretary from effectuating this massive policy change in how DSH adjustments are calculated without giving hospitals fair notice. *See Allina I*, 746 F.3d at 1108

(admonishing Secretary that "agencies may not 'pull a surprise switcheroo on regulated entities'"). But the Secretary could not let it go. In June 2014, the Secretary published a spreadsheet containing the Medicare fractions for every hospital in the nation, to be used in calculating each hospital's FY 2012 DSH adjustment. *See* Pet.App.5a-6a, 24a, 32a & n.2; FY 2012 SSI Ratios, CMS, https://go.cms.gov/2CmkPju (last visited Dec. 20, 2018). And the spreadsheet summarily declared, without explanation, that the Part C days were included in these Medicare fractions. In other words, the Secretary attempted to impose by fiat, rather than through notice and comment or under §1395hh(e), exactly the same "substantive departure from her prior practice of excluding M+C days from the Medicare fraction," *Ne. Hosp.*, 657 F.3d at 17, that the FY 2005 Rule had failed to achieve.

* * *

As the foregoing illustrates, this case does not arise out of an effort to force the Secretary to use notice and comment in a novel, or even unusual, context. To the contrary, the Secretary himself voluntarily used notice-and-comment rulemaking each prior time he sought to alter (or, as he would put it, "clarify") his policy for calculating the fractions used to determine a hospital's DSH adjustment—first in 2004, and then again in 2013. Indeed, as explained, *supra* Part I.A, the Secretary routinely uses notice-and-comment rulemaking for all manner of issues relating to the calculation of the DSH payment adjustment. The Secretary departed from that practice for the fiscal year at issue here only because the agency's effort to effectuate its preferred policy

through the 2004 rulemaking *failed*, on account of its failure to provide the regulated community with the notice necessary to enable it to comment, and the Secretary could not apply his FY 2014 Rule retroactively.

This is thus the very last case in which the Court should free the Secretary from the constraints of notice-and-comment rulemaking, as the Secretary abandoned that process only in a last-ditch effort to salvage a failed rulemaking and circumvent the statutory constraints on his authority to make retroactive rules. Not only does that confirm that the decision below should be affirmed regardless of how the Court answers the first question presented. *See* 42 U.S.C. 1395hh(a)(2). It also confirms that requiring the Secretary to employ notice-and-comment before effectuating a policy change of this magnitude would not impose any serious or novel burden—let alone "cripple effective administration of the Medicare program." Pet'r.Br.18. Instead, as Congress recognized in both Section 1395hh(a)(2) and Section 1395hh(a)(4), notice and comment is the best antidote to the Secretary's seeming inability to resist the temptation to try to effectuate billion-dollar changes to the Medicare payment scheme *sub silentio*.

CONCLUSION

For the foregoing reasons, this Court should affirm the judgment of the D.C. Circuit.

Respectfully submitted,

PAUL D. CLEMENT
Counsel of Record
ERIN E. MURPHY
LAUREN N. BEEBE
KIRKLAND & ELLIS LLP
655 Fifteenth Street, NW
Washington, DC 20005
(202) 879-5000
paul.clement@kirkland.com

Counsel for Amici Curiae

December 20, 2018

APPENDIX

APPENDIX OF AMICI CURIAE

Albany Memorial Hospital, *Provider No. 33-0003 (New York)*

Banner Baywood Medical Center, *Provider No. 03-0088 (Arizona)*

Banner Casa Grande Medical Center (formerly Casa Grande Regional Medical Center), *Provider No. 03-0016 (Arizona)*

Banner Del E. Webb Medical Center, *Provider No. 03-0093 (Arizona)*

Banner Desert Medical Center, *Provider No. 03-0065 (Arizona)*

Banner Estrella Medical Center, *Provider No. 03-0115 (Arizona)*

Banner Gateway Medical Center, *Provider No. 03-0122 (Arizona)*

Banner Goldfield Medical Center, *Provider No. 03-0134 (Arizona)*

Banner Mesa Lutheran Medical Center (formerly Mesa Lutheran Medical Center), *Provider No. 03-0018 (Arizona)*

Banner Thunderbird Medical Center, *Provider No. 03-0089 (Arizona)*

Banner University Medical Center Phoenix (formerly Banner Good Samaritan Medical Center), *Provider No. 03-0002 (Arizona)*

Berkshire Medical Center, *Provider No. 22-0046 (Massachusetts)*

Bethesda Hospital, *Provider No. 36-0179 (Ohio)*

Central Washington Hospital, *Provider No. 50-0151 (Washington)*

CHI Health Creighton University Medical Center - Bergan Mercy (formerly Bergan Mercy Medical Center), *Provider No. 28-0060 (Nebraska)*

CHI Health Creighton University Medical Center - University Campus, *Provider No. 28-0030 (Nebraska)*

CHI Health Good Samaritan, *Provider No. 28-0009 (Nebraska)*

CHI Health Immanuel, *Provider No. 28-0081 (Nebraska)*

CHI Health Mercy Council Bluffs, *Provider No. 16-0028 (Iowa)*

CHI Saint Alexius Health Bismarck, *Provider No. 22-0074 (North Dakota)*

CHI Health Saint Elizabeth, *Provider No. 28-0020 (Nebraska)*

CHI Health Saint Francis, *Provider No. 28-0023 (Nebraska)*

CHI Saint Luke's Health - Baylor St. Luke's Medical Center (formerly Saint Luke's Episcopal Hospital), *Provider No. 45-0193 (Texas)*

CHI Saint Luke's Health - Sugar Land Hospital, *Provider No. 67-0053 (Texas)*

CHI Saint Luke's Health - The Vintage Hospital, *Provider No. 57-0075 (Texas)*

CHI Saint Luke's Health - The Woodlands Hospital, *Provider No. 45-0862 (Texas)*

CHI Saint Vincent Infirmary Medical Center, *Provider No. 04-0007 (Arkansas)*

CHI Saint Vincent North, *Provider No. 04-0137 (Arkansas)*

The Christ Hospital, *Provider No. 36-0163 (Ohio)*

Flaget Memorial Hospital, *Provider No. 18-0025 (Kentucky)*

Good Samaritan Hospital, *Provider No. 36-0134 (Ohio)*

Harrison Medical Center, *Provider No. 50-0039 (Washington)*

Heywood Hospital, *Provider No. 22-0095 (Massachusetts)*

Highline Medical Center - CHI Franciscan Health, *Provider No. 50-0011 (Washington)*

Jewish Hospital & Saint Mary's HealthCare, *Provider No. 18-0040 (Kentucky)*

Jewish Hospital Shelbyville, *Provider No. 18-0016 (Kentucky)*

Lourdes Medical Center of Burlington County (formerly Rancocas Hospital), *Provider No. 31-0061 (New Jersey)*

Marian Community Hospital, *Provider No. 39-0095 (Pennsylvania)*

McKee Medical Center, *Provider No. 06-0030 (Colorado)*

Memorial Hermann Hospital System, *Provider No. 45-0184 (Texas)*

Memorial Hermann Katy Hospital, *Provider No. 45-0847 (Texas)*

Memorial Hermann Memorial City Medical Center, *Provider No. 45-0610 (Texas)*

Memorial Hermann Northeast Hospital, *Provider No. 45-0684 (Texas)*

Memorial Hermann Sugar Land Hospital, *Provider No. 45-0848 (Texas)*

Memorial Hermann Texas Medical Center, *Provider No. 45-0068 (Texas)*

Mercy Catholic Medical Center, Provider No. 39-0156 (Pennsylvania)

Mercy Hospital - Miami, *Provider No. 10-0061 (Florida)*

Mercy Medical Center - Springfield, *Provider No. 22-0066 (Massachusetts)*

Mercy Medical Center - Williston, *Provider No. 35-0017 (North Dakota)*

Mercy Medical Center - Roseburg, *Provider No. 38-0027 (Oregon)*

Mercy Medical Center - Des Moines, *Provider No. 16-0083 (Iowa)*

Nazareth Hospital, *Provider No. 39-0204 (Pennsylvania)*

North Colorado Medical Center, *Provider No. 06-0001 (Colorado)*

Our Lady of Lourdes Medical Center, *Provider No. 31-0029 (New Jersey)*

Northern Light Mercy Hospital, *Provider No. 20-0008 (Maine)*

Saint Clare Hospital, *Provider No. 50-0021 (Washington)*

Saint Francis Hospital - Federal Way, *Provider No. 50-0141 (Washington)*

Saint Francis Hospital - Wilmington, *Provider No. 08-0003 (Delaware)*

Saint Francis Medical Center, *Provider No. 31-0021 (New Jersey)*

Saint Joseph East, *Provider No. 18-0143 (Kentucky)*

Saint Joseph Hospital, *Provider No. 18-0010 (Kentucky)*

Saint Joseph London Hospital, *Provider No. 18-0011 (Kentucky)*

Saint Joseph Medical Center, *Provider No. 50-0108 (Washington)*

Saint Mary's Health Care System, Inc., *Provider No. 11-0006 (Georgia)*

Saint Michael's Medical Center, *Provider No. 31-0096 (New Jersey)*

Saint Peter's Hospital, *Provider No. 33-0057 (New York)*

Samaritan Hospital, *Provider No. 33-0180 (New York)*

Seton Health, *Provider No. 33-0232 (New York)*

Signature Healthcare Brockton Hospital, *Provider No. 22-0052 (Massachusetts)*

South County Hospital, *Provider No. 41-0008 (Rhode Island)*

Southwest Consulting Associates

Suburban Community Hospital (formerly Mercy Suburban Hospital), *Provider No. 39-0116 (Pennsylvania)*

University of Arkansas Medical Sciences Medical Center, *Provider No. 04-0016 (Arkansas)*

UMass Memorial - HealthAlliance Hospital, *Provider No. 22-0001 (Massachusetts)*

UMass Memorial HealthAlliance-Clinton Hospital, *Provider No. 22-0058 (Massachusetts)*

UMass Memorial - Marlborough Hospital, *Provider No. 22-0049 (Massachusetts)*

UMass Memorial Medical Center, *Provider No. 22-0163 (Massachusetts)*

Vanderbilt University Medical Center, *Provider No. 44-0039 (Tennessee)*