[ORAL ARGUMENT NOT YET SCHEDULED]
No. 16-5255

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

ALLINA HEALTH SERVICES, *et al.*,
Plaintiffs-Appellants,

v.

THOMAS E. PRICE, M.D., Secretary, United States Department of Health and Human Services,
Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

BRIEF FOR APPELLEE THOMAS E. PRICE, M.D.

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Counsel for the Department of Justice certifies the following:

A. Parties and Amici.

Allina Health Services d/b/a United Hospital d/b/a Unity Hospital, d/b/a Abbott Northwestern Hospital; Florida Health Sciences Center d/b/a Tampa General Hospital; Montefiore Medical Center; Mount Sinai Medical Center of Florida, Inc. d/b/a Mount Sinai Medical Center; New York Hospital Medical Center of Queens; New York Methodist Hospital; and New York and Presbyterian Hospital d/b/a New York Presbyterian Hospital Weill Cornell Medical Center were plaintiffs before the district court and appear as appellants before this Court.

Sylvia M. Burwell, in her official capacity as Secretary of the United States Department of Health and Human Services ("Secretary"), was the defendant before the district court and appeared as appellee before this Court. Pursuant to Fed. R. App. P. 43(c)(2), the successors to public officers who have left office are automatically substituted as parties. Accordingly, Thomas E. Price, M.D., the current Secretary of Health and Human Services appears in his official capacity as appellant before this Court.

No intervenors or amici appeared in the district court proceedings.

B. Rulings Under Review.

Plaintiffs seek review of the August 17, 2016 final order and memorandum opinion of the district court (Kessler, J.), granting summary judgment to the Secretary in *Allina Health Services* v. *Burwell*, D.D.C. No. 14-1415, which will be reported at –- F. Supp.3d --, 2016 WL 4409181(D.D.C. 2016). Prior to entering the August 17, 2016 final order, the district court issued an order and opinion denying the Secretary's motion to dismiss for lack of subject matter jurisdiction, which is reported at 141 F. Supp.3d 17 (D.D.C. 2015).

C. Related Cases.

This case has not previously been before this Court. Plaintiffs in the present case were also plaintiffs in *Allina Health Services v. Sebelius*, 746 F.3d 1102 (D.C. Cir. 2014) (hereinafter *Allina I*), which involved related issues and the same defendant. Plaintiffs in *Allina I* filed another action, *Allina Health System* v. *Burwell*, D.D.C. No. 16-150, which also involves related issues and the same defendant. That case is currently pending in the United States District Court for the District of Columbia and challenges the Secretary's decision on remand following this Court's decision in *Allina I*.

Additional cases involving the same defendant and related legal issues are also currently pending in the United States District Court for the District of Columbia: (1) *Adcare Hosp. of Worcester, Inc.* v. *Burwell*, (D.D.C. No. 10-2009); (2) *Miriam Hosp.* v. *Burwell*, (D.D.C. No. 11-704); (3) *Sisters of Charity Hosp. v. Burwell*, (D.D.C. No. 13-304);

(4) *Integris Southwest Med. Ctr. v. Burwell*, (D.D.C. No. 13-858); (5) *Novant Health Forsyth Med. Ctr. v. Burwell*, (D.D.C. No. 14-1054); (6) *University of Arizona Med. Ctr. v. Burwell*, (D.D.C. No. 14-1558); (7) *Community Mem. Hosp. of San Buenaventura v. Burwell*, (D.D.C. No. 14-1592); (8) *Bethesda Mem. Hosp. v. Burwell*, (D.D.C. No. 14-2068); and (9) *Allina Health System v. Burwell*, (D.D.C. No. 15-800).

Respectfully submitted,

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TABLE OF CONTENTS

Page(s)

TABLE OF AUTHORITIES

Cases: **Page(s)**

* Authorities upon which we chiefly rely are marked with asterisks.

Statutes:

Administrative Procedure Act:

Social Security Act:

Regulations:

Rule:

Other Authorities:

GLOSSARY

"APA"	Administrative Procedure Act
"BBA"	Balanced Budget Act of 1997
"Board"	Provider Reimbursement Review Board
"CMS"	Centers for Medicare & Medicaid Services
"DSH"	Disproportionate share hospital
"EJR"	Expedited Judicial Review
"FY"	Fiscal year
"HHS"	United States Department of Health and Human Services
"HMO"	Health maintenance organization
"IPPS"	Inpatient Prospective Payment System
"NPR"	Notice of Program Reimbursement
"PRRB"	Provider Reimbursement Review Board
"Secretary"	Secretary of Health and Human Services
"SSI"	Supplemental security income

STATEMENT OF SUBJECT MATTER AND APPELLATE JURISDICTION

Plaintiffs' complaint invoked the district court's jurisdiction under 42 U.S.C. 1395oo(f)(1). R1 at ¶4, JA -.[1] The government moved to dismiss for lack of subject matter jurisdiction, and, on October 30, 2015, the district court denied the motion. R23, JA -. As we explain below, plaintiffs failed to satisfy Medicare statute requirements for obtaining expedited judicial review, and the district court thus lacked subject matter jurisdiction. On August 17, 2016, the district court issued a final order entering summary judgment in favor of the government. R38, JA -. Plaintiffs filed a timely notice of appeal on August 26, 2016. R40. This Court has jurisdiction over the appeal under 28 U.S.C. 1291.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

In this case, plaintiff hospitals challenge the Secretary of Health and Human Services (Secretary)'s[2] treatment of the patient days of individuals enrolled in Medicare

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[1] Citations to the record include the page or paragraph number therein, in the following form: "R[docket number] at --." When a document is designated for the Joint Appendix, an additional cite will appear as follows: "JA -."

[2] Pursuant to Fed. R. App. P. 43(c)(2), Thomas E. Price, M.D., the current Secretary, is automatically substituted for Sylvia Mathews Burwell.

Part C for purposes of calculating plaintiffs' disproportionate share hospital (DSH) adjustment for fiscal year (FY) 2012. The questions presented are:

1. Whether the district court erred by holding that it had subject matter jurisdiction over plaintiffs' case pursuant to 42 U.S.C. 1395oo(f)(1).

2. Whether the district court correctly held that the Secretary was not required to engage in notice-and-comment rulemaking under the Administrative Procedure Act (APA) or the Medicare statute prior to including Medicare Part C patient days in plaintiffs' Medicare/SSI DSH fractions for FY 2012.

3. Whether the district court correctly held that the Secretary provided a reasoned explanation for including Medicare Part C patient days in the Medicare/SSI fraction of the DSH calculation.

STATUTES AND REGULATIONS INVOLVED

Relevant statutory and regulatory provisions are attached in addenda to this brief and plaintiffs-appellants' opening brief.

STATEMENT OF THE CASE

A. Nature Of The Case And Factual Background.

1. Plaintiffs are nine hospitals that challenge the Secretary's calculation of their Medicare payments for fiscal year (FY) 2012 with respect to adjustments – known as "disproportionate share hospital" or "DSH" adjustments – that reflect their provision of care to disproportionate numbers of low-income patients. In calculating such

adjustments, as discussed in greater detail below, it is necessary to determine the patient days attributable to patients "entitled to benefits under [Medicare] part A." 42 U.S.C. 1395ww(d)(5)(F)(vi). Under the Secretary's interpretation, Medicare Part C enrollees, who receive their Medicare benefits through managed care organizations, are "entitled to benefits under part A" because to enroll in Part C, they must meet the statutory criteria for entitlement to Medicare Part A benefits (42 U.S.C. 1395w-21(a)(3)), and they continue to do so after enrollment.

2. This Court previously addressed a 2004 regulation in which HHS explained that it was including Part C days in calculating the number of patient days attributable to individuals entitled to benefits under Medicare Part A for purposes of the DSH calculation. See *Allina Health Services v. Sebelius*, 746 F.3d 1102 (D.C. Cir. 2014) ("*Allina I*"). The Court affirmed the vacatur of that portion of the 2004 Final Rule on the ground that it violated the APA notice requirement. At the same time, however, the Court reversed the district court's order insofar as it prohibited the Secretary from applying her interpretation to the *Allina I* plaintiffs' FY 2007 DSH adjustments on remand. Subsequent to the district court's decision in *Allina I*, in 2013, the Secretary issued a regulation following notice-and-comment rulemaking explaining that the agency would continue to treat Medicare Part C patients as entitled to Part A benefits in calculating DSH payments. See 78 Fed. Reg. 50,496, 50,614-20 (Aug. 19, 2013). And in the remand proceedings in *Allina I*, the Secretary issued a final decision in

2015 applying the same interpretation. R29-4, JA -. Plaintiffs' challenge to that decision is pending in district court. See *Allina Health System v. Burwell*, D.D.C. No. 16-150.

3. In the present case, plaintiffs – who were all plaintiffs in *Allina I* – seek to challenge the Secretary's treatment of Part C patient days in calculating their DSH payments for FY 2012. Under the Medicare statute, hospitals that challenge Medicare payment determinations must exhaust administrative remedies before the Provider Reimbursement Review Board (PRRB or Board) prior to seeking judicial review in district court. The Medicare statute and applicable regulations provide for a narrow exception under which the Board may grant expedited judicial review (EJR) when a hospital's appeal turns on the validity of statutory provisions or agency regulations. The Board must deny EJR, however, whenever a hospital neither challenges the constitutionality of a statute nor the validity of an agency regulation or CMS Ruling. Here, the Board authorized expedited judicial review because in its view, it was bound by the Secretary's 2004 Final Rule and lacked authority to decide the legality of the Secretary's challenged actions after *Allina I*.

In district court, the Secretary moved to dismiss on jurisdictional grounds because the Board committed clear error. The Secretary explained that the Board could not have been bound by the 2004 rule because this Court had affirmed vacatur of the rule in *Allina I*. The district court denied the motion, holding that EJR was

proper because the Board lacked authority to decide plaintiffs' claims that HHS applied the vacated 2004 Final Rule to their DSH calculations for FY 2012 and that the agency's treatment of Part C days improperly adopted a new rule.

Accordingly, the district court reached the merits and granted summary judgment for the Secretary. The court held that the Secretary's treatment of Part C days in calculating DSH payments did not constitute a legislative rule and therefore did not require notice-and-comment rulemaking. The court further concluded that HHS had provided a reasonable explanation for its interpretation of the statute and that there was no basis for setting aside the agency's challenged action. This appeal followed.

B. Statutory And Regulatory Framework.

1. Medicare DSH Adjustment.

The Medicare program, Title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*, provides health insurance coverage to individuals who are at least 65 years old and are entitled to monthly Social Security benefits, and to disabled individuals who meet specified eligibility requirements. 42 U.S.C. 426(a), (b). Those persons are automatically entitled to benefits under Medicare Part A, which authorizes payments for covered inpatient hospital, home health and hospice treatment and related services. 42 U.S.C. 426(a). The Secretary administers the program through the Centers for Medicare & Medicaid Services (CMS).

Generally, under the Medicare hospital inpatient prospective payment system, Medicare pays hospitals for inpatient services furnished to Medicare beneficiaries on the basis of prospectively determined rates. Hospitals that "serve[] a significantly disproportionate number of low-income patients" may receive a "disproportionate share hospital" or "DSH" adjustment. 42 U.S.C. 1395ww(d)(5)(F)(i)(I). Whether a hospital qualifies for the Medicare DSH adjustment and the amounts of any adjustment depend on the hospital's "disproportionate patient percentage." See 42 U.S.C. 1395ww(d)(5)(F)(v). As defined by statute, the "disproportionate patient percentage" is calculated by adding two fractions: (i) the Medicare/SSI fraction, and (ii) the Medicaid fraction. 42 U.S.C. 1395ww(d)(5)(F)(vi)(I) & (II). The Medicare/SSI fraction is a proxy for the percentage of low-income Medicare patients. The numerator of the Medicare/SSI fraction consists of "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 [Medicare] part A" and "were entitled to [SSI] benefits," while the denominator consists of "patient days for such fiscal year which were made up of patients who (for such days) were entitled to benefits under [Medicare] part A." 42 U.S.C. 1395ww(d)(5)(F)(vi)(I).

The Medicaid fraction is a proxy for low-income non-Medicare patients. The numerator consists of those patient days attributable to "patients who (for such days)

were eligible" for Medicaid, but "not entitled to benefits under [Medicare] part A," and the denominator consists of total patient days. 42 U.S.C. 1395ww(d)(5)(F)(vi)(II).

2. Medicare Payment Determinations.

Hospitals submit cost reports at the end of each fiscal year to contractors, known as Medicare Administrative Contractors (MACs or contractors), which are generally private insurance companies that perform certain functions on behalf of CMS. See 42 C.F.R. 405.1801(b)(1), 413.24(f). CMS determines the Medicare/SSI fraction of the DSH adjustment and provides that information to the contractors. 42 C.F.R. 412.106(b)(2). The contractor determines the total payment (including any hospital-specific adjustments) and issues a Notice of Program Reimbursement (NPR), informing the provider how much it will be paid for the fiscal year at issue. 42 C.F.R. 405.1803.

If a provider that has filed a timely cost report is dissatisfied with its NPR and meets the amount-in-controversy requirement, it may appeal to the PRRB "if * * * [it] files a request for a hearing within 180 days after notice of the intermediary's final determination." 42 U.S.C. 1395oo(a). If a provider has not received an NPR from the contractor within 12 months of filing a cost report and meets the amount-in-controversy requirement, the provider may appeal to the Board if it files a request for a hearing within 180 days after notice of the contractor's final determination "would have been received" if timely. See *id.*; 42 C.F.R. 405.1835(c). The decision of the

Board is final unless the Secretary reverses, affirms, or modifies the decision within 60 days.[3] 42 U.S.C. 1395oo(f)(1). A hospital may seek judicial review of "any final decision of the Board" by filing suit in federal district court within 60 days. *Id.*

If "the Board determines (on its own motion or at the request of a provider * * *) that it is without authority to decide" a "question of law or regulations" presented by the hospital, the Board may grant expedited judicial review (EJR), allowing the provider to proceed directly to federal district court. 42 U.S.C. 1395oo(f)(1); see 42 C.F.R. 405.1842(f)(1)(ii). The Board "must deny EJR," however, if the legal question at issue is "neither a challenge to the constitutionality of a provision of a statute, nor a challenge to the substantive or procedural validity of a regulation or CMS Ruling." 42 C.F.R. 405.1842(f)(2)(ii).

3. Medicare Part C.

From 1972 to 1998, as an alternative to the traditional fee-for-service system, Medicare beneficiaries could enroll with a managed care organization, such as a health maintenance organization (HMO), which entered into a payment contract with Medicare. Those contracts were governed by section 1876 of the Social Security Act, 42 U.S.C. 1395mm. Section 1876 provided for two types of contracts: (1) "cost" contracts under which a managed care organization was reimbursed for its reported

[3] The Secretary has authorized the Administrator of CMS to act on his behalf in reviewing the Board's decisions, and the Administrator's decision on review of a Board ruling is considered the final decision of the Secretary. 42 C.F.R. 405.1875.

costs (subject to auditing for reasonableness); and (2) "risk" contracts, under which Medicare made fixed monthly payments. 42 U.S.C. 1395mm(a), (g), (h).

The Balanced Budget Act of 1997 (BBA), Pub. L. No. 105 -33, 111 Stat. 251, 426-32 (Aug. 5, 1997), provided that section 1876 risk contracts could not be renewed after January 1, 1999. See 42 U.S.C. 1395mm(k)(1)(B). The BBA added a new "Part C" to the Medicare statute, also called Medicare + Choice (or M+C).[4] See 42 U.S.C. 1395w-21-1395w-28. Part C expanded the types of private health plans through which Medicare beneficiaries may receive coverage of the Part A benefits to which they are entitled and the Part B benefits for which they have enrolled. See 42 U.S.C. 1395w-21(a)(1).

To enroll in Medicare Part C, a beneficiary must be "entitled to benefits under [Medicare] part A * * * and enrolled under [Medicare] part B." 42 U.S.C. 1395w-21(a)(3). For Medicare beneficiaries enrolled in Part C plans, the Medicare program does not directly pay hospitals. Instead, using money from the Medicare Part A and Part B trust funds, Medicare pays the Part C plan a predetermined per-patient rate. See 42 U.S.C. 1395w-23(f).

[4] The M+C program is now known as the Medicare Advantage (MA) program. See Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, § 201(b), 117 Stat. 2066, 2176. References herein to "Part C" patient days encompass M+C days before the change and MA days thereafter.

4. 2004 Rulemaking.

In the years following the creation of Medicare Part C, CMS began to receive questions about how Part C patient days should be treated in calculating hospitals' DSH adjustments. See 68 Fed. Reg. 27,154, 27,208 (May 19, 2003). In the 2004 final rule, the Secretary sided with commenters who argued that Part C days belong in the Medi*care* fraction, because M+C enrollees are "just as much Medicare beneficiaries as those beneficiaries in the traditional fee-for-service program." 69 Fed. Reg. 48,916, 49,099 (Aug. 11, 2004) (2004 Final Rule). In the 2004 Final Rule, the agency thus stated that it was "revising [its] regulations" – which at the time simply parroted the ambiguous language of the statute – to specifically "include the days associated with M+C beneficiaries in the Medicare fraction of the DSH calculation." *Id.*

C. Prior Proceedings In *Allina I* And The Present Litigation.

1. *Allina I* Litigation.

a. Plaintiffs in the present case were also plaintiffs in *Allina I*, in which they challenged the Secretary's treatment of Medicare Part C patient days for purposes of their FY 2007 Medicare DSH calculations. See Compl. ¶1, JA -. In *Allina I*, the district court held that HHS violated the APA's notice requirement in the 2004 Final Rule when it determined that Part C days should be included in the Medicare/SSI fraction. 904 F. Supp. 2d 75, 89-92 (D.D.C. 2012). With respect to remedy, the court

vacated the relevant portion of the 2004 Final Rule and prohibited the Secretary from applying her interpretation to plaintiffs on remand. *Id.* at 95.[5]

On appeal, this Court affirmed the district court's vacatur of the portion of the Secretary's 2004 Final Rule that addressed the treatment of Part C patient days. See *Allina*, 746 F.3d at 1110-1111. Most significant for the present appeal, however, this Court held that the district court erred by directing the agency how to calculate plaintiffs' DSH adjustments, and thus reversed the district court's order prohibiting the Secretary from applying her interpretation on remand. *Id.* at 1111. The Court explained that because the "question whether the Secretary could reach the same result through adjudication was not before the district court; therefore the court erred by directing the Secretary how to calculate the hospitals' reimbursements, rather than just remanding after identifying the error." *Id.* Accordingly, this Court left it to the Secretary "'to deal with the problem afresh'" on remand. See *id.* (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 201 (1947)).

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[5] Following the district court's decision in *Allina I*, the Secretary issued a legislative rule after notice-and-comment that "readopt[ed] the policy of counting the days of patients enrolled in MA [Part C] plans in the Medicare fraction." 78 Fed. Reg. 50,496 (Aug. 19, 2013) (2013 Final Rule). While the 2013 Final Rule applies only prospectively to FY 2014 and subsequent years, HHS made clear in the rulemaking that it was readopting its policy "in an abundance of caution" in light of the *Allina I* litigation, and that the 2013 Final Rule did not represent a change in policy, but instead "readopt[ed] a policy that we finalized" in the 2004 Final Rule consistent with the agency's longstanding interpretation of the phrase "entitled to benefits under [Medicare] part A" in the Medicare DSH provision. *Id.* at 50,614-15, 50,619-20.

b. On December 2, 2015, while the present case was pending before the district court, the Administrator of CMS issued the agency's final decision on remand in *Allina I*. R29-4, JA -. The Administrator recognized that pursuant to this Court's decision, the agency must decide whether Part C days should be included in the Medicare/SSI fraction "afresh," without application of the now-vacated 2004 Final Rule. *Id.* at 25, JA -. The Administrator also noted that this Court had already found that "'[p]rior to 2004, the regulation did not specify where M+C [Part C] enrollees should be counted,'" and thus, there was no pre-2004 official policy or regulation that would require the exclusion of Part C days from the Medicare/SSI fraction on remand. *Id.* at 26, JA – (quoting *Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 14 (D.C. Cir. 2011)).

The Administrator further determined that "it has never been CMS policy for Part C days to be included in the numerator of the Medicaid fraction, nor has CMS included such days" as a matter of practice. R29-4 at 35, JA -. After examining at length the Secretary's past practice with respect to the treatment of Part C days for DSH purposes as well as the statutory language of the Medicare DSH provision and the Medicare statute as a whole, the Administrator held that individuals enrolled in Part C remained "entitled to benefits under part A" for purposes of the DSH calculation. *Id.* at 35-45, JA -. The Administrator thus concluded that Part C days should be included in plaintiff hospitals' FY 2007 Medicare/SSI DSH fractions. *Id.*

2. The Present Litigation.

a. On June 13, 2014, after this Court's decision in *Allina I*, but before the Secretary's final decision through adjudication on remand, CMS published the Medicare/SSI fractions for calculating plaintiff hospitals' 2012 DSH adjustments. See Compl. ¶36, JA -; District Court slip opinion, R39 ("op.") 7, JA -. In the absence of an applicable regulation governing the treatment of Part C days for purposes of calculating the DSH fractions, CMS nonetheless had to apply some interpretation of the statute in order to calculate hospitals' Medicare/SSI fractions. See Decl. of Ing Jye Cheng, R29-3 ("Cheng Decl.") ¶6, JA -. The agency's computation of the Medicare/SSI fraction for a particular hospital is only a preliminary step in calculating the hospital's DSH adjustment for a particular cost year. *Id.* ¶7, JA -; see 42 C.F.R. 412.106(b)(1), (2) (hospital's disproportionate patient percentage determined by "adding the results of two computations"; Medicare/SSI fraction is "First computation").

CMS makes the Medicare/SSI fractions available to the Medicare Administrative Contractors, which then determine the "[s]econd computation," – the Medicaid fraction – based on data submitted by the providers. 42 C.F.R. 412.106(b)(4); Cheng Decl. ¶7, JA -. The contractors add the Medicare/SSI and Medicaid fractions to determine the provider's disproportionate patient percentage, which is used to calculate the provider's DSH payment for the cost year at issue. 42

C.F.R. 412.106(b)(5); Cheng Decl. ¶7, JA -. Accordingly, a posted Medicare/SSI fraction is not a final payment determination; a provider's DSH payment is not finalized until issuance of the NPR. See *id.*

b. In July 2014, plaintiffs appealed to the PRRB, challenging the inclusion of Part C days in their FY 2012 Medicare/SSI fractions. Administrative Record, R- (AR) 232, 742; see Compl. ¶39, JA -. Although none of the plaintiffs had received NPRs for FY 2012, they invoked the Board's jurisdiction pursuant to 42 U.S.C. 1395oo(a)(1)(B)-(C), under which a hospital may appeal to the Board if the contractor has not issued an NPR within 12 months after the hospital filed its cost report or supplementary cost report. 42 U.S.C. 1395oo(a)(1)(B)-(C); see 42 C.F.R. 1835(c); Compl. ¶¶32, 38-40.

Plaintiffs petitioned the PRRB for expedited judicial review of their appeals. See AR 11-27. Plaintiffs alleged that CMS had applied the 2004 Final Rule in calculating their FY 2012 Medicare/SSI DSH fractions and that the Board lacked authority to determine the validity of that regulation. AR 24. On August 13, 2014, the Board granted the petition based on its finding that it was bound by the 2004 Final Rule, and that it lacked authority to decide either the validity of the regulation or "whether the Secretary's actions subsequent to the decision in *Allina* are legal." AR 1-6, JA -.

c. On August 19, 2014, plaintiffs filed the present action in district court. R1, JA -. Plaintiffs alleged that HHS violated the APA and the Medicare statute by including Part C patient days in the Medicare/SSI fractions for FY 2012 based on the portion of the 2004 Final Rule vacated in *Allina I*. *Id.* ¶¶46-47, JA -. Plaintiffs further contended that the inclusion of Part C days in the FY 2012 Medicare/SSI fractions was arbitrary and capricious and "constitute[d] the adoption of a new rule for which notice-and-comment rulemaking is required." *Id.* ¶¶51-52, JA. Plaintiffs sought declaratory and injunctive relief prohibiting the Secretary from including Part C days in the Medicare/SSI fraction prior to October 2013 and directing the Secretary to calculate plaintiffs' DSH payments accordingly. *Id.* ¶53, JA -

The Secretary moved to dismiss plaintiffs' case for lack of subject matter jurisdiction or, in the alternative, for voluntary remand. R15. The Secretary argued that the PRRB committed clear error when it held that it was bound to apply the Secretary's 2004 Final Rule because the relevant portion of the 2004 Final Rule had been vacated and was not binding on the Board. *Id.* In the alternative, the Secretary sought a voluntary remand to allow the Board to consider plaintiffs' challenge. *Id.*

The district court denied the motion. October 30, 2015 Order, R23, JA -. Although the court held that the PRRB's expedited judicial review determination was reviewable, it ruled that the Board correctly concluded that it lacked authority because "[e]ven if the 2004 Final Rule became non-binding upon vacatur, Plaintiffs allege that

the Secretary unlawfully continued to apply it." *Id.* at 9, JA -. The court further held that the Board lacked authority over plaintiffs' claim that the agency's calculation of the 2012 Medicare/SSI fractions constitutes "a procedurally invalid adoption of a new rule." *Id.* at 10. The court denied the alternative relief of a voluntary remand on the same grounds. *Id.* at 10-11, JA -.

d. On August 17, 2016, the district court granted summary judgment in favor of the Secretary. The court held that plaintiffs failed to show that the Secretary relied on the vacated portion of the 2004 Final Rule to calculate their 2012 DSH Medicare/SSI fractions; to the contrary, the Secretary "appropriately relied on and interpreted the underlying DSH statute to calculate the 2012 DSH Calculations." Op. 15, JA -. In addition, the court ruled that the Secretary was not required to engage in notice-and-comment rulemaking because the Medicare statute "itself provides an adequate legislative basis for including Part C days in the Medicare fraction, and therefore the rule underlying the 2012 DSH Calculations is interpretive." Op. 19, JA - (internal quotations omitted).

The court further determined that the Secretary's decision to include Part C days in plaintiffs' 2012 DSH Medicare/SSI fractions was not arbitrary and capricious. Op. 24-30, JA -. The court concluded that "[a]lthough the agency gave no explicit contemporaneous explanation" at the time the fractions were published, HHS "had made its interpretation of the statute clear" in the 2004 Final Rule, the 2013 Final

Rule, and the Administrator's decision on remand in *Allina I*. Op. 28, JA -. The court also held that the Secretary's interpretation that individuals enrolled in Part C remained "entitled to benefits under part A" within the meaning of the Medicare DSH provision was reasonable and entitled to deference. Op. 29-30, JA -.

SUMMARY OF ARGUMENT

A. The district court lacked subject matter jurisdiction over plaintiffs' case. Here, the Board concluded that it lacked authority to decide plaintiffs' challenge because it was bound to apply the Secretary's 2004 Final Rule. This was clear error because the relevant portion of the 2004 Final Rule had already been vacated.

The district court found it sufficient that plaintiffs *alleged* that the Secretary applied the vacated portion of the 2004 Final Rule. But that mere allegation does not create a legal issue regarding the validity of a regulation that was no longer in effect following this Court's binding decision in *Allina I*. Nor does the Board's holding that it was without authority to decide whether the Secretary failed to comply with this Court's decision in *Allina I* render expedited judicial review appropriate. As HHS regulations make clear, the Board "must deny EJR" if the legal question at issue is "neither a challenge to the constitutionality of a provision of a statute, nor a challenge to the substantive or procedural validity of a regulation or CMS Ruling." 42 C.F.R. 405.1842(f)(2)(ii). Whether the Secretary's treatment of Part C days in calculating plaintiff hospitals' 2012 DSH Medicare/SSI fractions is consistent with this Court's

precedent and statutory rulemaking requirements therefore falls outside the narrow exception authorizing expedited judicial review.

B. If this Court holds that the district court had jurisdiction, it should affirm the court's judgment on the merits. Assuming *arguendo* that the 2012 Medicare/SSI fractions are rules, the district court correctly held that they are interpretive rules that are not subject to notice-and-comment requirements. But at the threshold, the Medicare/SSI fractions challenged here are not "rules" under the APA, nor do they qualify as "rule[s], requirement[s], or other statement[s] of policy" under the Medicare statute. Rather, they are merely the first step in calculating the DSH payments for particular providers in a particular cost year. These fractions do not articulate any principles of general future applicability, nor do they apply prospectively to DSH payments for different providers or different cost years.

Even if the Secretary's calculation of plaintiffs' 2012 Medicare/SSI fractions implicitly adopted a rule – which it did not – notice-and-comment rulemaking would not be required. Because the Medicare statute sets forth the substantive legal standard for calculating DSH payments, the Secretary's interpretation at issue here – *i.e.*, that individuals enrolled in Part C remain "entitled to benefits under part A" within the meaning of the Medicare/SSI fraction – is at most an interpretive rule that falls outside the notice-and-comment requirements under either the APA or the Medicare statute. The Medicare statute "places notice and comment requirements on the

Secretary's substantive rulemaking similar to those created by the APA," *Monmouth Med. Ctr.* v. *Thompson*, 257 F.3d 807, 814 (D.C. Cir. 2001), and thus, courts have generally construed the procedural requirements in §1395hh to be coextensive with those under the APA.

Indeed, both statutes exempt interpretive, non-substantive rules from notice-and-comment rulemaking. See 5 U.S.C. 553(b), (d) (APA); 42 U.S.C. 1395hh(a)(2) (Medicare statute); *Monmouth Med. Ctr.*, 257 F.3d at 814 n.2. Here the "substantive legal standard" is derived from the statutory Medicare DSH provision itself. The Secretary is simply interpreting the legal standard adopted by Congress in statutory language that this Court has already held is ambiguous and does not preclude the Secretary's interpretation. See *Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 6-13 (D.C. Cir. 2011). Moreover, this Court's precedent makes clear that after the 2004 Final Rule was vacated, the agency could reach the same result through case-by-case adjudication. See *Allina I*, 746 F.3d at 1111; *Catholic Health Initiatives Iowa Corp. v. Sebelius*, 718 F.3d 914, 922 (D.C. Cir. 2013).

C. The district court also properly held that the Secretary's decision to include Part C days in plaintiffs' Medicare/SSI fractions for FY 2012 was not arbitrary and capricious. At the outset, this Court has already held that the Medicare statute does not foreclose the Secretary's interpretation that an individual enrolled in Part C remains entitled to benefits under Part A within the meaning of the DSH provision.

Northeast, 657 F.3d at 6-13, 17-18. And, as this Court has held in a related context, the Secretary's interpretation of "entitled to benefits under part A" is at the very least permissible. *Catholic Health*, 718 F.3d at 920 (Secretary's interpretation is "the better one," though "it is not quite inevitable").

The inclusion of Part C days in the Medicare/SSI fraction reflects congressional intent that the Medicare/SSI fraction serve as the proxy for the percentage of low-income Medicare patients served by the hospital. Individuals by definition must be "entitled to benefits under part A" in order to enroll in Part C, 42 U.S.C. 1395w-21(a)(3), and while enrolled, they continue to meet the statutory criteria for entitlement to Medicare Part A set forth in Sections 426(a) and (b) and continue to receive Part A benefits and services. See 42 U.S.C. 1395w-23(f). Plaintiffs' interpretation, in contrast, contravenes Congress' intent by eliminating an entire subset of patients entitled to Medicare Part A from the Medicare/SSI DSH fraction.

Moreover, that HHS did not offer any explanation of its interpretation contemporaneous with the 2012 Medicare/SSI fractions in June 2014 simply reflects the fact that these fractions are only the first step in calculating plaintiffs' DSH payments for the particular fiscal year. Under these circumstances, it was eminently reasonable for the district court to examine non-contemporaneous sources to determine whether the agency's interpretation was reasonable.

As the district court explained, the usual concerns about post-hoc rationalizations for agency action – "that the judiciary, rather than the agency, will supply the reasons underlying the action and that the real reasons for agency action will escape judicial scrutiny" – are "not present here." Op. 28, JA – (internal quotations omitted). The agency itself has explained the basis for its interpretation "on multiple occasions" (*id.*), including in the 2004 and 2013 Final Rules, and in the Administrator's decision on remand in *Allina I* in 2015. In addition, plaintiffs here are also parties in *Allina I* and had the opportunity to (and did) raise their objections to the Secretary's interpretation as applied to a fiscal year (2007), like that at issue here (2012), which falls between the vacated 2004 Final Rule and the 2013 Final Rule. The Administrator's 45-page decision on remand in *Allina I* includes a thorough explanation of the agency's interpretation and fully considers and refutes the same arguments raised by plaintiffs in this case.

STANDARD OF REVIEW

This Court reviews *de novo* whether the district court had subject matter jurisdiction over plaintiffs' case. *Trudeau v. FTC*, 456 F.3d 178, 183 (D.C. Cir. 2006). This Court also reviews a district court's grant of summary judgment under a *de novo* standard. *Gilvin v. Fire*, 259 F.3d 749, 756 (D.C. Cir. 2001).

The Medicare statute incorporates APA standards (42 U.S.C. 1395oo(f)(1)), under which this Court will not set aside the Secretary's decision unless it is "arbitrary,

capricious, an abuse of discretion, or otherwise not in accordance with law," or "without observance of procedure required by law." 5 U.S.C. 706(2)(A), (D). In determining whether an agency has provided a reasoned explanation for its decision, the Court applies the deferential "arbitrary and capricious" standard, pursuant to which "the scope of review" is "narrow" and a "court is not to substitute its judgment for that of the agency." *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). So long as the agency's construction of the statute is permissible and its "path may reasonably be discerned," the court must uphold the agency's interpretation under the APA. *Id.*

ARGUMENT

I. THE DISTRICT COURT LACKED SUBJECT MATTER JURISDICTION BECAUSE THE PRRB COMMITTED CLEAR ERROR IN GRANTING EXPEDITED JUDICIAL REVIEW.

A. Under the Medicare statute, providers must exhaust administrative remedies before the PRRB prior to seeking judicial review. 42 U.S.C. 1395oo(f); see *Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1, 12 (2000); 42 U.S.C. 1395ii. The expedited judicial review (EJR) provision creates a narrow exception to this jurisdictional prerequisite where "the Board determines * * * that it is without authority to decide" a "question of law or regulations." 42 U.S.C. 1395oo(f)(1). This EJR provision recognizes that the Board, as a subordinate administrative tribunal of HHS, is bound by and obligated to apply statutes and regulations that have the force

of law and lacks the authority to declare them unconstitutional or invalid. See *Bethesda Hosp. Ass'n v. Bowen*, 485 U.S. 399, 406-07 (1988). Under the Medicare statute and applicable HHS regulations, EJR thus is appropriate where the provider's appeal turns on the validity of statutes or regulations beyond the PRRB's authority to review. But the Board "must deny EJR," if the legal question at issue is "neither a challenge to the constitutionality of a provision of a statute, nor a challenge to the substantive or procedural validity of a regulation or CMS Ruling." 42 C.F.R. 405.1842(f)(2)(ii).

Here, the Board granted plaintiffs' request for EJR on the ground that it was bound by the 2004 Final Rule, and was "without the authority to decide the legal question of whether the regulation regarding the treatment of Medicare Part C days is valid and whether the Secretary's actions subsequent to the decision in *Allina* are legal." AR 6, JA -. This ruling was plain error. Because this Court had affirmed the district court's vacatur of the relevant portion of the 2004 Final Rule, the Board was *not* bound by that regulation, and its legal validity was not at issue. See *Allina I*, 746 F.3d at 1110-11. Moreover, the Board has authority to determine whether the Secretary's challenged actions in this case were consistent with this Court's decision in *Allina I*, as that inquiry does not require the Board to decide the validity of a statutory provision, agency regulation, or CMS Ruling. See 42 C.F.R. 405.1842(f)(2)(ii).

B. The district court properly held that the Board's EJR decision is judicially reviewable. See Order at 6-8, JA -. As the court explained, pursuant to Section

1395oo(f)(1) of the Medicare statute, the Board's grant of EJR on the ground that it lacks authority to decide a legal question is "a final decision" subject to judicial review. 42 U.S.C. 1395oo(f)(1). Indeed, "the statute itself establishes a right to judicial review of the Board's determination that it lacks the authority to decide a question of law or regulations by designating that determination a 'final decision.'" *Edgewater Hosp., Inc. v. Bowen*, 857 F.2d 1123, 1130 (7th Cir. 1988) (quoting 42 U.S.C. 1395oo(f)(1)); see *Providence Yakima Med. Ctr. v. Sebelius*, 611 F.3d 1181, 1187-88 & n.7 (9th Cir. 2010).

The court erred, however, by holding that the Board correctly granted plaintiffs' request for EJR in this case. The court found it sufficient, for purposes of affirming the Board's EJR determination, that plaintiffs *alleged* that the Secretary applied the vacated portion of the 2004 Final Rule. But that mere allegation does not create a legal issue regarding the validity of a regulation that was no longer in effect following this Court's binding decision in *Allina I*. Because this Court affirmed vacatur of the rule, the Board was not bound by the vacated portion of the regulation and did not need to determine its validity. Rather, the relevant question before the PRRB – which it had authority to decide – was whether the Secretary's treatment of Part C days in the Medicare/SSI fractions was lawful in the absence of the 2004 Final Rule.

The district court's error became even more apparent when it properly found at the summary judgment stage that plaintiffs failed to present any evidence that HHS

had, in fact, applied the vacated regulation when it calculated the 2012 Medicare/SSI fractions.[6] Op. 13-15, JA -. And although the court's further holdings that (1) this Court's decision in *Allina I* "made it clear that it was possible the agency could and might adopt the same interpretation contained in the 2004 Final Rule"; and (2) "the Secretary appropriately relied on and interpreted the underlying DSH statute to calculate the 2012 DSH calculation," are correct on the merits (op. 15, JA -), they also demonstrate that the court lacked subject matter jurisdiction in the first instance. This is because the Board has authority to determine, in the absence of a binding regulation or CMS Ruling, whether the challenged HHS actions are consistent with the Medicare statute. See 42 C.F.R. 405.1842(f)(2)(ii).

The Board's additional finding that it was without authority to decide whether the Secretary's actions following *Allina I* are legal (AR 6, JA -) does not render expedited judicial review appropriate. As demonstrated, because reviewing the legality of the Secretary's actions post-*Allina I* involves "neither a challenge to the constitutionality of a provision of a statute, nor a challenge to the substantive or procedural validity of a regulation or CMS Ruling," the Board was required to deny EJR. 42 C.F.R. 405.1842(f)(2)(ii). Contrary to the district court's holding (Order at 10-11, JA -), whether the Secretary's treatment of Part C days in calculating plaintiff

[6] On appeal, plaintiffs do not challenge the district court's holding (op. 15, JA -) that the Secretary did not actually rely on the vacated 2004 Final Rule in issuing the 2012 Medicare/SSI fractions. See Pl. Br. 1, 23-54.

hospitals' 2012 DSH Medicare/SSI fractions is consistent with this Court's precedent and Medicare statute and APA requirements therefore falls outside the narrow exception authorizing expedited judicial review without prior exhaustion of administrative remedies.

The Ninth Circuit's decision in *Providence Yakima, supra*, is instructive. In that case, providers challenged the Secretary's methodology for calculating their Medicare direct graduate medical education payments under an agency regulation. 611 F.3d at 1184. The Board granted EJR on the ground that it lacked authority to determine whether the applicable HHS regulation "as applied by the Intermediaries [via the challenged methodology] to each of the Providers in this appeal" violates the Medicare statute. *Id.* at 1185. After the district court granted summary judgment in favor of plaintiff hospitals, the Secretary appealed, arguing, *inter alia*, that the Board's EJR determination was erroneous and that the district court lacked jurisdiction over the provider's challenge to the agency's methodology. *Id.* at 1186. The Ninth Circuit reviewed whether the Secretary's challenged methodology presented a "'question of law or regulations relevant to the matters in controversy'" within the meaning of the EJR provision in Section 1395oo(f)(1). *Id.* at 1187. The court agreed with the Secretary that the methodology was an "ad hoc" policy and not a regulation under the statute and that the district court lacked subject matter jurisdiction because the Board had erroneously granted expedited judicial review. *Id.* at 1187-88.

Similarly, plaintiffs' challenge to their 2012 Medicare/SSI fractions was not a challenge to the 2004 Final Rule, which had already been vacated; nor was it a challenge to a new rulemaking. Rather, the issuance of the fractions was merely the first step in the process of determining plaintiff hospitals' final 2012 DSH payments. See 42 C.F.R. 412.106(b)(1), (2) (hospital's disproportionate patient percentage determined by "adding the results of two computations"; Medicare/SSI fraction is "First computation"). To be sure, in the absence of any binding regulation, CMS had to apply some interpretation of the treatment of Part C days under the Medicare statute to calculate the Medicare/SSI fractions. But the PRRB had authority to review that interpretation because it did not implicate the validity of any agency regulation or CMS Ruling.

In short, expedited judicial review is available only for a provider appeal that challenges the validity of a law or regulation that is binding upon the PRRB. See 42 C.F.R. 405.1842(f)(2)(ii). It is therefore unavailable where, as here, no binding agency regulation or ruling governs the Board's decision.

C. Although the district court ultimately reached the correct result on the merits of plaintiffs' challenge, the Board's erroneous grant of EJR resulted in prejudice to the Secretary and the systemic interest served by requiring exhaustion of administrative remedies. As the Secretary argued below, the unique procedural posture of this case required the agency to rely on non-contemporaneous sources to

demonstrate the reasonableness of the agency's interpretation at issue here. Had the PRRB denied plaintiffs' request for EJR, the Administrator would have had the opportunity to issue an adjudicative decision in this case. Because the Board erroneously granted EJR, however, the court was required to examine non-contemporaneous sources that both pre-date and post-date the issuance of the challenged FY 2012 Medicare/SSI fractions in order to evaluate the agency's treatment of Part C days for purposes of the DSH provision.

Here, the Secretary had already provided a reasoned explanation for the interpretation in both the 2004 and 2013 rulemakings, and did so again in the Administrator's decision on remand in *Allina I*. See *infra* pp. 51-54. But that will not always be possible in cases where the Board improvidently grants EJR and deprives not only itself but also the Administrator of the opportunity to review the challenged agency action. Indeed, the Supreme Court has repeatedly stressed the importance of exhaustion in ensuring the compilation of a record adequate to permit judicial review, and in enabling the agency to "apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts applying 'ripeness' or 'exhaustion' exceptions case by case." *Illinois Council*, 529 U.S. at 13; see also *Heckler v. Ringer*, 466 U.S. 602, 619 n.12 (1984). Plaintiffs' request for EJR and the Board's grant of that request impermissibly circumvented this process here.

This Court should therefore remand the case to the district court to dismiss for lack of subject matter jurisdiction.

II. THE SECRETARY WAS NOT REQUIRED TO ENGAGE IN NOTICE-AND-COMMENT RULEMAKING PRIOR TO ISSUING PLAINTIFFS' FY 2012 MEDICARE/SSI FRACTIONS.

If this Court holds that the district court had subject matter jurisdiction, it should affirm the court's grant of summary judgment in favor of the Secretary on the merits.

A. The Challenged Medicare/SSI Fractions Are Not Rules Subject To Notice-And-Comment Rulemaking Requirements Under The APA Or The Medicare Statute.

Assuming *arguendo* that the challenged Medicare/SSI fractions qualified as rules, the district court was right to hold that they are interpretive rules that are not subject to notice-and-comment rulemaking requirements. But at the threshold, the challenged action in the present case – the publication of the FY 2012 Medicare/SSI fractions – is not a "rule" under the APA or a "rule, requirement, or other statement of policy" that "establishes or changes a substantive legal standard" under the Medicare statute. See 5 U.S.C. 551(4) (APA); 42 U.S.C. 1395hh(a)(2) (Medicare statute). Rather, these fractions are merely the first step in calculating the DSH payments for particular providers in a particular cost year. Cheng Decl. ¶7, JA -; see 42 C.F.R. 412.106(b)(1), (2) (hospital's disproportionate patient percentage determined by "adding the results of two computations"; Medicare/SSI fraction is

"First computation"). The fractions do not articulate any principles of general future applicability, nor do they apply prospectively to DSH payments for different providers or different cost years. *Id.* Indeed, the fractions are not even final payment determinations for the particular providers to which they apply. *Id.* As such, the calculation of the Medicare/SSI fractions is more accurately viewed as the first step in an adjudication of a provider's DSH payment for a particular year.

Here, although none of the plaintiffs had received NPRs for FY 2012, they invoked the PRRB's jurisdiction pursuant to 42 U.S.C. 1395oo(a)(1)(B)-(C), which provides that a hospital may appeal to the Board if the contractor has not issued an NPR within 12 months after the hospital filed its cost report or supplementary cost report. 42 U.S.C. 1395oo(a)(1)(B)-(C); see 42 C.F.R. 405.1835(c); Compl. ¶¶32, 38-40, JA -. Thus, the PRRB's jurisdiction over plaintiffs' appeal was based on the *absence* of final agency action.[7]

[7] The present case illustrates that the Medicare/SSI fractions are not intended to establish a final governing rule. When plaintiffs filed suit, they were receiving interim Medicare payments pending issuance of their NPRs. But the FY 2012 Medicare/SSI fractions that they challenge generally were not applied to them for purposes of interim Medicare payments. See AR 43-54, JA -. Rather, CMS had instructed contractors to use Medicare/SSI fractions calculated for FY 2011 specifically for plaintiffs to exclude Part C days pending completion of the *Allina I* litigation. See *id.* While CMS did not calculate new FY 2012 fractions for plaintiffs that excluded Part C days (see Compl. ¶37, JA -), contractors generally continued to use the FY 2011 fractions excluding Part C days for plaintiffs' FY 2012 interim payments until the Administrator's final decision on remand in *Allina I*.

Plaintiffs' contention (Br. 4) that the publication of the Medicare/SSI fractions "summarily reinstated the change made by the 2004 rule" therefore is unavailing. While in light of the vacatur of the 2004 Final Rule, CMS was required to apply some interpretation of the Medicare statute to calculate the 2012 Medicare/SSI fractions, publication of those fractions does not have any of the characteristics of a rule. See *JEM Broad. Co. v. FCC*, 22 F.3d 320, 325 (D.C. Cir. 1994) ("rules, by definition, must have prospective application"). The district court thus erred in concluding (op. 17, JA -) that the Medicare/SSI fractions challenged here qualify as a rule.

This Court therefore can affirm the district court's holding that notice-and-comment rulemaking was not required without any further analysis. In any event, as set forth below, even assuming *arguendo* that the 2012 Medicare/SSI fractions implicitly adopted a final rule, statement of policy or requirement, the district court correctly determined that notice-and-comment rulemaking was not required under the APA or the Medicare statute.

B. The Secretary Was Free To Adopt The Challenged Interpretation Of Part C Days Through Adjudication.

As the district court properly held, HHS was not required to engage in notice-and-comment rulemaking prior to including Part C days in the 2012 DSH Medicare/SSI fractions. Although the Secretary chose to address the treatment of Part C days for purposes of the DSH calculation in notice-and-comment rulemaking

in 2004, she did not need to do so in order to effect a change from prior practice. To the contrary, it is well-established that an agency can apply a new interpretation or policy in the course of an individual adjudication. See *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 97 (1995); *SEC v. Chenery Corp.*, 332 U.S. 194, 201-04 (1947).

Indeed, as this Court recently made clear, HHS may establish a new policy or practice in an adjudication, which "is by its nature retroactive" unless plaintiffs can show, inter alia, that "'deny[ing] retroactive effect' * * * is 'necessary . . . to protect the settled expectations of those who had relied on the preexisting rule.'" *Catholic Health*, 718 F.3d at 922 (quoting *Williams Natural Gas Co. v. FERC*, 3 F.3d 1544, 1554 (D.C. Cir. 1993)). In the present case, plaintiffs cannot claim that they relied on any contrary "practice" of the agency from 2004 forward. The problem the court identified in *Northeast* was that the agency had a practice of excluding Part C days from the Medicare/SSI fraction prior to 2004, and thus, the 2004 final rule "attached new legal consequences to hospitals' treatment of low-income patients" during fiscal years 1999-2002. 657 F.3d at 17. The agency altered its practice in accordance with the 2004 final rule, however, and thus – as this Court recognized in *Allina I* when it reversed the district court's order requiring the Secretary to exclude Part C days from plaintiffs' FY 2007 Medicare/SSI fractions on remand – the Secretary should be able to decide how to treat Part C days in plaintiffs' DSH calculations by adjudication. While HHS could no longer rely on the vacated 2004 regulation to include Part C days

in the Medicare/SSI fraction, there was no reason that it could not reach the same result by adjudication on remand. See *Heartland Regional Med. Ctr. v. Sebelius*, 415 F.3d 24, 29-30 (D.C. Cir. 2005).

It was therefore well within the Secretary's discretion to include Part C days in the 2012 Medicare/SSI fractions, regardless of whether that interpretation was a continuation or departure from prior policy or practice. Here, as in *Catholic Health*, plaintiffs nowhere articulate any legitimate reliance interest on a pre-2004 Final Rule practice of excluding Part C days from the Medicare/SSI fraction as it relates to their *2012* DSH payments. And they would be hard-pressed to do so. Although it was ultimately vacated, the 2004 Final Rule put plaintiffs on notice of the Secretary's interpretation. Moreover, even apart from that rule, the Secretary had already decided through adjudication that Part C days should be included in the Medicare/SSI fraction for fiscal years in which the 2004 rule did not apply. *St. Joseph's Hosp. v. Blue Cross Blue Shield Ass'n*, 2007 WL 4861952 at *5 (CMS Adm'r Nov. 13, 2007). The inclusion of Part C days in the Medicare/SSI fraction for FY 2012 thus was not impermissibly retroactive. See *Catholic Health*, 718 F.3d at 922.

C. The Pre-2004 DSH Regulation Did Not Address Part C Days And Thus, The 2012 Medicare/SSI Fractions Did Not Amend A Legislative Or Substantive Rule.

Plaintiffs contend (Br. 38-45), however, that the Secretary was required to engage in notice-and-comment rulemaking before issuing the 2012 Medicare/SSI

fractions because the agency's pre-2004 legislative rule required the exclusion of Part C days. That regulation provided that the Medicare/SSI fraction numerator would include "the number of covered patient days" attributable to patients "who were entitled to both Medicare Part A and SSI." 42 C.F.R. 412.106(b)(2) (2003). Plaintiffs attribute great significance to the fact that the regulation was amended pursuant to the 2004 Final Rule to delete the term "covered" and to expressly include Part C days. See 42 C.F.R. 412.106(b)(2) (2004).

As set forth above, however, this Court's decisions in *Northeast* and *Allina I* preclude this argument. In *Northeast*, the Court expressly recognized that "[p]rior to 2004, the regulation [42 C.F.R. 412.106(b)(2)] did not specify where M + C [Part C] enrollees should be counted." 657 F.3d at 1. And in *Allina I*, this Court rejected plaintiffs' contention that, following vacatur of the 2004 Final Rule, the Secretary was required by pre-2004 regulations to exclude Part C days from their Medicare/SSI fractions for FY 2007. 746 F.3d at 1111.

Plaintiffs argue, however, that the Court's statement in *Northeast* "means only that the pre-existing regulation did not 'expressly' mention part C days," and by including only "covered" (i.e., paid) Medicare days in the Medicare fraction, the regulation necessarily excluded Part C days. Pl. Br. 41-42 & n.16. This argument fails for several reasons. While this Court held in *Northeast* that the agency had a *practice* prior to the 2004 rulemaking of excluding Part C days from the Medicare/SSI

fraction, the Court never identified any agency regulation, authoritative statement of policy, or legal interpretation that required the agency to do so. See *Northeast*, 657 F.3d at 14-17. To the contrary, as this Court recognized, prior to 2004, HHS regulations did not specify whether Part C days are included in or excluded from the Medicare/SSI fraction. *Id.* at 14.

In fact, plaintiffs made the same argument in *Allina I* (Pl. Brief, *Allina I*, 2013 WL 4648310 at **57-58), but this Court rejected it when it reversed the portion of the district court's remedial order that directed the Secretary to exclude Part C days from the Medicare fraction. See *Allina I*, 746 F.3d at 1111. If the Court had accepted plaintiffs' contention, it would not have concluded that the "government is right to object" when it "complains that, even if the 2004 rule is invalid, the Secretary might achieve the same result through adjudication." *Id.* The government would not have been right to object if, as plaintiffs claim, there had been a pre-2004 binding legislative rule that required Part C days to be included in the Medicare/SSI fraction.

In any event, plaintiffs' argument also misconstrues the term "covered" in the regulation. The "covered" days limitation was *not* based on any interpretation of "entitled to benefits under part A," nor did it establish any policy that would have excluded Part C days. Rather, as the Secretary explained in the 1986 rulemaking that established the limitation to "covered" days, the parenthetical "for such days" in the Medicare/SSI fraction numerator – which consists of "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 [Medicare] part A" – modified the phrase "entitled to benefits under part A" such that Congress intended to "refer only to Medicare covered days" for which Medicare was required to make payment. See 51 Fed. Reg. 31,454, 31,460-31,461 (Sept. 3, 1986). The agency did not distinguish between patient days attributable to individuals under the traditional fee-for-service program and those attributable to individuals enrolled in managed care plans. See *id.*

In fact, HMO days or Part C days are considered to be paid or "covered" days even though Medicare payments for such days are made to managed care plans rather than directly to hospitals. 42 U.S.C. 1395w-23(f). In a 1990 rulemaking, the Secretary made clear that HMO days *were* included in the Medicare/SSI fraction because "these beneficiaries are entitled to Part A benefits." 55 Fed. Reg. 35,990, 35,994 (Sept. 4, 1990). When Congress subsequently created Part C, it changed the administration of benefits of a Medicare Part A beneficiary who chooses to enroll in a managed care plan, but it did not change anything about the source of payment of the benefits. There is no indication that Congress intended Part C days to be treated differently from HMO days in calculating the DSH adjustment. To the contrary, the fact that Congress required that Part C enrollees be "entitled to benefits under part A" – the same language it used in the DSH provision to delineate which patient days should be included in the Medicare/SSI fraction – shows that Part C days, like HMO days, are

attributable to individuals "entitled to benefits under part A." 42 U.S.C. 1395w-21(a)(3).

Plaintiffs also create a false dichotomy between Medicare Part A and Part C – a dichotomy already rejected by this Court in *Northeast*. See 657 F.3d at 7-9; cf. Pl. Br. 42. A Part C enrollee is entitled to receive benefits under Medicare Part A through the Part C plan in which he is enrolled, and such benefits are paid from the Medicare Part A Trust Fund. 42 U.S.C. 1395w-23(f). The fact that a Part C enrollee's benefits are *administered* under Part C does not make the enrollee any less "entitled to benefits under part A."

Nor does the deletion of the term "covered" after the 2004 rulemaking indicate that Part C days were not considered "covered" or "paid" days. Rather, that term was deleted in order to make clear that certain patient days attributable to individuals who were "entitled to benefits under part A," but who had exhausted coverage for a particular hospital stay, would be counted in the Medicare/SSI fraction even though the days were not paid due to the exhausted coverage. See 69 Fed. Reg. at 49,098-49,099 (all patient days for individual Medicare Part A beneficiaries, whether or not Medicare actually paid for those days, are included in the Medicare/SSI fraction).

Plaintiffs also contend (Br. 44) that the Secretary's exclusion of Part B days from the Medicare/SSI fraction somehow demonstrates that Part C days were also excluded. This contention is equally meritless. To enroll in Part B, an individual need

not be "entitled to benefits under part A." 42 U.S.C. 1395o(2). Thus, under the plain language of the DSH provision, regardless of whether only "covered" days were included, a patient day attributable to an individual enrolled in Part B who has not met the statutory criteria for entitlement to benefits under the Medicare statute would be excluded from the Medicare/SSI fraction because it is not attributable to an individual "entitled to benefits under part A."

In sum, this Court's decisions in *Northeast* and *Allina I* foreclose plaintiffs' arguments that a pre-2004 legislative rule precluded the Secretary from including Part C days in the Medicare/SSI fraction. But even if such arguments were not already foreclosed, they fail on the merits.

D. Neither The APA Nor The Medicare Statute Required The Secretary To Engage In Notice-And-Comment Rulemaking.

As demonstrated above, the inclusion of Part C days in plaintiffs' 2012 Medicare/SSI fractions is not a rule, and, instead, is more accurately viewed as the first step in an adjudication. And it is clear from this Court's precedent that the Secretary has the discretion – regardless of pre-2004 practice or policy—to proceed via adjudication in lieu of notice-and-comment rulemaking. But even assuming *arguendo* that the 2012 Medicare/SSI fractions qualify as "rules" under the APA and the Medicare statute, they would be interpretive rules exempt from notice-and-comment requirement under either statute.

1. The APA expressly exempts the formulation, amendment, and repeal of interpretive rules from the Act's notice-and-comment rulemaking provisions. 5 U.S.C. 553(b), (d). An interpretive rule is an "agency statement * * * designed to * * * interpret * * * law," 5 U.S.C. 551(4), "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." *Guernsey Mem'l Hosp.*, 514 U.S. at 99 (internal quotations omitted); 5 U.S.C. 553(b)(A) (the Act's notice-and-comment requirement "does not apply * * * to interpretative rules"); *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1206 (2015). An interpretive rule "does not contain new substance of its own but merely expresses the agency's understanding of a congressional statute." See *National Latino Media Coalition v. FCC*, 816 F.2d 785, 788 (D.C. Cir. 1987). In contrast, a legislative rule – also known as a "substantive rule" – "stands in the place of Congress and makes law." *Id.*

Accordingly, while legislative rules may create new *extra-statutory* requirements that bind both private parties and the courts, interpretive rules do not carry any independent force and effect of law – although courts typically defer to an agency's interpretation of its governing statute in light of the "status conferred on an agency as the delegate of Congress and by its expertise[.]" *National Latino Media Coalition*, 816 F.2d at 788. As the district court recognized (op. 18, JA -), this Court examines the following factors to determine if an agency rule is legislative:

(1) whether in the absence of the rule there would not be an

> adequate legislative basis for enforcement action or other agency action to confer benefits or ensure the performance of duties;
>
> (2) whether the agency has published the rule in the Code of Federal Regulations;
>
> (3) whether the agency has explicitly invoked its general legislative authority; or
>
> (4) whether the rule effectively amends a prior legislative rule.

American Mining Cong. v. Mine Safety & Health Admin., 995 F.2d 1106, 1112 (D.C. Cir. 1993). Here, as the district court correctly held, the answer to each of these questions is "no," and thus, the Secretary's inclusion of Part C days in the 2012 Medicare/SSI fractions is not a legislative rule. Op. 18-19, JA -.

First, in the absence of the fractions, HHS has authority under the Medicare statute and its regulations to determine the meaning of the statutory phrase "entitled to benefits under part A" for purposes of the DSH provision. Cf. *American Mining Conf.*, 995 F.2d at 1112. And the Medicare statute itself provides the substantive legal standard – indeed, expressly defines the formula for calculating the DSH Medicare/SSI fraction. 42 U.S.C. 1395ww(d)(5)(F)(vi)(I). The Secretary is simply interpreting the statutory phrase "entitled to benefits under part A" – a phrase that this Court has held is ambiguous and within the agency's authority to interpret – in order to implement the substantive legal standard adopted by Congress. *Catholic Health*, 718 F.3d at 920; *Northeast*, 657 F.3d at 13.

Second, the challenged 2012 Medicare/SSI fractions were not published in the Federal Register. Third, HHS did not invoke its legislative rulemaking authority in issuing the fractions; rather the agency simply published the relevant ratios for particular providers for FY2012.[8] Finally, the 2014 Draft Guidance did not "effectively amend" a prior legislative rule. As this Court concluded, prior to 2004, the HHS regulation implementing the DSH provision "did not specify where M + C [Part C] enrollees should be counted." *Northeast*, 657 F.3d at 14. After the 2004 Final Rule was vacated, the agency could adopt either of the two possible interpretations with respect to Part C days – either patients enrolled in Part C are "entitled to benefits under part A" and their patient days must be included in the Medicare/SSI fraction, or they are not so entitled, and their patient days must be excluded. Neither interpretation would "effectively amend" a prior legislative rule. And even assuming *arguendo* that the agency's practice of excluding Part C days from pre-2004 Medicare/SSI fractions could be characterized as an interpretive rule, notice-and-comment rulemaking is not required to amend an interpretive rule. *Mortgage Bankers Ass'n*, 135 S. Ct. at 1206.

In short, the agency's interpretive choice in the course of adjudicating plaintiff providers' 2012 DSH payments is thus (if it is a rule at all) a "quintessential"

[8] See http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY-2012-SSI-Ratios-for-web-posting.zip.

interpretive rule exempt from APA notice-and-comment requirements. See *Orengo Caraballo v. Reich*, 11 F.3d 186, 195 (D.C. Cir. 1993).

2. The district court correctly held that the Medicare statute similarly does not require the Secretary to engage in notice-and-comment rulemaking. The Medicare statute requires notice-and-comment rulemaking for 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) (emphasis added). Although plaintiffs make much of the fact that the Medicare statute's requirements apply not only to rules, but to "requirement[s]" and "other statement[s] of policy" (see Pl. Br. 25, 29), that is of no import, where, as here, the Medicare/SSI fractions at issue do not "establish[] or change[] a substantive legal standard." Nor does it make any difference that the Medicare statute does not contain a separate provision exempting interpretive rules from notice-and-comment requirements. Cf. Pl. Br. 30-31. Because the notice-and-comment requirement under the Medicare statute is limited to agency rules or policies that "establish[] or change[] a substantive legal standard," there was no need for Congress to specifically exempt interpretive rules. In fact, such a provision would be superfluous, as interpretive rules do not establish or change substantive legal standards.

3. Plaintiffs' reliance (Br. 31-32) on Section 1395hh(c)(1)(B), which requires the Secretary to publish in the Federal Register "a list of all *manual instructions*,

interpretative rules, statements of policy, and *guidelines* of general applicability" that have not previously been published, is equally misplaced. 42 U.S.C. 1395hh(c)(1)(B) (emphasis added). In fact, this Court cited this exception as evidence that the Medicare statute *does* exempt interpretive rules. *Monmouth Med. Ctr. v. Thompson*, 257 F.3d 807, 814 n.2 (D.C. Cir. 2001). Moreover, plaintiffs omit the fact that this provision also applies to manual instructions and guidelines, which – like interpretive rules – do not require notice-and-comment rulemaking. See *Guernsey Mem'l Hosp.*, 514 U.S. at 99-100 (HHS manual provision valid interpretive rule); *South Shore Hosp., Inc. v. Thompson*, 308 F.3d 91, 103 (1st Cir. 2002) (Provider Reimbursement Manual "primarily an interpretive guide" without force of law). Plaintiffs also fail to acknowledge that HHS voluntarily engages in notice-and-comment rulemaking when it is not required to do so. That is what the Secretary did with respect to the interpretation of "entitled to benefits under part A" and treatment of Part C days in both the 2004 and 2013 Final Rules. Indeed, "an agency may choose to invoke its general legislating authority out of an abundance of caution." Op. 19-20, JA – (citing *American Mining Cong.*, 995 F.2d at 1110-11).

Plaintiffs' reliance (Br. 32) on Section 1395hh(e)(1)(A), which addresses retroactive application of "substantive changes," is also unavailing. Plaintiffs again notably omit the fact that the provision not only applies to "interpretative rules" and "statements of policy," but also to "manual instructions" and "guidelines of general

applicability," thereby making clear that the provision extends beyond agency actions that are subject to notice-and-comment rulemaking. 42 U.S.C. 1395hh(e)(1)(A). In any event, Section 1395hh(a)(2), the relevant provision requiring notice-and-comment rulemaking, applies only to rules, requirements or statements of policy that "establish[] or change[] a substantive legal standard." 42 U.S.C. 1395hh(a)(2). As demonstrated, the challenged Medicare/SSI fractions do not establish or change any substantive legal standard. That should be the end of the inquiry.

As this Court thus recognized, the Medicare statute "places notice and comment requirements on the Secretary's *substantive* rulemaking similar to those created by the APA." *Monmouth Med. Ctr.*, 257 F.3d at 814 (emphasis added). And though this Court did not expressly decide the question (cf. Pl. Br. 32-33), it noted that "it seems fair to infer that, as the Medicare Act was drafted after the APA," Section 1395hh(a)(2) adopted an exemption from such requirements for interpretive rules "at least *similar* in scope to that of the APA." *Monmouth*, 257 F.3d at 814. And other courts of appeals have generally construed the procedural requirements in Section 1395hh to be coextensive with those under the APA. *E.g.*, *Via Christi Regional Med. Ctr., Inc. v. Leavitt*, 509 F.3d 1259, 1271 n.11 (10th Cir. 2007); *Baptist Health v. Thompson*, 458 F.3d 768, 776-77 & n.8 (8th Cir. 2006); *Warder v. Shalala*, 149 F.3d 73, 79 n.4 (1st Cir. 1998). Moreover, courts have treated the term "substantive" interchangeably with "legislative" when discussing whether an agency action is a

legislative rule subject to notice-and-comment rulemaking requirements. See, *e.g.*, *American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987).

In any event, even assuming *arguendo* that the Medicare statute imposes stricter rulemaking requirements than those applicable under the APA, here, as in *Monmouth*, *supra*, there is "no reason to explore the possibility." See 257 F.3d at 814; *Erringer v. Thompson*, 371 F.3d 625, 633 (9th Cir. 2004). In *Monmouth*, the HHS rule at issue provided a "definition of eligible inpatient days" that "elucidate[d] * * * rights and duties created by Congress," and had "none of the indicia that would lead [the Court] to think it a legislative rule under the APA." 257 F.3d at 814. The 2012 Medicare/SSI fractions similarly reflect an interpretation of the phrase "entitled to benefits under part A" that "elucidates" substantive standards set by Congress, and therefore notice-and-comment rulemaking is not required. Indeed, an interpretation of a statutory provision "may suppl[y] crisper and more detailed lines than the authority being interpreted" without becoming a legislative rule. *Orengo Caraballo*, 11 F.3d at 195 (internal quotations omitted).

4. In addition, the legislative history of the Medicare statute rulemaking provisions upon which plaintiffs rely (Br. 34-36), actually supports the Secretary's position. Plaintiffs cite (Br. 36) the original House version of the bill to argue that Congress intended that Section 1395hh(a)(2) would sweep more broadly than the APA. But as plaintiffs acknowledge, the House Conference Committee amended the

proposed provision so that the rulemaking requirement applied solely to "the change or establishment of a 'substantive legal standard.'" Pl. Br. 36. As the Conference Committee explained, it amended the proposed bill in order "to clarify that *only* policies establishing or changing a *substantive* legal standard * * * must be promulgated as regulations." H.R. Conf. Rep. No. 100-495 at 566, *reprinted in* 1987 U.S.C.C.A.N. 2313-1245, 2313-1313 (1987) (emphasis added). The amendment therefore shows Congress's intent to maintain the distinction between substantive (or legislative) rules or standards and interpretive rules.

As demonstrated, the 2012 Medicare/SSI fractions do not adopt or change a substantive legal standard; at most, they interpret a legal standard set by Congress. Moreover, even assuming *arguendo* that they did adopt a standard, there was no prior substantive legal standard with respect to Part C days from which they could depart. See *Northeast*, 657 F.3d at 14.

Given the lack of a prior substantive legal standard pre-2004, if the Medicare statute rulemaking requirement were construed consistent with plaintiffs' interpretation, then the Secretary would also be prohibited from *excluding* Part C days from the 2012 Medicare/SSI fractions. Because Section 1395hh(a)(2) applies to the "establish[ment]" of substantive legal standards as well as to changes to such standards, and because the Secretary did not address the treatment of Part C days in a legislative rule until the 2004 Final Rule, under plaintiffs' interpretation, HHS would

be required to engage in notice-and-comment rulemaking regardless of which interpretation it chose. See *Mortgage Bankers*, 135 S. Ct. at 1206-08 (no distinction with respect to APA rulemaking requirements between initial promulgation of rule and subsequent amendment). But as set forth above, and as this Court's precedent in *Northeast* and *Allina* I make clear, HHS was free to adopt an interpretation of the substantive standard set by Congress following vacatur of the 2004 Final Rule without first engaging in notice-and-comment rulemaking.

III. THE SECRETARY PROVIDED A REASONED EXPLANATION FOR THE DECISION TO INCLUDE PART C PATIENT DAYS IN THE MEDICARE/SSI FRACTION.

A. The district court also properly rejected plaintiffs' argument (Br. 46-47) that the issuance of the 2012 DSH Medicare/SSI fractions was arbitrary and capricious because the agency offered no contemporaneous explanation for its inclusion of Part C days and did not show any awareness that it was changing positions. At the outset, this Court's holding in *Northeast* that the Secretary's construction of the DSH provision in 2004 was a departure from the agency's past practice with respect to Part C days does not require "more searching" or "heightened" review of the agency's action under the APA. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 514-15 (2009). As demonstrated, in the 2004 final rule, the agency did not change a past authoritative statement of Medicare payment policy with respect to Part C days. In any event, even if it had, an "agency's interpretation of a statute is entitled to no less deference * * *

simply because it has changed over time." *National Home Equity Mortgage Ass'n v. Office of Thrift Supervision*, 373 F.3d 1355, 1360 (D.C. Cir. 2004). An agency's new interpretation is not arbitrary and capricious so long as it "provide[s] a reasoned analysis," in the rulemaking. See *id.* Indeed, the APA "makes no distinction" with respect to the standard of review between "initial agency action and subsequent agency action undoing or revising that action." *Fox Television*, 556 U.S. at 515.

B. Plaintiffs' contentions about the lack of a contemporaneous record also miss the mark. There is no contemporaneous record due to the unusual procedural posture of the case. As set forth above, because plaintiffs challenged the first computation of a multi-step Medicare payment determination, and because plaintiffs requested expedited judicial review and the PRRB erroneously granted plaintiffs' request, there was no final decision of the Administrator or further development of the record. Under these circumstances, the district court properly examined non-contemporaneous sources – which both pre-date and post-date issuance of the challenged DSH fractions – to determine whether the agency's interpretation was reasonable. Where the context and history of the agency's position make its rationale clear, courts will sustain the agency's decision even if there was some defect in the initial contemporaneous explanation. See *Global Crossing Telecomms., Inc. v. Metrophones Telecomms., Inc.*, 550 U.S. 45, 63-64 (2007); *Public Serv. Co. v. ICC*, 749 F.2d 753, 759-60 (D.C. Cir. 1984).

In the present case, as the district court recognized (op. 28, JA -), "the agency had made its interpretation of the statute clear in the 2004 Final Rule," which was vacated on solely procedural grounds, as well as in the 2013 rulemaking, which the agency completed prior to the publication of the challenged FY 2012 fractions at issue here See 78 Fed. Reg. at 50,614-20. The district court also properly relied on the Administrator's decision on remand in *Allina I*, which provides a more than adequate basis from which "the agency's path may reasonably be discerned." *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). As the district court explained, the usual concerns about post-hoc rationalizations for agency action – "that the judiciary, rather than the agency, will supply the reasons underlying the action and that the real reasons for agency action will escape judicial scrutiny" – are "not present here." Op. 28, JA – (internal quotations omitted). Moreover, a remand for a reasoned explanation would serve no purpose, since "the agency has supplied its reasons on multiple occasions, including the Administrator's recent decision and the 2013 Rulemaking."[9] *Id.*

[9] As explained *supra* pp. 22-29, the proper course in the present case would be to dismiss this case for lack of subject matter jurisdiction. Plaintiffs' challenge to the substance of the Secretary's interpretation and the adequacy of the Administrator's decision on remand is currently pending in district court following the remand in *Allina I*. The Administrator's decision is more appropriately reviewed in the case in which it was issued, and where the court has jurisdiction.

C. Moreover, this Court's prior decisions support the district court's holding that the Secretary's interpretation is reasonable and consistent with the Medicare statute. In *Northeast*, this Court held that the plain language of the Medicare statute did not foreclose the Secretary's interpretation that an individual who meets the criteria for entitlement set forth in Section 426(a) or (b) is "entitled to benefits under Part A" within the meaning of the DSH provision, regardless of whether the individual has enrolled in an M+C plan under Medicare Part C or whether Medicare Part A has actually made payment for the days at issue. See *Northeast*, 657 F.3d at 6-13, 17-18. The Court determined that Congress "has left a statutory gap, and it is for the Secretary, not the court, to fill that gap." *Id.* at 13.

Although the Court in *Northeast* did not reach whether the Secretary's interpretation was reasonable at *Chevron* step 2, subsequent decisions of this Court confirm that the Secretary's interpretation is at the very least permissible. In *Catholic Health*, this Court upheld the Secretary's interpretation of the same statutory language at issue here when it decided whether a Medicare beneficiary who has exhausted his coverage for a particular hospital stay remains "entitled to benefits under part A" within the meaning of the DSH provision. 718 F.3d at 920. In doing so, this Court concluded that the Secretary's interpretation of "entitled to benefits under part A" is

"the better one," though "it is not quite inevitable."[10] *Id.*; see *Hall v. Sebelius*, 667 F.3d 1293, 1296 (D.C. Cir. 2012).

D. Plaintiffs contend (Br. 49-54) that the district court erred by holding that the 2004 Final Rule, the 2013 Final Rule, and the Administrator's decision in *Allina I* provide an adequate basis for the Secretary's decision. Plaintiffs further argue (Br. 50) that HHS failed to recognize its change in policy or acknowledge the financial impact of its decision to readopt the policy when it issued the challenged 2012 Medicare/SSI fractions. Plaintiffs' contentions are unavailing.

HHS adopted the same interpretation challenged here in 2004, and the rule in which it did so was not vacated until the *Allina I* litigation. This case involves FY 2012, and thus, providers have had years of notice of the agency's interpretation, as well as years to consider its financial effects. And as set forth *infra* pp. 52-54, both the 2013 Final Rule and the Administrator's *Allina I* decision acknowledge and refute plaintiffs' concerns about the financial impact of including Part C days in the Medicare/SSI fraction. 78 Fed. Reg. at 50,615; R.29-4 at 42-44, JA –.

Indeed, the Secretary's interpretation is based on a consistent understanding of what it means to be "entitled to benefits under part A" within the meaning of the Medicare DSH provision and the Medicare statute as a whole. In the 2004 Final Rule,

[10] In district court, plaintiffs argued that the Secretary's statutory interpretation was unreasonable at *Chevron* step 2, but on appeal, they confine their argument to a footnote and reserve it "for any *en banc* review by this Court." Pl. Br. 53 n.20.

the Secretary agreed with commenters who argued that Part C enrollees "are just as much Medicare beneficiaries as those beneficiaries in the traditional fee-for-service program," and therefore should be included in the Medicare/SSI fraction. 69 Fed. Reg. at 49,099. And, although that portion of the rule was vacated in *Allina I* on procedural grounds, HHS explained in the 2013 notice-and-comment rulemaking that it was "readopt[ing] the policy of counting the days of patients enrolled in MA [Part C] plans in the Medicare fraction." 78 Fed. Reg. at 50,615. While the 2013 final rule applies only prospectively to FY 2014 and subsequent years, HHS made clear in the rulemaking that it was acting "in an abundance of caution" in light of the *Allina I* litigation, and that the 2013 final rule did not represent a change in policy, but instead "readopt[ed] a policy that we finalized" in the 2004 Final Rule consistent with the agency's longstanding interpretation of the phrase "entitled to benefits under [Medicare] part A" in the Medicare DSH provision. *Id.* at 50,614, 50619-20.

The agency also specifically addressed hospitals' comments that Medicare Part C enrollees generally have higher incomes that those Part A beneficiaries not enrolled in Part C: "[W]e disagree and note that research, such as the findings from the Medicare Current Beneficiary Survey as listed in the table below, has shown that Part C enrollees tend to have lower incomes at similar rates as Medicare beneficiaries who are not enrolled in Part C." *Id.* at 50,615.

Plaintiffs' criticism (Br. 51-54) of the Administrator's decision in *Allina I* is also misplaced. First, plaintiffs argue that the Administrator erred by failing to acknowledge that the agency had a "prior policy treating part C days as non-part A days prior to 2004." But the Administrator fully considered the hospitals' allegations on this issue, and explained the causes of the pre-2004 practice of excluding Part C days from the Medicare/SSI fraction, as well as why the hospitals' characterization of that practice as a policy is erroneous. R.29-4 at 30-35. As the Administrator concluded, "with respect to CMS' prior practice, CMS has not always had the capacity to capture the Part C patient days as Medicare days, due to operational, not policy issues." *Id.* at 30, 35 JA -. Moreover, "CMS has not identified any instructions, or policy, requiring the exclusion of the days from the Medicare fraction, or any policy statements or instructions, that the inpatient days for enrollees for Part C days were not to be treated as Part A days or that these dually eligible individuals were to be treated as not entitled to Medicare Part A benefits for purposes of the DSH payment calculation." *Id.*

Nor does plaintiffs' argument regarding the agency's alleged failure to consider the financial impact of its interpretation on hospitals advance their position. Like the 2013 rulemaking, the Administrator's decision noted comments from hospitals about potential financial impact and responded accordingly. See R29-4 at 42-44, JA –. Indeed, the Administrator cited Medicare Current Beneficiary Survey statistics and

concluded that "this policy does not result in a disproportionate distortion of the disproportionate patient percentage or have a result that would be contrary to the Congressional purpose of the DSH payment in its effect." *Id.*

Finally, plaintiffs argue (Br. 54) that the agency's exclusion of Part B days and patient days from other parts of the hospital that are not paid under the inpatient prospective payment system (IPPS) renders its interpretation inconsistent. This contention is equally meritless. As discussed *supra* p. 38, to enroll in Part B, an individual need not be "entitled to benefits under part A." 42 U.S.C. 1395o(2). Thus, under the plain language of the DSH provision, a patient day attributable to an individual enrolled in Part B who has not met the statutory criteria for entitlement to benefits under the Medicare statute should be excluded from the Medicare/SSI fraction because it is not attributable to an individual "entitled to benefits under part A." And, as the Administrator explained, the restriction on patient days to certain units of the hospital is entirely unrelated to the Secretary's interpretation of "entitled to benefits under part A"; rather, it is based on an interpretation of the term "patient days" in the DSH provision as limited to inpatient days payable under the IPPS. See R29-4 at 44-45, JA -; 42 C.F.R. 412.106(a)(1)(ii)(A); 53 Fed. Reg. 38,476, 38,480 (Sept. 30, 1988).

In sum, the Administrator's decision in *Allina I* easily satisfies the narrow and deferential APA standard of review applicable in Medicare cases. 42 U.S.C.

1395oo(f)(1). Although the district court in the present case therefore correctly upheld the Secretary's interpretation on the merits, it should have dismissed for lack of subject matter jurisdiction based on the PRRB's erroneous grant of expedited judicial review. Plaintiffs here are also plaintiffs in the suit challenging the Administrator's decision on remand in *Allina I*. That case is currently pending in district court, and thus, if this case were dismissed for lack of jurisdiction, the Administrator's decision could be reviewed in the case in which it was issued.

CONCLUSION

For the foregoing reasons, this Court should remand to the district court to dismiss plaintiffs' case for lack of subject matter jurisdiction. If this Court determines that the district court had jurisdiction, it should affirm the court's judgment in favor of the Secretary.

Respectfully submitted,

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February 22, 2017

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief complies with the type-volume limitation in Fed. R. App. P. 32(a)(7)(B), the typeface requirements of Fed. R. App. P. 32(a)(5), and the type style requirements of Fed. R. App. 32(a)(6). The word processing program (Microsoft Word 2010) used to prepare the brief reports that the brief is 12,844 words long. The brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 with Garamond, 14 point font.

/s/ Stephanie R. Marcus
Stephanie R. Marcus

CERTIFICATE OF SERVICE

I hereby certify that on this 22nd day of February, 2017, I electronically filed the foregoing Brief for Appellee with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system.

I further certify that on this 22nd day of February, 2017, I served the foregoing Brief for Appellee by electronic service via the CM/ECF system on counsel of record for appellants:

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ADDENDUM

ADDENDUM
TABLE OF CONTENTS

Page(s)

Statutes:

Regulations:

42 U.S.C § 1395oo. Provider Reimbursement Review Board

(a) Establishment

Any provider of services which has filed a required cost report within the time specified in regulations may obtain a hearing with respect to such cost report by a Provider Reimbursement Review Board (hereinafter referred to as the "Board") which shall be established by the Secretary in accordance with subsection (h) of this section and (except as provided in subsection (g)(2) of this section) any hospital which receives payments in amounts computed under subsection (b) or (d) of section 1395ww of this title and which has submitted such reports within such time as the Secretary may require in order to make payment under such section may obtain a hearing with respect to such payment by the Board, if—

(1) such provider—

(A)(i) is dissatisfied with a final determination of the organization serving as its fiscal intermediary pursuant to section 1395h of this title as to the amount of total program reimbursement due the provider for the items and services furnished to individuals for which payment may be made under this subchapter for the period covered by such report, or

(ii) is dissatisfied with a final determination of the Secretary as to the amount of the payment under subsection (b) or (d) of section 1395ww of this title,

(B) has not received such final determination from such intermediary on a timely basis after filing such report, where such report complied with the rules and regulations of the Secretary relating to such report, or

(C) has not received such final determination on a timely basis after filing a supplementary cost report, where such cost report did not so comply and such supplementary cost report did so comply,

(2) the amount in controversy is $10,000 or more, and

(3) such provider files a request for a hearing within 180 days after notice of the intermediary's final determination under paragraph (1)(A)(i), or with respect to appeals under paragraph (1)(A)(ii), 180 days after notice of the Secretary's final determination, or with respect to appeals pursuant to paragraph (1)(B) or (C), within 180 days after notice of such determination would have been received if such determination had been made on a timely basis.

. . . .

(f) Finality of decision; judicial review; determinations of Board authority; jurisdiction; venue; interest on amount in controversy

(1) A decision of the Board shall be final unless the Secretary, on his own motion, and within 60 days after the provider of services is notified of the Board's decision, reverses, affirms, or modifies the Board's decision. Providers shall have the right to obtain judicial review of any final decision of the Board, or of any reversal, affirmance, or modification by the Secretary, by a civil action commenced within 60 days of the date on which notice of any final decision by the Board or of any reversal, affirmance, or modification by the Secretary is received. Providers shall also have the right to obtain judicial review of any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the Board determines (on its own motion or at the request of a provider of services as described in the following sentence) that it is without authority to decide the question, by a civil action commenced within sixty days of the date on which notification of such determination is received. If a provider of services may obtain a hearing under subsection (a) of this section and has filed a request for such a hearing, such provider may file a request for a determination by the Board of its authority to decide the question of law or regulations relevant to the matters in controversy (accompanied by such documents and materials as the Board shall require for purposes of rendering such determination). The Board shall render such determination in writing within thirty days after the Board receives the request and such accompanying documents and materials, and the determination shall be considered a final decision and not subject to review by the Secretary. If the Board fails to render such determination within such period, the provider may bring a civil action (within sixty days of the end of such period) with respect to the matter in controversy contained in such request for a hearing. Such action shall be brought in the district court of the United States for the judicial district in which the provider is located (or, in an action brought jointly by several providers, the judicial district in which the greatest number of such providers are located) or in the District Court for the District of Columbia and shall be tried pursuant to the applicable provisions under chapter 7 of Title 5 notwithstanding any other provisions in section 405 of this title. Any appeal to the Board or action for judicial review by providers which are under common ownership or control or which have obtained a hearing under subsection (b) of this section must be brought by such providers as a group with respect to any matter involving an issue common to such providers.

(2) Where a provider seeks judicial review pursuant to paragraph (1), the amount in controversy shall be subject to annual interest beginning on the first day of the first month beginning after the 180-day period as determined pursuant to subsection (a)(3) of this section and equal to the rate of interest on obligations issued for purchase by

the Federal Hospital Insurance Trust Fund for the month in which the civil action authorized under paragraph (1) is commenced, to be awarded by the reviewing court in favor of the prevailing party.

(3) No interest awarded pursuant to paragraph (2) shall be deemed income or cost for the purposes of determining reimbursement due providers under this chapter.

. . . .

42 U.S.C. § 1395w-21. 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

In this subchapter, 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.

. . . .

42 U.S.C. § 1395w-23. Payments to Medicare+Choice organizations

. . . .

(f) Payments from trust funds

The payment to a Medicare+Choice organization under this section for individuals enrolled under this part with the organization and for payments under subsection (l) and subsection (m) and payments to a Medicare+Choice MSA under subsection (e)(1) of this section shall be made from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in such proportion as the Secretary determines reflects the relative weight that benefits under part A of this subchapter and under part B of this subchapter represents of the actuarial value of the total benefits under this subchapter. Payments to MA organizations for statutory drug benefits provided under this subchapter are made from the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund. Monthly

payments otherwise payable under this section for October 2000 shall be paid on the first business day of such month. Monthly payments otherwise payable under this section for October 2001 shall be paid on the last business day of September 2001. Monthly payments otherwise payable under this section for October 2006 shall be paid on the first business day of October 2006.

. . . .

42 C.F.R. § 405.1842 Expedited judicial review.

. . . .

(f) *Board's decision on EJR: Criteria for granting EJR.* Subject to paragraph (h)(3) of this section, the Board is required to issue an EJR decision following either the completion of the Board's own motion consideration under paragraph (c) of this section, or a notice issued by the Board in accordance with paragraph (e)(3)(i) of this section.

(1) The Board's decision must grant EJR for a legal question relevant to a specific matter at issue in a Board appeal if the Board determines the following conditions are satisfied:

(i) The Board has jurisdiction to conduct a hearing on the specific matter at issue in accordance with § 405.1840 of this subpart.

(ii) The Board lacks the authority to decide a specific legal question relevant to the specific matter at issue because the legal question is a challenge either to the constitutionality of a provision of a statute, or to the substantive or procedural validity of a regulation or CMS Ruling.

(2) The Board's decision must deny EJR for a legal question relevant to a specific matter at issue in a Board appeal if any of the following conditions are satisfied:

(i) The Board determines that it does not have jurisdiction to conduct a hearing on the specific matter at issue in accordance with § 405.1840 of this subpart.

(ii) The Board determines it has the authority to decide a specific legal question relevant to the specific matter at issue because the legal question is neither a challenge to the constitutionality of a provision of a statute, nor a challenge to the substantive or procedural validity of a regulation or CMS Ruling.

(iii) The Board does not have sufficient information to determine whether the criteria specified in paragraph (f)(1)(i) or (f)(1)(ii) of this section are met.

(3) A copy of the Board's decision must be sent promptly to—

(i) Each party to the Board appeal (as described in § 405.1843 of this subpart) and

(ii) The Office of the Attorney Advisor.

. . . .

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 412 and 413

[BPD-673-F]

RIN 0938-AE56

Medicare Program; Changes to the Inpatient Hospital Prospective Payment System and Fiscal Year 1991 Rates

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: We are revising the Medicare inpatient hospital prospective payment system to implement necessary changes arising from legislation and our continuing experience with the system. In addition, in the Addendum to this final rule, we are describing changes in the amounts and factors necessary to determine prospective payment rates for Medicare inpatient hospital services. In general, these changes are applicable to discharges occurring on or after October 1, 1990. We also set forth rate-of-increase limits for hospitals and hospital units excluded from the prospective payment system.

This final rule also responds to comments received concerning changes to hospital payments made in an April 20, 1990 final rule with comment. These changes include mid-year changes to the inpatient hospital prospective payment system that implemented provisions of the Omnibus Budget Reconciliation Act of 1989; and adjustments applicable to prospective payment hospitals and to the target amounts of hospitals and units excluded from the prospective payment system due to the elimination of the day limitation on covered inpatient hospital days made by the Medicare Catastrophic Coverage Act of 1988 and later repealed by provisions in the Medicare Catastrophic Repeal Act of 1989. The April 20, 1990 final rule with comment also incorporated changes to these provisions made by the Family Support Act of 1988, which clarified the criteria for adjusting the target amounts and implementation date.

In addition, this final rule clarifies the documentation requirements necessary to support the cost allocation of teaching physicians and the allowability of costs for rotating residents in determining payment for the direct costs of an approved graduate medical education program. This clarification is being made as a result of a September 29, 1989 final rule that made changes in Medicare policy concerning payment for the direct graduate medical education costs of providers associated with approved residency programs in medicine, osteopathy, dentistry, and podiatry.

EFFECTIVE DATE: The provisions of this final rule are effective on October 1, 1990, except for the changes concerning § 412.118, the count of full-time equivalent residents for purposes of the indirect medical education adjustment, which apply to cost reporting periods beginning on or after July 1, 1991.

FOR FURTHER INFORMATION CONTACT: Barbara Wynn, (301) 966-4529.

ADDRESSES: To obtain individual copies of this document, contact the following: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 783-3238. The charge for individual copies is $1.50 for each issue or for each group of pages as actually bound, payable by check or money order to the Superintendent of Documents.

SUPPLEMENTARY INFORMATION:

I. Background

A. Summary

Under section 1886(d) of the Social Security Act (the Act), a system of payment for acute inpatient hospital stays under Medicare Part A (Hospital Insurance) based on prospectively-set rates was established effective with hospital cost reporting periods beginning on or after October 1, 1983. Under this system, Medicare payment is made at a predetermined, specific rate for each hospital discharge. All discharges are classified according to a list of diagnosis-related groups (DRGs). The regulations governing the inpatient hospital prospective payment system are located in 42 CFR Part 412.

B. Summary of December 29, 1989 Notice

On September 1, 1989, we published a final rule (54 FR 36452) to implement the seventh year of the prospective payment system. However, on December 19, 1989, the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101-239) was enacted. The portions of sections 6001, 6002, 6003, 6004, 6021, 6110, and 6205 of Public Law 101-239 that affected Medicare payments to hospitals in Federal fiscal year (FY) 1990 and that were self-implementing, were announced in a **Federal Register** notice published on December 29, 1989 (54 FR 53754). These statutory changes provided for the following:

- For discharges occurring on or after January 1, 1990 and before October 1, 1990, the applicable percentage increase used to update the standardized amounts for prospective payment system hospitals is—
  - —9.72 percent for hospitals located in rural areas;
  - —5.62 percent for hospitals located in large urban areas; and
  - —4.97 percent for hospitals located in other urban areas.

(The increase in the target amount for excluded hospitals and units was not changed and, therefore, continues to be 5.5 percent.)

- Effective for portions of cost reporting periods or discharges occurring during the period beginning January 1, 1990 and ending September 30, 1990, payments for capital-related costs of inpatient services of hospitals under the prospective payment system are reduced by 15 percent.
- For cost reporting periods beginning on or after October 1, 1989, the hospital-specific rate of sole community hospitals is updated by the percentage increase applicable to the geographic area in which the hospital is located. This increase is applicable to discharges occurring on or after January 1, 1990.
- Hospitals that were classified as rural referral centers as of September 30, 1989 continue to be classified as rural referral centers for cost reporting periods beginning on or after October 1, 1989 and before October 1, 1992.
- Hospitals classified as cancer hospitals are excluded from the prospective payment system effective with cost reporting periods beginning on or after October 1, 1989. The reduction for payment of capital costs is eliminated for hospitals classified as cancer hospitals as of December 19, 1989 efffective for portions of cost reporting periods or discharges occurring on or after October 1, 1986. For hospitals classified after December 19, 1989, the reduction for payment of capital costs is eliminated for cost reporting periods beginning on or after the date of classification. Special provisions were also made for hospitals that qualify for cancer status before December 31, 1990 (or before December 31, 1991 for hospitals located in States operating a demonstration project under section 1814(b) of the Act as of December 19, 1989). Effective January 18, 1990, a cancer hospital is eligible to receive periodic interim payments if it meets the criteria for receiving these payments. For cost reporting periods beginning on or after April 1, 1989, the base year for determining target amounts for cancer hospitals is to be the hospital's cost reporting period beginning during FY 1987 unless the use of its initial base

Comment: One commenter believes that the disproportionate share adjustment calculation should be expanded to include days that Medicare patients utilize health maintenance organizations (HMOs) since these beneficiaries are entitled to Part A benefits.

Response: Based on the language of section 1886(d)(5)(F)(vi) of the Act, which states that the disproportionate share adjustment computation 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. Prior to December 1, 1987, we were not able to isolate the days of care associated with Medicare patients in HMOs and, therefore, were unable to fold this number into the calculation. However, as of December 1, 1987, a field was included on the Medicare Provider Analysis and Review (MEDPAR) file that allows us to isolate those HMO days that are associated with Medicare patients. Therefore, since that time, we have been including HMO days in SSI/Medicare percentage.

B. Payments to Sole Community Hospitals and Medicare-Dependent, Small Rural Hospitals (§§ 412.92 and 412.108)

Under the prospective payment system, special payment protections are provided to SCHs. An SCH is a hospital that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other hospitals, is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. The regulations that set forth the criteria that a hospital must meet to be classified as an SCH and the special payment adjustments available to those hospitals are at § 412.92.

Prior to enactment of Public Law 101–239, section 1886(d)(5)(C)(ii) of the Act provided that SCHs be paid a blended rate based on 75 percent of the hospital-specific rate and 25 percent of the Federal regional rate. In addition, for cost reporting periods beginning before October 1, 1990, an SCH is eligible for a payment adjustment if, for reasons beyond its control, it experiences a decline in volume of greater than 5 percent compared to its preceding cost reporting period. (This adjustment is also available to a hospital that could qualify as an SCH but chooses not to be paid as an SCH.)

Section 6003(e) (1) and (2) of Public Law 101–239, which amended section 1886(d)(5) of the Act, revised both the qualifying criteria and payment methodology for SCHs. However, section 6003(e)(3) of Public Law 101–239 specifically states that any hospital classified as an SCH on December 19, 1989 will continue to be so classified regardless of whether it meets the revised criteria resulting from changes made in implementing section 6003(e)(1) of Public Law 101–239.

Section 1886(d)(5)(D)(iii)(I) of the Act incorporates the mileage standard that was established by regulation effective October 1, 1989 (54 FR 36480; September 1, 1989). Thus, Congress has ratified our policy that a hospital can qualify for SCH status if it is more than 35 road miles from another hospital. Since this policy had already been incorporated into the regulations at § 412.92(a)(1), we made no further change in the April 20, 1990 final rule with comment.

Section 6003(e) of Public Law 101–239 also revised the payment methodology for hospitals classified as SCHs effective with cost reporting periods beginning on or after April 1, 1990. As of that date, as provided in section 1886(d)(5)(D)(i) of the Act, SCHs will be paid based on whichever of the following rates yields the greatest aggregate payment for the cost reporting period: the Federal national rate applicable to the hospital, the updated hospital-specific rate based on FY 1982 cost per discharge, or the updated hospital-specific rate based on FY 1987 cost per discharge.

In the April 20, 1990 final rule with comment, we stated that the SCH's fiscal intermediary will determine for each cost reporting period which of the payment options will yield the highest payment rate. Payments will automatically be made at the highest rate based on the best data available at the time of the intermediary's determination. However, it may not be possible for the fiscal intermediary to determine in advance precisely which of the rates will yield the highest aggregate payment for the year. This is because, in many instances, the hospital's FY 1987 cost report had not yet been audited and, in all instances, it was not possible to forecast the October 1, 1990 update factor for the Federal rates, outlier payments, the amount of the disproportionate share adjustment, or the indirect medical education adjustment, all of which are applicable only to payment based on the Federal rate. Therefore, the intermediary will make its determination based on what appears to yield the highest payment amount.

We provided that a final adjustment be made at the close of the hospital's cost reporting period to determine precisely which of the three payment rates yielded the highest payment to the hospital. The settlement will take into account all of the adjustments described above. If a hospital disagrees with the intermediary's determination regarding the final amount of program payment to which it is entitled under this provision, it has the right to appeal the intermediary's decision in accordance with the criteria in subpart R of part 405 of the regulations, which concern provider payment determinations and appeals.

The April 20, 1990 document described the methodology we will use to calculate the hospital-specific rate based on an FY 1987 cost reporting period. We stated that FY 1987 cost reporting periods are those 12-month or longer cost reporting periods ending on or after September 30, 1987 and before September 30, 1988. If the hospital's last cost reporting period ending before September 30, 1988 is for a period of less than 12 months, we use the hospital's most recent 12-month or longer cost reporting period ending before the short period report.

The final rule with comment provided that if a hospital has no cost reporting period beginning in FY 1987, it will not have a hospital-specific rate based on FY 1987. The hospital will not be allowed to substitute any other base period for the FY 1987 base period.

We stated that for each SCH, the intermediary will calculate an FY 1987 hospital-specific rate as follows:

- Determine the hospital's total allowable Medicare inpatient operating cost, as stated on the FY 1987 cost report.
- Divide the total Medicare inpatient operating cost by the number of Medicare discharges in the cost reporting period to determine the FY 1987 base-period cost per case.
- Divide the base-period cost per case by the hospital's case-mix index applicable to the FY 1987 cost reporting period.

Each SCH will be informed of its FY 1987 hospital-specific rate within 180 days of the start of its cost reporting period beginning on or after April 1, 1990 (the first cost reporting period to which the new payment methodology applies). We also provided that, based on the decision of the U.S. Court of Appeals for the District of Columbia circuit in *Georgetown University Hospital* v. *Bowen*, 862 F. 2d 323 (D.C. Cir., 1988), any adjustments made to a hospital's FY 1987 hospital-specific rate due to a favorable appeal would be made retroactively to the time of the intermediary's initial determination. We added a new § 412.75 to describe

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 412, 413, 418, 460, 480, 482, 483, 485, and 489

[CMS–1428–F]

RIN 0938–AM80

Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems; and to implement a number of changes made by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that was enacted on December 8, 2003. In addition, in the Addendum to this final rule, we describe the changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. These changes are applicable to discharges occurring on or after October 1, 2004. We also are setting forth rate-of-increase limits as well as policy changes for hospitals and hospital units excluded from the IPPS that are paid in full or in part on a reasonable cost basis subject to these limits.

Among the policy changes that we are making are: Changes to the classification of cases to the diagnosis-related groups (DRGs); changes to the long-term care (LTC)–DRGs and relative weights; changes in the wage data, labor-related share of the wage index, and the geographic area designations used to compute the wage index; changes in the qualifying threshold criteria for and the approval of new technologies and medical services for add-on payments; changes to the policies governing postacute care transfers; changes to payments to hospitals for the direct and indirect costs of graduate medical education; changes to the payment adjustment for disproportionate share rural hospitals; changes in requirements and payments to critical access hospitals (CAHs); changes to the disclosure of information requirements for Quality Improvement Organization (QIOs); and changes in the hospital conditions of participation for discharge planning and fire safety requirements for certain health care facilities.

DATES: The provisions of this final rule are effective on October 1, 2004.

FOR FURTHER INFORMATION CONTACT:

Jim Hart, (410) 786–9520, Operating Prospective Payment, Diagnosis-Related Groups (DRGs), Wage Index, New Medical Services and Technology, Standardized Amounts, Hospital Geographic Reclassifications, Postacute Care Transfers, and Disproportionate Share Hospital Issuesp; Tzvi Hefter, (410) 786–4487, Capital Prospective Payment, Excluded Hospitals, Graduate Medical Education, Critical Access Hospitals, and Long-Term Care (LTC)–DRGs Issues;

Mary Collins, (410) 786–3189, CAH Bed Limits and Distinct Part Unit Issues; John Eppinger, (410) 786–4518, CAH Periodic Interim Payment Issues; Maria Hammel, (410) 786–1775, Quality Improvement Organization Issues; Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Project Issues; Jeannie Miller, (410) 786–3164, Bloodborne Pathogens Standards, Hospital Conditions of Participation for Discharge Planning, and Fire Safety Requirements Issues; Dr. Mark Krushat, (410) 786–6809; and Dr. Anita Bhatia, (410) 786–7236, Quality Data for Annual Payment Update Issues.

SUPPLEMENTARY INFORMATION:

Availability of Copies and Electronic Access

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Acronyms

ACGME—Accreditation Council on Graduate Medical Education
AHIMA—American Health Information Management Association
AHA—American Hospital Association
AOA—American Osteopathic Association
ASC—Ambulatory Surgical Center
BBA—Balanced Budget Act of 1997, Pub. L. 105–33
BIPA—Medicare, Medicaid, and SCHIP [State Children's Health Insurance Program] Benefits Improvement and Protection Act of 2000, Pub. L. 106–554
BLS—Bureau of Labor Statistics
CAH—Critical access hospital
CART CMS—Abstraction & Reporting Tool
CBSAs—Core-Based Statistical Areas
CC—Complication or comorbidity
CMS—Centers for Medicare & Medicaid Services
CMSA—Consolidated Metropolitan Statistical Area
COBRA—Consolidated Omnibus Reconciliation Act of 1985, Pub. L. 99–272
CoP—Condition of Participation
CPI—Consumer Price Index
CRNA—Certified registered nurse anesthetist
DRG—Diagnosis-related group
DSH—Disproportionate share hospital
ESRD—End-stage renal disease
FDA—Food and Drug Administration
FQHC—Federally qualified health center
FSES—Fire Safety Evaluation System
FTE—Full-time equivalent
FY—Federal fiscal year
GME—Graduate medical education
HCRIS—Hospital Cost Report Information System
HIPC—Health Information Policy Council
HIPAA—Health Insurance Portability and Accountability Act of 1996, Pub. L. 104–191
HHA—Home health agency
HPSA—Health Professions Shortage Area
ICD–9–CM—International Classification of Diseases, Ninth Revision, Clinical Modification
ICD–10–PCS—International Classification of Diseases, Tenth Edition, Procedure Coding System
ICF/MRs—Intermediate care facilities for the mentally retarded
IME—Indirect medical education
IPPS—Acute care hospital inpatient prospective payment system
IPF—Inpatient psychiatric facility
IRF—Inpatient rehabilitation facility
JCAHO—Joint Commission on the Accreditation of Healthcare Organizations
LAMA—Left Against Medical Advice
LTC–DRG—Long-term care diagnosis-related group

periods beginning on or after October 1, 2004.

3. Dual-Eligible Patient Days

As described above, the DSH patient percentage is equal to the sum of the percentage of Medicare inpatient days attributable to patients entitled to both Medicare Part A and SSI benefits, and the percentage of total inpatient days attributable to patients eligible for Medicaid but not entitled to Medicare Part A benefits. If a patient is a Medicare beneficiary who is also eligible for Medicaid, the patient is considered dual-eligible and the patient days are included in the Medicare fraction of the DSH patient percentage but not the Medicaid fraction. This is consistent with the language of section 1886(d)(5)(F)(vi)(II) of the Act, which specifies that patients entitled to benefits under Part A are excluded from the Medicaid fraction.

It has come to our attention that we inadvertently misstated our current policy with regard to the treatment of certain inpatient days for dual-eligibles in the proposed rule of May 19, 2003 (68 FR 27207). In that proposed rule, we indicated that a dual-eligible beneficiary is included in the Medicare fraction even after the patient's Medicare Part A hospital coverage is exhausted. That is, we stated that if a dual-eligible patient is admitted without any Medicare Part A hospital coverage remaining, or the patient exhausts Medicare Part A hospital coverage while an inpatient, the non-covered patient days are counted in the Medicare fraction. This statement was not accurate. Our policy has been that only covered patient days are included in the Medicare fraction (§ 412.106(b)(2)(i)). A notice to this effect was posted on CMS's Web site (*http://www.cms.hhs.gov/providers/hipps/dual.asp*) on July 9, 2004.

Comment: We received numerous comments that commenters were disturbed and confused by our recent Web site posting regarding our policy on dual-eligible patient days. The commenters believed that this posting was a modification or change in our current policy to include patient days of dual-eligible Medicare beneficiaries whose Medicare Part A coverage has expired in the Medicaid fraction of the DSH calculation. In addition, the commenters believed that the information in this notice appeared with no formal notification by CMS and without the opportunity for providers to comment.

Response: The notice that was posted on our Web site was not a change in our current policy. Our current policy is, if a patient is a Medicare beneficiary who is also eligible for Medicaid, the patient is considered dual-eligible and the patient days are included in the Medicare fraction of the DSH patient percentage but not the Medicaid fraction. This is consistent with the language of section 1886(d)(5)(F)(vi)(II) of the Act, which specifies that patients entitled to benefits under Medicare Part A are excluded from the Medicaid fraction.

The Web site posting is a correction of an inadvertent misstatement made in the May 19, 2003 proposed rule (68 FR 27207). This Web site posting was not a new proposal or policy change. As a result, we do not believe it is necessary to utilize the rule making process in correcting a misstatement that was made in the May 19, 2003 proposed rule regarding this policy.

In the proposed rule of May 19, 2003 (68 FR 27207), we proposed to change our policy to begin to count in the Medicaid fraction of the DSH patient percentage the patient days of dual-eligible Medicare beneficiaries whose Medicare coverage has expired. We note that the statutory provision referenced above stipulates that the Medicaid fraction is to include patients who are eligible for Medicaid. However, the statute also requires that patient days attributable to patients entitled to benefits under Medicare Part A are to be excluded from the Medicaid fraction.

Comment: Numerous commenters opposed our proposal to begin to count in the numerator of the Medicaid fraction of the DSH patient percentage, the patient days of dual-eligible Medicare beneficiaries whose Medicare inpatient coverage has expired. They objected that the proposal would result in a reduction of DSH payments when the exhausted coverage days are removed from the Medicare fraction and included in the Medicaid fraction. According to these commenters, any transfer of a particular patient day from the Medicare fraction (based on total Medicare patient days) to the Medicaid fraction (based on total patient days) would dilute the value of that day and, therefore, reduce the overall patient percentage and the resulting DSH payment adjustment.

One commenter observed that a patient who exhausts coverage for inpatient hospital services still remains entitled to other Medicare Part A benefits. This commenter found it difficult to reconcile the position that these patients are not entitled to Medicare Part A benefits when they can receive other covered Part A services, such as SNF services.

In addition, some commenters stated that these days should not be included in either the Medicare or Medicaid fraction. They indicated that the days should not be included in the Medicare fraction because that computation includes the number of patient days actually furnished to patients who were entitled to both Medicare Part A and SSI benefits. The commenters stated that the days should also be excluded from the Medicaid fraction because that computation excludes hospital patient days for patients who, for those days, were entitled to benefits under Medicare Part A.

Commenters also indicated that the proposal would put an increased administrative burden on the hospitals to support including these patient days in the Medicaid fraction. They recommended that if we finalize this policy, the requirement that hospitals submit documentation justifying the inclusion of the days in the Medicaid fraction should be removed.

Response: We proposed this change to facilitate consistent handling of these days across all hospitals, in recognition of the reality that, in some States, fiscal intermediaries are reliant upon hospitals to identify days attributable to dual-eligible patients whose Medicare Part A hospitalization benefits have expired. We believe it is important that all IPPS policies be applied consistently for all hospitals around the country.

However, we acknowledge the point raised by the commenter that beneficiaries who have exhausted their Medicare Part A inpatient coverage may still be entitled to other Part A benefits. We also agree with the commenter that including the days in the Medicare fraction has a greater impact on a hospital's DSH patient percentage than including the days in the Medicaid fraction. This is necessarily so because the denominator of the Medicare fraction (total Medicare inpatient days) is smaller than the denominator of the Medicaid fraction (total inpatient days). However, we note that we disagree with the commenter's assertion that including days in the Medicaid fraction instead of the Medicare fraction always results in a reduction in DSH payments. For instance, if a dual-eligible beneficiary has not exhausted Medicare Part A inpatient benefits, and is not entitled to SSI benefits, the patient days for that beneficiary are included in the Medicare fraction, but only in the denominator of the Medicare fraction (because the patient is not entitled to SSI benefits). The inclusion of such patient days in the Medicare fraction has the result of decreasing the Medicare fraction in the DSH patient percentage.

For these reasons, we have decided not to finalize our proposal stated in the May 19, 2003 proposed rule to include dual-eligible beneficiaries who have exhausted their Part A hospital coverage in the Medicaid fraction. Instead, we are adopting a policy to include the days associated with dual-eligible beneficiaries in the Medicare fraction, whether or not the beneficiary has exhausted Medicare Part A hospital coverage. If the patient is entitled to Medicare Part A and SSI, the patient days will be included in both the numerator and denominator of the Medicare fraction. This policy will be effective for discharges occurring on or after October 1, 2004. We are revising our regulations at § 412.106(b)(2)(i) to include the days associated with dual-eligible beneficiaries in the Medicare fraction of the DSH calculation.

4. Medicare+Choice (M+C) Days

Under existing § 422.1, an M+C plan means ''health benefits coverage offered under a policy or contract by an M+C organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the M+C plan.'' Generally, each M+C plan must provide coverage of all services that are covered by Medicare Part A and Part B (or just Part B if the M+C plan enrollee is only entitled to Part B).

We have received questions whether the patient days associated with patients enrolled in an M+C Plan should be counted in the Medicare fraction or the Medicaid fraction of the DSH patient percentage calculation. The question stems from whether M+C plan enrollees are entitled to benefits under Medicare Part A since M+C plans are administered through Medicare Part C.

We note that, under existing regulations at § 422.50, an individual is eligible to elect an M+C plan if he or she is entitled to Medicare Part A and enrolled in Part B. However, once a beneficiary has elected to join an M+C plan, that beneficiary's benefits are no longer administered under Part A. In the proposed rule of May 19, 2003 (68 FR 27208), we proposed that once a beneficiary elects Medicare Part C, those patient days attributable to the beneficiary would not be included in the Medicare fraction of the DSH patient percentage. Under our proposal, these patient days would be included in the Medicaid fraction. The patient days of dual-eligible M+C beneficiaries (that is, those also eligible for Medicaid) would be included in the count of total patient days in both the numerator and denominator of the Medicaid fraction.

Comment: Several commenters indicated that they appreciated CMS's attention to this issue in the proposed rule. The commenters also indicated that there has been insufficient guidance on how to handle these days in the DSH calculation. However, several commenters disagreed with excluding these days from the Medicare fraction and pointed out that these patients are just as much Medicare beneficiaries as those beneficiaries in the traditional fee-for-service program.

Response: Although there are differences between the status of these beneficiaries and those in the traditional fee-for-service program, we do agree that once Medicare beneficiaries elect Medicare Part C coverage, they are still, in some sense, entitled to benefits under Medicare Part A. We agree with the commenter that these days should be included in the Medicare fraction of the DSH calculation. Therefore, we are not adopting as final our proposal stated in the May 19, 2003 proposed rule to include the days associated with M+C beneficiaries in the Medicaid fraction. Instead, we are adopting a policy to include the patient days for M+C beneficiaries in the Medicare fraction. As noted previously, if the beneficiary is also an SSI recipient, the patient days will be included in the numerator of the Medicare fraction. We are revising our regulations at § 412.106(b)(2)(i) to include the days associated with M+C beneficiaries in the Medicare fraction of the DSH calculation.

M. Payment Adjustments for Low-Volume Hospitals (§ 412.101)

Section 406 of Public Law 108–173 amended section 1886(d) of the Act to add a new subclause (12) to provide for a new payment adjustment to account for the higher costs per discharge of low-volume hospitals under the IPPS. Section 1886(d)(12)(C)(i) of the Act, as added by section 406, defines a low-volume hospital as a ''subsection (d) hospital * * * that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year.'' Section 1886(d)(12)(C)(ii) of the Act further stipulates that the term ''discharge'' refers to total discharges, and not merely to Medicare discharges. Specifically, the term refers to the ''inpatient acute care discharge of an individual regardless of whether the individual is entitled to benefits under part A.'' Finally, the provision requires the Secretary to determine an applicable percentage increase for these low-volume hospitals based on the ''empirical relationship'' between ''the standardized cost-per-case for such hospitals and the total number of discharges of these hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges.'' The statute thus mandates the Secretary to develop an empirically justifiable adjustment formula based on the relationship between costs and discharges for these low-volume hospitals. The statute also limits the adjustment to no more than 25 percent.

MedPAC has published an analysis of the financial performance and cost profiles of low-volume hospitals (MedPAC June 2001 Report to Congress, page 66). Its analysis indicated that hospitals with 500 discharges or less generally have negative Medicare margins. Specifically, hospitals with 200 discharges or less have margins of −16.4 percent, and hospitals with 201 to 500 discharges have margins of −2.1 percent. MedPAC's analysis further revealed that hospitals with a small volume of discharges have higher costs per discharge than larger facilities, after controlling for the other cost factors recognized in the payment system. MedPAC's analysis thus indicates that low-volume providers are disadvantaged by payment rates based on average volume. In analyzing the relationship between costs per case and discharges, MedPAC also found that this relationship begins to level off and reaches zero variation at around 500 discharges. Therefore, MedPAC recommended an adjustment formula in the form of:

1.25 −(.0005*D), if D<500 discharges

Where 1.25 represents the maximum 25-percent add-on, .0005 is the payment adjustment per case (derived by dividing .25 by 500 discharges) and ''D'' is the number of discharges.

Using FY 2001 cost report data, we found an even larger disparity than MedPAC found between low-volume providers and their higher-volume counterparts. Although Medicare margins remain healthy overall at 9.32 percent, the Medicare margin for providers with 200 or less discharges is −46.26 percent, and the margin for providers with 201 to 500 discharges is −11.74 percent. For the May 18, 2004 proposed rule, we employed a bivariate regression analysis to determine the fit between total hospital discharges and operating costs from FY 2001.

As discussed in the proposed rule, we found a very strong correlation between costs and the total number of discharges. We then examined the variation in cost-per-case among subsection (d) hospitals, using both log

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 414, 419, 424, 482, 485, and 489

[CMS–1599–F; CMS–1455–F]

RINs 0938–AR53 and 0938–AR73

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Final rules.

SUMMARY: We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems. Some of the changes implement certain statutory provisions contained in the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (collectively known as the Affordable Care Act) and other legislation. These changes will be applicable to discharges occurring on or after October 1, 2013, unless otherwise specified in this final rule. We also are updating the rate-of-increase limits for certain hospitals excluded from the IPPS that are paid on a reasonable cost basis subject to these limits. The updated rate-of-increase limits will be effective for cost reporting periods beginning on or after October 1, 2013.

We also are updating the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) and implementing certain statutory changes that were applied to the LTCH PPS by the Affordable Care Act. Generally, these updates and statutory changes will be applicable to discharges occurring on or after October 1, 2013, unless otherwise specified in this final rule.

In addition, we are making a number of changes relating to direct graduate medical education (GME) and indirect medical education (IME) payments. We are establishing new requirements or have revised requirements for quality reporting by specific providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities (IPFs)) that are participating in Medicare.

We are updating policies relating to the Hospital Value-Based Purchasing (VBP) Program and the Hospital Readmissions Reduction Program. In addition, we are revising the conditions of participation (CoPs) for hospitals relating to the administration of vaccines by nursing staff as well as the CoPs for critical access hospitals relating to the provision of acute care inpatient services.

We are finalizing proposals issued in two separate proposed rules that included payment policies related to patient status: payment of Medicare Part B inpatient services; and admission and medical review criteria for payment of hospital inpatient services under Medicare Part A.

DATES: *Effective Date:* These final rules are effective on October 1, 2013.

FOR FURTHER INFORMATION CONTACT:

Tzvi Hefter, (410) 786–4487, and Ing-Jye Cheng, (410) 786–4548, Operating Prospective Payment, MS–DRGs, Hospital-Acquired Conditions (HAC), Wage Index, New Medical Service and Technology Add-On Payments, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, and Medicare Disproportionate Share Hospital (DSH) Issues.

Michele Hudson, (410) 786–4487, and Judith Richter, (410) 786–2590, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Mollie Knight, (410) 786–7948 and Bridget Dickensheets, (410) 786–8670, Market Basket for IPPS Hospitals and LTCHs Issues.

Siddhartha Mazumdar, (410) 786–6673, Rural Community Hospital Demonstration Program Issues.

James Poyer, (410) 786–2261, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Program Administration, Validation, and Reconsideration Issues.

Shaheen Halim, (410) 786–0641, Hospital Inpatient Quality Reporting—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues; and Readmission Measures for Hospitals Issues.

Elizabeth Goldstein, (410) 786–6665, Hospital Inpatient Quality Reporting—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Mary Pratt, (410) 786–6867, LTCH Quality Data Reporting Issues.

Kim Spalding Bush, (410) 786–3232, Hospital Value-Based Purchasing Efficiency Measures Issues.

James Poyer, (410) 786–2261, PPS-Exempt Cancer Hospital Quality Reporting Issues.

Allison Lee, (410) 786–8691 and Jeffrey Buck, (410) 786–0407, Inpatient Psychiatric Facility Quality Reporting Issues.

Sarah Fahrendorf, (410) 786–3112, Conditions of Participation (CoPs) for CAHs Issues.

Commander Scott Cooper, USPHS, (410) 786–9465, Hospital Conditions of Participation (CoPs)—Pneumococcal Vaccine Issues.

Ann Marshall, (410) 786–3059, Medicare Part B Inpatient Billing: Payable Part B Inpatient and Part B Outpatient Services and Beneficiary Utilization Days; and Physician Order and Certification for Payment of Hospital Inpatient Services under Medicare Part A Issues.

Susanne Seagrave, (410) 786–0044, Physician Order and Certification for Payment of Inpatient Rehabilitation Facility Services under Medicare Part A Issues.

Jennifer Dupee, (410) 786–6537, and Jennifer Phillips, (410) 786–1023, Medical Review Criteria for Payment of Hospital Inpatient Services under Medicare Part A Issues.

David Danek, (617) 565–2682, Medicare Part B Inpatient Billing: Hospital and Beneficiary Appeals Issues.

Fred Grabau, (410) 786–0206, Medicare Part B Inpatient Billing: Time Limits for Filing Claims Issues.

Brian Pabst, (410) 786–2487, Medicare Part B Inpatient Billing: Coordination of Benefits Issues.

Anthony Hodge, (410) 786–6645, Qualification for Coverage of Skilled Nursing Facilities Services Issues.

SUPPLEMENTARY INFORMATION:

Electronic Access

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Tables Available Only Through the Internet on the CMS Web Site

In the past, a majority of the tables referred to throughout this preamble and in the Addendum to the proposed rule and the final rule were published in the **Federal Register** as part of the annual proposed and final rules. However, beginning in FY 2012, some of

payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to needy patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the most common, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the DSH statutory references (under section 1886(d)(5)(F) of the Act) to ''days'' apply only to hospital acute care inpatient days. Regulations located at § 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

2. Counting of Patient Days Associated With Patients Enrolled in Medicare Advantage Plans in the Medicare and Medicaid Fractions of the Disproportionate Patient Percentage (DPP) Calculation

The regulation at 42 CFR 422.2 defines Medicare Advantage (MA) plan to mean ''health benefits coverage offered under a policy or contract by an MA organization that includes a specific set of health benefits offered at a uniform premium and uniform level of cost-sharing to all Medicare beneficiaries residing in the service area of the MA plan. . . .'' Generally, each MA plan must at least provide coverage of all services that are covered by Medicare Part A and Part B, but also may provide for Medicare Part D benefits and/or additional supplemental benefits. However, certain items and services, such as hospice benefits, continue to be covered under Medicare fee-for-service (FFS). Under § 422.50 of the regulations, an individual is eligible to elect an MA plan if he or she is entitled to Medicare Part A and enrolled in Medicare Part B. Dual eligible beneficiaries (individuals entitled to Medicare and eligible for Medicaid) also may choose to enroll in a MA plan, and, as an additional supplemental benefit, the MA plan may pay for Medicare cost-sharing not covered by Medicaid.

In the FY 2004 IPPS proposed rule (68 FR 27208), in response to questions about whether the patient days associated with patients enrolled in an MA plan (then called a Medicare + Choice (M+C) plan) should be counted in the Medicare fraction or the Medicaid fraction of the disproportionate patient percentage (DPP) calculation, we proposed that once a beneficiary enrolls in an MA plan, those patient days attributable to the beneficiary would not be included in the Medicare fraction of the DPP. Instead, those patient days would be included in the numerator of the Medicaid fraction, if the patient also were eligible for Medicaid. In the FY 2004 IPPS final rule (68 FR 45422), we did not respond to public comments on this proposal, due to the volume and nature of the public comments we received, and we indicated that we would address those comments later in a separate document. In the FY 2005 IPPS proposed rule (69 FR 28286), we stated that we planned to address the FY 2004 comments regarding MA days in the IPPS final rule for FY 2005. In the FY 2005 IPPS final rule (69 FR 49099), we determined that, under § 412.106(b)(2)(i) of the regulations, MA patient days should be counted in the Medicare fraction of the DPP calculation. We explained that, even where Medicare beneficiaries elect Medicare Part C coverage, they are still entitled to benefits under Medicare Part A. Therefore, we noted that if a MA beneficiary is also an SSI recipient, the patient days for that beneficiary will be included in the numerator of the Medicare fraction (as well as in the denominator) and not in the numerator of the Medicaid fraction. We note that, despite our explicit statement in the final rule that the regulations also would be revised, due to a clerical error, the corresponding regulation at § 412.106(b)(2)(i) was not amended to explicitly reflect this policy until 2007 (72 FR 47384).

On November 15, 2012, in a ruling in the case of *Allina Health Services* v. *Sebelius (Allina),* the Federal District Court for the District of Columbia (the court) held that the final policy of putting MA patient days in the Medicare fraction adopted in the FY 2005 IPPS final rule was not a logical outgrowth of the FY 2004 IPPS proposed rule (904 F. Supp. 2d 75 (D.D.C. 2012), *appeal docketed,* No. 13–5011 (D.C. Cir. Jan. 11, 2013). The court held that interested parties had not been put on notice that the Secretary might adopt a final policy of counting the days in the Medicare fraction and were not provided an adequate further opportunity for public comment.

We continue to believe that individuals enrolled in MA plans are ''entitled to benefits under part A'' as the phrase is used in the DSH provisions at section 1886(d)(5)(F)(vi)(I) of the Act. Section 226(a) of the Act provides that an individual is automatically ''entitled'' to Medicare Part A when the person reaches age 65 or becomes disabled, provided that the individual is entitled to Social Security benefits under section 202 of the Act. Beneficiaries who are enrolled in MA plans provided under Medicare Part C continue to meet all of the statutory criteria for entitlement to Medicare Part A benefits under section 226 of the Act. Moreover, in order to enroll in Medicare Part C, or to change from one MA plan to another MA plan offered under Part C, a beneficiary must be ''entitled to benefits under Part A and enrolled under Part B'' (section 1852(a)(1)(B)(i) of the Act). Thus, by definition, a beneficiary must be entitled to Part A to be enrolled in Part C. There is nothing in the Act that suggests that beneficiaries who enroll in a Medicare Part C plan forfeit their entitlement to Medicare Part A benefits. To the contrary, a beneficiary who enrolls in Medicare Part C is entitled to receive benefits under Medicare Part A through

the MA plan in which he or she is enrolled, and the MA organization's costs in providing such Part A benefits are paid for by CMS with money from the Medicare Part A Trust Fund. In addition, under certain circumstances, Medicare Part A pays directly for care furnished to patients enrolled in Medicare Part C plans, rather than indirectly through Medicare Part A Trust Fund payments to MA organizations. For example, if, during the course of the year, the scope of benefits provided under Medicare Part A expands beyond a certain cost threshold due to Congressional action or a national coverage determination, Medicare Part A will pay the provider directly for the cost of those services (section 1852(a)(5) of the Act). Similarly, Medicare Part A also pays directly for federally qualified health center services and hospice care furnished to MA patients (section 1853(a)(4) and section 1853(h)(2) of the Act, respectively). Thus, we continue to believe that a patient enrolled in an MA plan remains entitled to benefits under Medicare Part A, and should be counted in the Medicare fraction of the DPP, and not the Medicaid fraction.

We also believe that our policy of counting patients enrolled in MA plans in the Medicare fraction was a logical outgrowth of the FY 2004 IPPS proposed rule, and, accordingly, have appealed the decision in *Allina.* However, in an abundance of caution and for the reasons discussed above, in the FY 2014 IPPS/LTCH PPS proposed rule (78 FR 27578), we proposed to readopt the policy of counting the days of patients enrolled in MA plans in the Medicare fraction of the DPP. We sought public comments from interested parties that may support or oppose the proposal to include the MA patient days in the Medicare fraction of the DPP calculation for FY 2014 and subsequent years. We indicated in the proposed rule that we would evaluate these public comments and consider whether a further change in policy is warranted, and would include our final determination in the FY 2014 IPPS/LTCH PPS final rule. We did not propose any change to the regulation text because the current text reflects the policy being proposed.

Comment: A few commenters supported CMS' proposal to readopt the policy of including MA patient days in the numerator and denominator of the Medicare fraction of the DPP calculation. One commenter recommended, for consistency purposes, that MA days continue to be included in the Medicare fraction. Another commenter stated that the proposal makes logical sense because these patients remain entitled to, and receive, Medicare Part A benefits, and have simply chosen to receive them through an MA plan offered under Medicare Part C. The commenter also opined that the effect on the Medicare fraction would likely be minimal because the commenter believed that the majority of patients who enroll in Medicare Part C would not be likely to meet the income eligibility requirement for SSI benefits. Other commenters supported CMS' proposal to readopt the policy, stating that CMS will have provided all interested parties with adequate time and information to meaningfully participate in the rulemaking process.

Response: We appreciate the commenters' support. We agree with commenters that a patient enrolled in a MA plan remains entitled to benefits under Part A and should be included in the Medicare fraction of the DPP and not the Medicaid fraction. We also agree with commenters that we have provided adequate notice and opportunity for the public to comment on our proposal to readopt our policy of counting the days of patients enrolled in MA plans in the Medicare fraction for FY 2014 and subsequent years. Furthermore, as discussed in more detail below, we continue to believe that we also provided adequate notice and opportunity for review and comment prior to the original adoption of the policy in the FY 2005 IPPS rule; and, therefore, we have appealed the court's decision in *Allina* which concluded that we did not. In addition, with regard to the commenter's assertion that the majority of patients who enroll in Medicare Part C would not be likely to meet the income eligibility requirement for SSI benefits, we disagree and note that research, such as the findings from the Medicare Current Beneficiary Survey as listed in the table below, has shown that Part C enrollees tend to have lower incomes at similar rates as Medicare beneficiaries who are not enrolled in Part C.

PERCENTAGE OF MEDICARE BENEFICIARIES BY INCOME LEVEL, FEE FOR SERVICE AND RISK HMO: 2009–2011 [12]

Beneficiaries (%)	2011 Total	2011 Fee-for-service	2011 Risk HMO	2010 Total	2010 Fee-for-service	2010 Risk HMO	2009 Total	2009 Fee-for-service	2009 Risk HMO
Less than $5,000	3.47	3.69	2.84	4.17	4.29	3.82	3.86	4.07	3.19
$5,000–$9,999	10.92	11.03	10.61	10.94	11.00	10.78	11.75	12.01	10.92
$10,000–$14,999	13.76	13.50	14.50	13.94	13.63	14.86	14.00	13.35	16.03
$15,000–$19,999	9.51	8.48	12.34	10.13	9.01	13.46	9.97	9.20	12.38
$20,000–$24,999	9.17	8.52	10.97	8.67	8.15	10.21	9.00	8.33	11.11
$25,000–$29,999	7.88	7.65	8.53	8.02	7.85	8.53	8.80	8.40	10.03
$30,000–$39,999	13.18	12.88	14.00	13.44	13.17	14.23	13.30	13.19	13.63
$40,000–$49,999	9.92	9.96	9.82	9.83	10.21	8.70	9.65	10.02	8.49
$50,000 or more	22.18	24.28	16.39	20.87	22.71	15.41	19.67	21.43	14.21

[12] Sources: Medicare Current Beneficiary Survey. 2011 Characteristics and Perceptions of the Medicare Population. 2010 Characteristics and Perceptions of the Medicare Population. 2009 Characteristics and Perceptions of the Medicare Population. Available at: *http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/MCBS/Data-Tables.html.*

Note: As described in the sources, income estimates are derived from imputed income data. Standard errors of income estimates may be underestimated as they have not been adjusted to reflect the imputation of missing data.

Comment: A few commenters stated that the policy proposal promotes the integrity of the 340B program. The commenters stated that the size of the 340B program has far exceeded Congress' intent to help safety-net providers cover the costs of uncompensated pharmaceutical care; and including MA patient days in the Medicare fraction helps to ensure that a hospital's DPP is not artificially inflated, thereby helping to curb some of the recent abuse and promote the program's original goals. In addition, the commenters stated that, given that section 3133 of the Affordable Care Act reduces aggregate DSH funding beginning in FY 2014, providing oversight of the 340B program will be critical. The commenters stated that, with less DSH funds available, ensuring

that entities with inflated DPPs do not divert funds from truly DSH eligible providers is critical to maintain that the support is provided where it will be the most beneficial, as intended by Congress. In addition, one commenter stated that CMS has an opportunity to provide protection for DPP values for hospitals located in States where Medicaid was not expanded under the intent of the Affordable Care Act. The commenter recommended that CMS issue rules that grandfather current providers who qualify for 340B prescription drug discounting until further impacts of the Affordable Care Act can be reviewed and a new standard be determined for hospitals located in States that are not expanding the Medicaid program to levels prescribed under the Affordable Care Act.

Response: Although we appreciate receiving the commenters' views on the 340B program, we note that this program is administered by HRSA and is not within the scope of this rulemaking. Additionally, we note that we believe the commenter that made the recommendation about issuing rules that would grandfather current providers who qualify for 340B prescription drug discounting until further impacts of the Affordable Care Act can be assessed for hospitals located in States that are not expanding the Medicaid program, may be confused about how the statute, specifically the Affordable Care Act, "protects" DPP values.

Comment: Many commenters opposed CMS' proposal and urged CMS to exclude MA patient days from the Medicare fraction of the DPP calculation. These commenters disagreed that individuals enrolled in Medicare Advantage are "entitled" to benefits under Part A, and asserted that the policy proposal is not dictated by the statute and is inconsistent with their view of the intent of Congress. The commenters argued that, in examining the statute and CMS' regulations, it is clear to them that MA enrollees are not entitled to benefits under Part A and, therefore, should be excluded from the Medicare fraction. These commenters cited three provisions of the statute in support of this argument:

- Section 226(c)(1) of the Act, which states "entitlement of an individual to hospital insurance benefits for a month [under Part A] shall consist of entitlement to have payment made under, and subject to the limitations in, [P]art A . . . ."
- Section 1851(a)(1) of the Act, which states that the persons eligible for Medicare Advantage are "entitled to elect to receive benefits" either "through the original [M]edicare fee-for-service program under [P]arts A and B, or through enrollment in a [Medicare Advantage] plan under [Part C]."
- Section 1851(i)(1) of the Act, which states that "payments under a contract with a [Medicare Advantage] organization . . . with respect to an individual electing a [Medicare Advantage] plan . . . shall be instead of the amounts which (in the absence of the contract) would otherwise be payable under [P]arts A and B . . . ."

The commenters contended that because individuals who enroll in an MA plan receive benefits under Part C and not Part A, they cannot be "entitled" to benefits under Part A because, in the commenters' view, they no longer receive benefits under Part A. They argued that beneficiaries are not "entitled" to benefits that the commenters believe the law denies them, and therefore, CMS' interpretation is unreasonable.

Response: We disagree that Medicare beneficiaries enrolled in Part C no longer receive benefits under Part A and that, because the payment structure of Part C applies (that is, CMS pays the MA plans so that the plans may make payment to hospitals for the care of the beneficiaries), those beneficiaries are not entitled to Part A benefits. As we stated above, section 226(A) of the Act provides that an individual is automatically "entitled" to Medicare Part A when the person reaches age 65 or becomes disabled, provided that the individual is entitled to Social Security benefits under section 202 of the Act.

This interpretation is consistent with our conclusion that Congress uses the phrase "entitled to benefits under part A" to consistently refer to an individual's status as a Medicare beneficiary. We agree with the United States Court of Appeals for the Sixth Circuit when it recently explained, "the phrase 'entitled to benefits under [Medicare] part A' appears in more than 30 other sections of the Medicare statute, indicating that the phrase has a specific, consistent meaning throughout the statutory scheme, rather than a varying, context-specific meaning in each section and subsection. (We refer readers to *Ali* v. *Fed. Bureau of Prisons,* 552 U.S. 214, 222 (2008) (noting that statutory construction "must, to the extent possible, ensure that the statutory scheme is coherent and consistent") and *Metro. Hosp.* v. *U.S. Dep't of Health & Human Servs.,* 712 F.3d 248, 260 (6th Cir. 2013) (holding that including patients who have exhausted inpatient benefits in the Medicare fraction is consistent with how "entitled to benefits under part A" is used throughout the Medicare statute).) Enrolling in Part C does not change an enrollee's status as a Medicare beneficiary and does not remove or reduce any benefits the beneficiary would otherwise have received; indeed, the MA plan must provide the benefits to which the beneficiary is entitled under Part A and may provide additional benefits as described by section 1852(a)(1)(A) of the Act. We agree with the Court of Appeals for the District of Columbia Circuit that "Congress has not clearly foreclosed the Secretary's interpretation that [Part C] enrollees are entitled to benefits under Part A. Rather, it has left a statutory gap, and it is for the Secretary . . . to fill that gap" (*Northeast Hosp. Corp.* v. *Sebelius;* 657 F.3d 1, 13 (D.C. Cir. 2011)). We further note that the D.C. Circuit has already rejected many of the commenters' view that the agency's interpretation is inconsistent with the plain language of the statute (*Id.* at 6–13).

Thus, for purposes of section 226(c)(1) of the Act, beneficiaries enrolled in Part C are having payment made under Part A for the month in question, via the Part A component of the monthly payment made to the MA organization, and are receiving Part A benefits subject to the limitations on such benefits provided for in Part A.

For purposes of section 1851(a)(1) of the Act, the "benefits" referenced in the phrase quoted by the commenters ("entitled to elect to receive benefits") are the benefits provided for in Part A and Part B. Thus, this language confirms that beneficiaries enrolled in Part C remain "entitled to" benefits under Part A, and thus supports our interpretation of the statute. It is only the vehicle "through" which such Part A benefits are received that changes, from the "fee-for-service" method spelled out under Part A, to the capitation payment method spelled out in Part C.

Section 1851(i)(1) of the Act similarly refers only to whether Part A benefits are provided via payments to, and by, the MA organization, or direct payments made under the "fee-for-service" payment procedures provided for in Part A and Part B. It is only the process for furnishing these benefits that is at issue, not entitlement to such benefits.

Comment: Another commenter objecting to our proposal noted that section 1886(d)(5)(F) of the Act, which defines the Medicare and Medicaid fractions of the DPP calculation, has not undergone any significant amendments since its enactment, and was never amended to explicitly address the creation of Medicare Part C. As such, the commenter asserted that Part C days

should clearly be excluded from the Medicare fraction because the commenter believed that services paid for under Part C cannot also result in a patient being entitled to benefits for those services under Part A. However, the commenter asserted that Part C days are clearly not excluded from the Medicaid fraction because ''the numerator of the Medicaid fraction includes all hospital patient days (regardless of under which 'Part' of Medicare) for which the patient was 'eligible' for Medicaid as well as Medicare, but for which the patient was not entitled to receive benefits under Part A of Medicare . . . .''

Response: The enactment of the current provisions in Medicare Part C authorizing an alternative way of receiving Part A benefits did not alter the criteria for entitlement to such benefits, any more than did earlier, similar provisions in section 1876 of the Act that were enacted in 1982. Indeed, language in section 1876 made clear that a beneficiary was still ''entitled to benefits under Part A'' while receiving Part A benefits through a private health plan paid by CMS to provide them because section 1876 provided for two classes of enrollees, one only enrolled in Part B, and another ''entitled to benefits under Part A'' and enrolled in Part B, and provided for Part A Trust Fund payments in the latter case, and only Part B payments in the former. There is no indication that Part C enrollees are not similarly ''entitled to benefits under Part A'' on an ongoing basis.

With regard to the Medicaid fraction, as stated in section 1886(d)(5)(F) of the Act, the number of patient days for patients who, for those days, were eligible for medical assistance under a State plan approved under Title XIX (Medicaid) but who were not entitled to benefits under Medicare Part A is divided by the total number of patient days for that same period. MA enrollees are entitled to benefits under Medicare Part A, and therefore, these patient days should not be included in the Medicaid portion of the calculation. It is CMS' interpretation that the statute provides support to include MA days in the Medicare fraction. The statute requires that the inpatient days be attributable to inpatients entitled to benefits under Part A. Section 1851(a)(3) of the Act defines an individual that is eligible to enroll in an MA plan as an individual who is entitled to benefits under Part A and enrolled under Part B. We have concluded that, based on section 1886(d)(5)(F) of the Act, MA enrollee patient days should be included in calculating the DSH adjustment by finding that such enrollees are otherwise entitled to benefits under Part A. In other words, MA patients are entitled to Medicare Part A prior to and after selecting Part C, and because they do not lose that entitlement when they choose to enroll in a Part C plan, our position is that the Medicare Part C days should be included in the Medicare fraction, regardless of whether the beneficiary opts for Part C coverage.

Comment: Another commenter argued that, while it is true that a patient must at some point be entitled to benefits under Part A in order to be eligible to enroll in Part C, once an enrollee has chosen Part C, he or she is no longer entitled to Part A benefits and instead, the payment structure in Part C applies, and CMS pays MA organizations for those beneficiaries, while the MA organizations pay the providers. The commenter also asserted that this was evidence that Congress did not intend to include Part C days in the Medicare fraction because if it had, Congress could have easily revised the DSH statute to indicate as such.

Response: Again, this commenter confuses the method for covering Part A benefits with whether an individual is entitled to receive such benefits. We refer readers to the previous response for a fuller discussion.

Comment: One commenter stated that the proposed policy would be inconsistent with prior practice and CMS' longstanding operational treatment of Part C days in Medicare Part A calculations because services furnished to Part C enrollees historically were recorded as non-Medicare days. The commenter further stated that, similarly, CMS has historically interpreted entitled to benefits under Part A to mean entitlement to payment for inpatient hospital care under the IPPS. The commenter also asserted that the proposed policy is inconsistent with CMS' interpretation of entitled to SSI benefits in the DSH statute because CMS construes this to mean including only those days for patients who were entitled to have SSI benefits actually paid to them on such days. Therefore, the commenter argued, even when an individual is entitled to payment of SSI benefits, CMS does not count the day as an SSI patient day if there is some other reason why the Social Security Administration does not make the payment owed to the individual.

Response: While we acknowledge that in the past CMS has not always captured MA patient days as Medicare days, this was an operational issue, not the result of an authoritative agency legal interpretation or Medicare payment policy decision not to include MA days in the Medicare fraction. We note that these operational issues persisted for a time after we expressly concluded that MA days should be counted in the Medicare fraction in the FY 2005 IPPS rule. Contrary to the commenter's assertion, we have not, as a matter of either legal interpretation or policy, considered the days of patients enrolled in MA plans to be non-Medicare days. Patients enrolled in Medicare Part C must be entitled to Medicare Part A and enrolled in Part B. Moreover, the days of patients enrolled in Medicare HMOs are considered to be paid or covered days even though the payment may be made indirectly through a section 1876 HMO or through an MA plan. We note that the original Medicare DSH regulations indicated that patients receiving their Part A benefits under section 1876 of the Act were to count as Medicare patient days.

We further disagree with the commenter that CMS' interpretation is unreasonable and inconsistently interprets the term ''entitled to benefits.'' To the contrary, we adopted this interpretation of ''entitled to benefits under part A'' in large part in order to be consistent with how that phrase is used elsewhere in the Act. Section 1886(d)(5)(F)(vi)(I) of the Act specifically notes that the numerator of the Medicare fraction must reflect patient days for patients ''entitled to benefits under part A'' who are also ''entitled to supplementary security income benefits (excluding any State supplementation) under title XVI of this Act.'' Regarding entitlement to SSI benefits, we note that section 1602 of the Act states that ''Every aged, blind, or disabled individual who is determined under part A to be eligible on the basis of his income and resources shall, in accordance with and subject to the provisions of this title, be paid benefits by the Commissioner of Social Security.'' Therefore, because SSI is a cash benefit, only a person who is actually paid these benefits can be considered entitled to these benefits. This differs from entitlement to Medicare benefits under Part A, which are a distinct set of health insurance benefits described under section 1812 of the Act, including coverage of inpatient hospital, inpatient critical access hospital, and post-acute care services as well as post-institutional home health and hospice services under certain conditions. We note that the agency has undertaken extensive effort and notice-and-comment rulemaking to establish a process to identify appropriately Medicare patient days for which a beneficiary was simultaneously eligible for SSI benefits in the FY 2011 IPPS/

LTCH PPS final rule (75 FR 50275 through 50286).

Comment: One commenter noted that the Medicare fraction does not include patient days for Medicare beneficiaries enrolled in Medicare Part B only. The commenter further argued that, similarly, the Medicare fraction does not include all patient days for some individuals who are eligible for and enrolled in Part A because Part A patient days in hospital units excluded from the IPPS are not included in the Medicare fraction, even if actually paid under Part A. The commenter asserted that as the DPP calculation is limited to patient days in areas of the hospital that provide services that are paid for under the IPPS, in the same way, the Medicare fraction should exclude patient days for Medicare beneficiaries who have elected to receive benefits under Part C—because these days are not paid under the IPPS, they should not be included in the Medicare fraction.

Response: In the case of a Medicare beneficiary enrolled only in Part B, we agree that such an individual is not ''entitled to benefits under Part A,'' and thus is clearly distinguishable from a beneficiary who is entitled to benefits under Part A, but has elected to enroll in a Part C plan.

We note that commenters may be misunderstanding our policy when they asserted that the days of patients enrolled in Part C should not be included in the Medicare/SSI fraction because the DSH calculation does not include patient days in hospital units excluded from the IPPS but paid under Part A. The regulation at 42 CFR 412.106(a)(1)(ii) limits the patient days used in determining a hospital's DPPs to patient days ''attributable to units or wards of the hospital providing acute care services generally payable under the [inpatient] prospective payment system.'' Patient days associated with beds in excluded distinct part hospital units are explicitly excluded from the DPP calculation in accordance with 42 CFR 412.105(a)(1)(ii)(A). In contrast, the days for MA beneficiaries that are counted in the Medicare/SSI fraction are days on which those beneficiaries received care that would be (and in some cases actually was) payable under IPPS. Accordingly, CMS' policies regarding patient days in excluded distinct part units provide no reason to treat Part C enrollees differently than other patients also entitled to benefits under Part A.

Comment: One commenter argued that the instances where a Part C beneficiary can have services paid under Part A are extremely limited, both in scope and duration, and asserted that CMS' descriptions of the exceptions overstate the extent to which Part A payments actually can be obtained by Part C beneficiaries. The commenter also contended that this illustrates that when Congress has wanted to explain how Part C and Part A benefits relate to one another, Congress has done so explicitly, and without ambiguity. Another commenter added that when Congress added Part C to the Medicare statute, it did not amend the DSH statute to require CMS to treat Part C days differently for DSH payment purposes, and that intent should be given effect by continuing to exclude Part C days from the Medicare fraction and including Medicaid eligible Part C days in the numerator of the Medicaid fraction.

Response: While we appreciate the comments noting that instances where a Part C beneficiary can have services paid under Part A are limited, we disagree that our description of these exceptions overstates the extent to which Part A payments can be obtained by Part C beneficiaries. Under the commenters' view of the statute, beneficiaries enrolled in MA plans are not ''entitled to benefits under Part A,'' which would suggest that Medicare Part A should not make any payments on their behalf. However, as discussed above, there are instances where Part A is required to do just that. The hospice benefit, for instance, is a significant part of the benefits available under Part A that is always paid for on a fee-for-service basis, even if the beneficiary is enrolled in an MA plan. We find these circumstances impossible to reconcile with the commenter's assertion that beneficiaries enrolled in MA plans are not ''entitled to benefits under Part A.'' Rather, these payments make clear that beneficiaries enrolled in MA plans are ''entitled to benefits under Part A,'' regardless of the frequency or magnitude of these claims for payment.

Comment: Commenters stated that CMS still does not discuss that including MA days in the Medicare fraction would be a reversal of its prior position and, therefore, is both substantively and procedurally flawed. Some commenters argued that CMS did not include a reasoned explanation for what they characterize as a reversal of policy.

Some commenters contended that CMS, in both the FY 2004 proposed rule and the FY 2005 final rule, acknowledged that the statute is susceptible to multiple interpretations, including the agency's own previous position that individuals enrolled in the MA plans should not be included in the Medicare fraction, and that the FY 2014 proposed rule only slightly elaborates on the assertion in the FY 2005 final rule that individuals enrolled in MA plans ''are still, in some sense entitled to benefits under Medicare Part A.'' Commenters stated that, in *Allina,* the court found the FY 2005 final rule was flawed because CMS did not acknowledge that the policy was a reversal of the agency's prior interpretation, and did not give a sufficient explanation for that reversal in interpretation, and that the FY 2014 proposed rule does not correct those deficiencies, but instead just states that CMS ''continues'' to believe that MA patient days should be included in the Medicare fraction.

Response: We disagree that including the MA days in the Medicare fraction is a reversal of prior policy. No final regulation, administrative decision, or subregulatory guidance issued by the Secretary has ever taken the position that MA days were to be excluded from the Medicare fraction. Similarly, no final regulation, administrative decision, or subregulatory guidance issued by the Secretary has ever taken the position that MA days should be included in the numerator of the Medicaid fraction. Accordingly, commenters are incorrect insofar as they suggest that including MA days in the Medicare fraction represents a reversal of a prior policy. However, we acknowledge that, although the DC Circuit held in *Northeast* that the agency had a practice of excluding MA days from the Medicare fraction prior to the FY 2005 rule (657 F.3d at 17), the court did not hold that the Secretary had adopted a legal interpretation of the phrase ''entitled to benefits under part A'' or an authoritative agency Medicare payment policy that would require excluding MA days from the Medicare fraction (*Id.* at 14–17).

In fact, in the FY 1990 IPPS final rule (55 FR 35994), CMS made clear that its policy was to include the days of patients enrolled in managed care plans in the Medicare fraction:

''Based on the language of section 1886(d)(5)(F)(vi) of the Act, which states that the disproportionate share adjustment computations should include 'patients who were entitled benefits under Part A', we believe it is appropriate to include the days associated with Medicare patients who receive care at a qualified [health maintenance organization (HMO)]. Prior to December 1, 1987, we were not able to isolate the days of care associated with Medicare patients in HMOs and, therefore, were unable to fold this number into the calculation. However, as of December 1, 1987, a field was

included on the Medicare Provider Analysis and Review (MedPAR) file that allows us to isolate those HMO days that are associated with Medicare patients. Therefore, since that time, we have been including HMO days in SSI/Medicare percentage.''

We note that a recent review of our records from the years immediately before the implementation of Part C demonstrates that the MedPAR data used to calculate Medicare fractions for those years includes the days of patients enrolled in section 1876 HMOs.

Prior to the FY 2004 proposed rule, this was the only authoritative agency interpretation relating to the treatment of patient days of individuals enrolled in managed care plans. When Congress created Part C in the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33, 111 Stat. 251 (Aug. 5, 1997)), section 1876 HMO days were being counted in the Medicare fraction, and were correspondingly being excluded from the Medicaid fraction. On January 1, 1999, patients enrolled in risk HMOs under section 1876 of the Act were automatically enrolled in M+C plans. We issued no guidance discussing how the change in the type of HMO, from section 1876 to M+C, would have affected the DSH calculation. We see no reason why the reorganization in the managed care structure, from section 1876 HMOs into Part C, should have any bearing on how a day counts in the DSH calculation. The BBA does not specifically address DSH, and we thus believe it was appropriate that MA patients should have continued to be counted in the Medicare fraction after its enactment. Indeed, the BBA provided that to enroll in an MA plan, an individual must be ''entitled to benefits under part A''—the same language used in the DSH provision. Individuals enrolled in MA plans continue to meet the age and disability requirements for entitlement to benefits under Medicare Part A, and thus should be included in the Medicare fraction.

Our contractors, having received no instructions to the contrary, continued to exclude the days of patients enrolled in Medicare HMOs (now mostly M+C) from the numerator of the Medicaid fraction. However, at this same time, and for reasons that are not clear to us now, the agency generally stopped collecting no-pay bills from hospitals and therefore lacked the data necessary to include Part C days in the Medicare fraction. We are aware of nothing to suggest that the failure to include Part C days in the Medicare fraction was the result of any reasoned decision making or even, in fact, that the relevant policy makers were aware the Part C days were not being counted in the Medicare fraction. Consequently, Medicare Part C days were largely not included in the DSH calculation at all, except for the denominator of the Medicaid fraction which includes all patient days.

We further note that even when the agency promulgated the FY 2005 IPPS final rule, which expressly stated that MA days should be included in Medicare fraction, the agency did not begin collecting the data that would have allowed for their inclusion. We believe that this suggests that relevant policymakers thought that MA days were being included in the Medicare fraction. However, as discussed in detail above, CMS has since taken action to ensure that we are collecting the data necessary to include these days in the Medicare fraction.

In short, we disagree that the decision in the FY 2005 IPPS rule to include MA days in the Medicare fraction, and to exclude them from the numerator of the Medicaid fraction, was a reversal of prior policy. We had not (in rulemaking or through subregulatory guidance) specifically addressed the treatment of MA days prior to the FY 2004 proposed rule, although we acknowledge that, as a matter of practice, MA days generally had not been counted in either fraction. Accordingly, commenters are incorrect insofar as they suggested that including MA days in the Medicare fraction, and excluding them from the Medicaid fraction, represents a reversal of prior policy.

In the FY 2005 IPPS final rule, CMS determined that M+C days should be included in the Medicare fraction because M+C beneficiaries ''. . . are still, in some sense, entitled to benefits under Medicare Part A'' (69 FR 49099). CMS acknowledged that, in the FY 2004 proposed rule, it had noted that although a beneficiary must be entitled to Medicare Part A to enroll in an M+C plan, when an individual enrolls in an M+C plan, his or her benefits are ''no longer administered under Part A,'' and had proposed to exclude M+C days from the Medicare fraction and to include them in the Medicaid fraction numerator if the M+C days enrollee was also eligible for Medicaid (69 FR 49099.) CMS further noted that the proposed rule recognized that whether MA days should be included in the Medicare or the Medicaid fraction ''stems from whether M+C plan enrollees are entitled to benefits under Medicare Part A'' (69 FR 49099). CMS thus made clear its view that MA days should be counted in one fraction or the other. CMS explained that after considering comments received to its proposal—including the comment that M+C enrollees ''are just as much Medicare beneficiaries as those beneficiaries in the traditional fee-for-service program''—it ultimately agreed with those that opposed its proposal on the ground that M+C enrollees remain ''entitled to benefits under part A'' in the relevant sense for determining whether they should be included in the Medicare or Medicaid fraction.

CMS thus responded to the comments that were most relevant to the question before the agency: how to interpret the phrase ''entitled to benefits under part A'' in the DSH provision and provided a reasoned explanation for including MA days in the Medicare fraction. As set forth above, CMS continues to believe that its interpretation reflects the statutory language and congressional intent. Indeed, when it enacted the DSH provision, Congress intended that the Medicare fraction serve as a proxy for the percentage of low-income Medicare patients and the Medicaid fraction serve as a proxy for the percentage of low-income non-Medicare patients. When Congress subsequently created Part C, it provided that to enroll in part C, an individual must be ''entitled to benefits under part A''—the same language that it used in the DSH provision. Thus, Part C enrollees are a subset of individuals ''entitled to benefits under part A,'' and therefore should be included in the Medicare fraction.

Comment: Some commenters added that it is unclear what CMS is actually proposing because the proposal to readopt the policy of counting MA patient days in the Medicare fraction is for FY 2014 and subsequent years, but CMS also stated that it believes the policy adopted in the FY 2005 final rule was a logical outgrowth of the FY 2004 proposed rule. The commenters asserted that CMS' statements suggest that CMS is also planning to apply the policy to correct retroactively invalid past rulemaking. Some commenters stated that CMS cannot retroactively validate invalid rulemakings by restating the positions it adopted in FY 2005, through notice-and-comment rulemaking for FY 2014, and in the absence of a Congressional grant of retroactive rulemaking authority, an attempt to cure prior deficient proceedings is similarly invalid.

Response: We disagree that the FY 2014 IPPS/LTCH PPS proposed rule seeks to validate retroactively an invalid rulemaking as the commenter asserted. We proposed to readopt the policy of counting the days of patients enrolled in MA plans in the Medicare fraction of the DPP for FY 2014 and subsequent years in an abundance of caution and have considered the public comments

received in support of and in opposition to our proposal in making our final determination.

Comment: Commenters stated that CMS cannot finalize its new proposed policy for FY 2014 because CMS has not corrected the deficiencies cited by the court in *Allina,* and by doing so, CMS would be acting in an arbitrary and capricious manner in violation of the Administrative Procedure Act. The commenters added that, while they urge CMS not to finalize its proposal, if it does choose to move forward, the agency must provide a thorough discussion and allow stakeholder comment on it before deciding whether to finalize its proposal. Some commenters also stated that the ambiguity in CMS' proposal does not provide affected parties adequate notice to properly comment on the proposal. Commenters stated that a complete and thorough discussion is critical because, citing the decision in *FCC* v. *Fox Television Stations* (556 U.S. 502 (2009), when stakeholders come to rely on a certain policy, an agency must give a more detailed explanation for changing its policy than would be necessary for a policy created on a blank slate.

Response: Our proposed rule did not propose a change in policy, but rather to readopt a policy that we finalized in the FY 2005 IPPS final rule. We believe that commenters favoring our proposal and those opposed have had a fair opportunity to comment both in response to the FY 2004 proposed rule and the present proposed rule. We also believe that we have fully explained why our proposal is an appropriate and consistent interpretation of the DSH statute.

Comment: Commenters stated that the court in *Northeast Hospital* v. *Sebelius* (657 F.3d at 5) opined that the fiscal impact of this policy change was a number in the hundreds of millions of dollars, and they requested that CMS release data as to whether this estimate is correct and, if not, provide the dollar impact so that hospitals can meaningfully assess this policy change in advance of issuing the final rule.

Response: We note that we proposed to readopt this policy for FY 2014 and subsequent years. Because this proposal is consistent with our longstanding policy, it is not considered a change in our policy. Accordingly, we do not believe that there will be additional savings or costs to the Medicare program, and by inference, to hospitals, as a result of this policy.

Comment: One commenter stated that the issue is further confused by the fact that, as discussed in the proposed budget presented by the President on April 10, 2013, the agency intends to ask Congress to ''clarify that individuals who have exhausted inpatient benefits under Part A or who have elected to enroll in part C plans should be included in the calculation of the Medicare fraction of hospitals' [DPP calculation].'' The commenter stated that the agency's position regarding where such days should be counted has been rejected by the courts in several cases such as *Northeast* v. *Sebelius* and *Allina* v. *Sebelius.* The commenter asserted that asking Congress to clarify how these days should be treated in the DSH calculation is an attempt to reverse unfavorable court decisions. The commenter also asserted that from the beginning of the DSH program until the FY 2005 final rule, CMS administered the program exactly as the commenter asserted that it should have been administered then and today stating that: ''1. CMS did not count Medicare managed care days in the SSI fraction; 2. From the outset of the Medicare + Choice program CMS instructed hospitals not receiving IME/GME reimbursement to not shadow bill M+C claims, which is the very data CMS needed to include the days in the SSI fraction; 3. CMS' practice from the beginning of the program was to count all Medicaid paid days in the Medicaid fraction, which included Part A exhausted days.''

Response: Although we appreciate receiving the commenter's views, proposals in the President's budget and/or pending legislation are outside the scope of this rulemaking. As we have previously stated, it has never been CMS policy that MA days were to be included in the Medicaid fraction. We remind commenters that CMS issued Change Request 6329 on March 6, 2009, and Change Request 5647 on July 20, 2007, to instruct hospitals to submit informational claims for MA patients for FY 2006 and FY 2007 and subsequent periods when it was brought to our attention that hospitals were not submitting these claims, and contrary to our regulations, we were administratively unable to include these MA days in the Medicare fraction. Furthermore, we note that CMS issued Change Request 5647 to provide hospitals additional time to submit FY 2007 claims when it was brought to our attention that compliance with our policy was uneven, partly due to the fact that teaching hospitals have a financial incentive to submit these claims because they receive IME payments for MA discharges while nonteaching hospitals receive no additional IME payment.

Comment: One commenter stated that if CMS maintains its view that MA days properly belong in the Medicare fraction, then IPPS hospitals should receive a DSH add-on payment for every MA beneficiary discharge in the same manner that IPPS hospitals receive an IME payment add-on for every MA beneficiary discharge.

Response: We appreciate receiving the commenters' views. However, we note that while section 1886(d)(11) of the Act explicitly provides for an IME payment add-on for each MA beneficiary discharge, section 1886(d)(5)(F) of the Act does not provide for a similar DSH payment add-on for each MA beneficiary discharge. A legislative change would be necessary to authorize such DSH payments to IPPS hospitals that treat MA beneficiaries.

After consideration of the public comments we received, we are finalizing our proposal to readopt the policy of counting the days of patients enrolled in MA plans in the Medicare fraction of the DPP for FY 2014 and subsequent years. We continue to believe this policy is most consistent with the language of the statute, congressional intent, and the structure of the DSH calculation.

3. New Payment Adjustment Methodology for Medicare Disproportionate Share Hospitals (DSHs) Under Section 3133 of the Affordable Care Act (§ 412.106)

a. General Discussion and Legislative Change

Section 3133 of the Patient Protection and Affordable Care Act (PPACA), as amended by section 10316 of PPACA and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a new section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. For purposes of this rule, we refer to these provisions collectively as section 3133 of the Affordable Care Act.

Currently, Medicare DSH adjustment payments are calculated under a statutory formula that considers the hospital's Medicare utilization attributable to beneficiaries who also receive Supplemental Security Income (SSI) benefits and the hospital's Medicaid utilization. Beginning for discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) will receive 25 percent of the amount they previously would have received under the current statutory formula for Medicare DSH payments. This provision