UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

EMMA L. BIXBY MEDICAL CENTER)
818 RIVERSIDE AVENUE)
ADRIAN, MI 49221)
)
MONROE REGIONAL HOSPITAL)
718 N. MACOMB STREET)
MONROE, MI 48162)
)
THE TOLEDO HOSPITAL)
2142 NORTH COVE BOULEVARD)
TOLEDO, OH 43606)
)
FLOWER HOSPITAL)
5200 HARROUN ROAD)
SYLVANIA, OH 43560)
)
MEMORIAL HOSPITAL)
715 SOUTH TAFT AVENUE)
FREMONT, OH 43420)
)
BAY PARK COMMUNITY HOSPITAL)
2801 BAY PARK DRIVE)
OREGON, OH 43616)
)
UH SAMARITAN MEDICAL CENTER)
1025 CENTER ST.)
ASHLAND, OH 44805)
)
UH PARMA MEDICAL CENTER)
7007 POWERS BOULEVARD)
PARMA, OH 44129)
)
UH REGIONAL HOSPITALS)
27100 CHARDON ROAD)
RICHMOND HEIGHTS, OH 44143)
)
UH PORTAGE MEDICAL CENTER)
6847 N. CHESTNUT STREET)
RAVENNA, OH 44266)
)
UH CLEVELAND MEDICAL CENTER)
11100 EUCLID AVENUE)
CLEVELAND, OH 44106)

UH ELYRIA MEDICAL CENTER 630 EAST RIVER STREET ELYRIA, OH 44035	
UH GEAUGA MEDICAL CENTER 13207 RAVENNA RD. CHARDON, OH 44024	
UH AHUJA MEDICAL CENTER 3999 RICHMOND ROAD BEACHWOOD, OH 44122	
LAFAYETTE GENERAL MEDICAL CENTER 1214 COOLIDGE AVENUE LAFAYETTE, LA 70503	
UNIVERSITY HOSPITAL & CLINICS 2390 WEST CONGRESS LAFAYETTE, LA 70506	
AMERICAN LEGION HOSPITAL 1305 CROWLEY RAYNE HIGHWAY CROWLEY, LA 70526	CASE NO. _____
LAFAYETTE GENERAL SURGICAL HOSPITAL 1000 W. PINHOOK RD. LAFAYETTE, LA 70503	
Plaintiffs,	
v.	
ALEX M. AZAR, II, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES 200 INDEPENDENCE AVENUE S.W. WASHINGTON, D.C. 20201	
Defendant.	

COMPLAINT

The above-captioned Plaintiff hospitals (the "Hospitals"), by and through their undersigned attorney, bring this action against defendant Alex M. Azar, II, in his official

capacity as the Secretary ("the Secretary") of the Department of Health and Human Services ("HHS"), and state as follows:

I. INTRODUCTION

1. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. §§1395 *et seq.* ("the Medicare Act"), and the Administrative Procedure Act ("APA"), 5 U.S.C. §§551 *et seq*. This action concerns the Secretary's implementation, and flawed remediation, of an across-the-board rate reduction for reimbursement for inpatient hospital services to hospitals that serve Medicare beneficiaries. The Secretary promulgated regulations, purportedly to clarify the standards the Medicare program will use to determine whether a patient should be admitted to a hospital as an inpatient or treated as an outpatient. Under the guise of offsetting dubiously predicted increases in overall Medicare program costs due to such standards, for federal fiscal years 2014 through 2016 the Secretary implemented a Medicare payment rate reduction.

2. Specifically, the Secretary, through a procedurally and substantively flawed rulemaking, implemented a 0.2% reduction to the Medicare Inpatient Prospective Payment System ("IPPS") (the "0.2% IPPS Reduction") rates for inpatient discharges at all IPPS hospitals, including the Hospitals, occurring on and after October 1, 2013, as set forth by the Centers for Medicare and Medicaid Services ("CMS"), in the Federal Fiscal Year ("FFY") 2014 IPPS Final Rule (the "Final Rule"). See 78 Fed. Reg. 50,496 (Aug. 19, 2013).

3. The 0.2% IPPS Reduction presumed that: (a) inpatient admissions are appropriate if the beneficiary's inpatient stay extends past two midnights; and (b) stays shorter than two midnights that do not involve services designated by CMS as "inpatient only" are "generally inappropriate for payment under Part A" as inpatient services, and should be provided as outpatient services, unless there is clear physician documentation in the medical record supporting the physician's order and expectation that the beneficiary would require care

spanning at least two midnights (even though this ultimately did not occur). This policy is commonly referred to as the "two-midnight" policy.

4. The Secretary estimated in the Final Rule that the 0.2% IPPS Reduction would result in a net shift of 40,000 patient encounters from outpatient departments to inpatient care, and surmised that this shift would cause IPPS expenditures to increase by approximately $220 million for FFY 2014 and subsequent periods. However, CMS provided very little support for these predictions, and the little support it did supply shows the predictions to be unjustifiable and inaccurate. Based on the problematic assumption, the Secretary took the extremely rare step of using CMS's special statutory "exceptions and adjustments" authority to reduce all IPPS payments by 0.2% for FFY 2014 and thereafter to offset the expected annual $220 million total increase in Medicare inpatient reimbursement under IPPS.

5. The following year, in the FFY 2015 IPPS Final Rule, the Secretary did not reverse or even address the 0.2% IPPS Reduction, and therefore the reduction carried forward to IPPS rates for FFY 2015. See 79 Fed. Reg. 49,854, 50,381-83 (Aug. 22, 2014); *see also Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 213-14 (D.C. Cir. 2011) (explaining that, except as otherwise adjusted in the final rule, the Medicare inpatient hospital payment rates per discharge are calculated by carrying forward the previous fiscal year's amount).

6. The 0.2% IPPS Reduction continued for FFY 2016. See 80 Fed. Reg. 49341, 49593-49594 (August 17, 2015) (the "2016 Final Rule").

7. The Secretary's 0.2% IPPS Reduction was met with massive litigation, in which the Hospitals are parties, currently pending in this Court. *Shands Jacksonville Medical Center et al. v. Sebelius*, No. 14-0263-RDM. In *Shands*, this Court ruled that the rulemaking promulgating the reduction had serious procedural flaws in violation of the APA. Mem. Op. at 33. This Court

found that the Secretary deprived the public of an opportunity for meaningful notice and comment on the 0.2% IPPS Reduction by failing to disclose critical aspects and assumptions of the methodology that CMS used to calculate the expected net increase in the number of inpatient admissions until after the comment period. *Id*. at 36.

8. In the FFY 2017 Final IPPS Rule, the Secretary rescinded the 0.2% IPPS Reduction for FFY 2017 and subsequent years, and provided for a one-time upward adjustment to Medicare payment rates for FY 2017 of 0.6 percent (the "2017 0.6% IPPS Increase") for the purpose of addressing the effect of the 0.2% IPPS Reduction to the payment rates for FFY 2014, FFY 2015, and FFY 2016. *See* 81 Fed. Reg. 56,762, 57058-57060 (August 22, 2016).

9. Although the Secretary took this remedial action in FFY 2017, this action will not compensate the Hospitals in full regarding the prior 0.2% IPPS Reduction to which they were subjected in FFYs 2014-2016.

10. Thus, while the Secretary has acknowledged that the one-time 2017 0.6% IPPS Increase may be inadequate to compensate providers for the 0.2% IPPS decrease they incurred during FFYs 2014-2016, the Secretary has refused to fully compensate providers. The Hospitals file this action to challenge the failure of the Secretary to assure that the 2017 0.6% IPPS Increase fully offsets the 0.2% IPPS Reduction occurring in FFYs 2014-2016.

11. The Hospitals are all Medicare participating hospitals that stand to suffer significant financial losses because the 2017 0.6% IPPS Increase does not fully compensate the Hospitals for the 0.2% IPPS Reductions imposed in FFYs 2014, 2015 and 2016.

12. The Hospitals ask the Court to order the Secretary to fully compensate the Hospitals for the total amount of the 0.2% IPPS Reduction the Hospitals suffered in FFYs 2014-2016, together with interest as prescribed by 42 U.S.C. § 1395oo(f)(2). To effectuate

this outcome the Court should order the Secretary to compare (i) the dollar amount that was deducted from each Hospital's FFY 2014-2016 discharges as a result of the 0.2% IPPS Reduction with (ii) the dollar amount realized from the 2017 0.6% IPPS Increase to its FY 2017 discharges. For Hospitals for which the 2017 0.6% IPPS Increase does not satisfy their loss resulting from the 0.2% IPPS Reduction, the Court should order the Secretary to pay those Hospitals the difference, with interest.

II. JURISDICTION AND VENUE

13. This action arises under the Medicare Act, Title XVIII of the Social Security Act (the "Act"), 42 U.S.C. § 1395 et seq., and the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 et seq.

14. Jurisdiction is proper under 42 U.S.C. § 1395oo(f)(1).

15. Venue is proper in this judicial district under 42 U.S.C. § 1395oo(f)(1).

III. PARTIES

16. During the fiscal periods at issue herein, the Hospitals were qualified as providers of hospital services under the federal Medicare Program pursuant to Title XVIII of the Social Security Act, 42 U.S.C. Section 1395. et seq. The Hospitals are:

a. Emma L. Bixby Medical Center, Provider No. 23-0005;

b. Monroe Regional Hospital, Provider No. 23-0099;

c. The Toledo Hospital, Provider No. 36-0068;

d. Flower Hospital, Provider No. 36-0074;

e. Memorial Hospital, Provider No. 36-0156;

f. Bay Park Community Hospital, Provider No. 36-0259;

g. UH Samaritan Medical Center, Provider No. 36-0002;

h. UH Parma Medical Center, Provider No. 36-0041;

i. UH Regional Hospitals, Provider No. 36-0075;

j. UH Portage Medical Center, Provider No. 36-0078;

k. UH Cleveland Medical Center, Provider No. 36-0137;

l. UH Elyria Medical Center, Provider No. 36-0145;

m. UH Geauga Medical Center, Provider No. 36-0192;

n. UH Ahuja Medical Center, Provider No. 36-0359;

o. Lafayette General Medical Center, Provider No. 19-0002;

p. University Hospital & Clinics, Provider No. 19-0006;

q. American Legion Hospital, Provider No. 19-0044 and

r. Lafayette General Surgical Hospital, Provider No. 19-0268.

17. Defendant Alex M. Azar, II is the Secretary of the Department of Health and Human Services, the federal department which contains CMS. The Secretary, the federal official responsible for administration of the Medicare Program, has delegated the responsibility to administer that program to CMS.

IV. STATUTORY AND REGULATORY BACKGROUND

A. Medicare Coverage of Inpatient and Outpatient Hospital Services

18. The Federal Medicare program provides health insurance to the aged, blind, and disabled under Title XVIII of the Social Security Act ("Act"). 42 U.S.C. § 1395 *et seq*. The Act consists of five parts, two of which are relevant here. Part A covers inpatient hospital services, *id.* § 1395d(a)(1), and Part B covers outpatient hospital services, *id*. §§ 1395k(a)(2)(B), 1395x(s)(2)(B). *See generally Northeast Hosp. Corp. v. Sebelius*, 657 F.3d 1, 2 (D.C. Cir. 2011).

19. Medicare Part A covers inpatient hospital services that are medically necessary and furnished to an individual who is admitted to the hospital on a physician's order. See 78 Fed. Reg. at 50,907-08. A treating physician makes the determination to order an

inpatient hospital admission based on "complex medical judgment that should take into consideration many factors." Id.

20. Until recently, Part A coverage for inpatient hospital services extended to beneficiaries admitted with an expectation of one overnight stay. See id. at 50,907; Medicare Benefit Policy Manual, ch. 1, § 10 ("Generally a patient is considered an inpatient if formally admitted as inpatient with the expectation that he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and does not actually use a hospital bed overnight."). In the same rule that effected the payment reduction at issue here, the Secretary adopted a new inpatient hospital coverage rule requiring an admission with an expectation of an inpatient stay for at least two nights. 78 Fed. Reg. at 50,938-52, 50,965.

21. Medicare Part B covers hospital services furnished to an individual on an outpatient basis. These outpatient services include "observation" services involving treatment and monitoring of an individual, pursuant to a physician's order, to determine whether he or she should be admitted as an inpatient. See Medicare Benefit Policy Manual, ch. 6, § 20.6. Observation services typically last fewer than 24 hours. Id.

B. Medicare Prospective Payment Systems for Inpatient Hospital Services

22. Medicare reimburses most hospitals under two prospective payment systems for the costs of inpatient hospital services; one system reimburses hospitals for the operating costs and the other covers the capital-related costs of these services. *See* 42 U.S.C. §§ 1395ww(d), 1395ww(g); 42 C.F.R. Part 412. Both systems provide for payment of prospectively-established rates for each hospital discharge. *See* 42 C.F.R. §§ 412.1(a)(1), 412.2(a); *Cape Cod Hosp.*, 630 F.3d at 205.

C. Prospective Payment for Operating Costs

23. Under the prospective payment system for operating costs, the payment per discharge is the product of a base payment rate per discharge, called the "standardized amount," a "wage index" value reflecting labor costs in each hospital's area relative to a national average, and a weighting factor reflecting resource usage required to treat patients in a given "diagnosis-related group" relative to the average for all diagnoses. *See Cape Cod Hosp.*, 630 F.3d at 205-06.

24. The statute prescribes the calculation of the standardized amount in precise detail, mandating that the rate for a federal fiscal year "is equal to" an amount calculated by the Secretary based on specific and precisely-defined determinations that the Secretary "shall" make. 42 U.S.C. §§ 1395ww(d)(1), (3).

D. Authorized Adjustments and Exceptions

25. By statute, the standardized amount for the operating costs of inpatient hospital services is subject to several upward payment adjustments and exceptions for special cases that are extraordinarily costly (called "outliers") and for particular categories of hospitals that reasonably incur higher than average costs per case. See 42 U.S.C. § 1395ww(d)(5). For example, the statute requires the Secretary to make upward percentage adjustments to payments per discharge to teaching hospitals and to hospitals that treat a disproportionate share of low-income patients, among others. Id. §§ 1395ww(d)(5)(B) & (F); see also id. §§ 1395ww(d)(5)(C) (regional and national referral centers), 1395ww(d)(5)(H) (hospitals in Alaska and Hawaii).

26. In addition, the statute accepts some special types of hospitals (called sole-community and Medicare-dependent hospitals) from the standard payment rate, such that

they may receive payment at a higher rate based in whole or in part on the hospitals' own cost per discharge, which is called the "hospital-specific rate." *Id*. §§ 1395ww(d)(5)(D) & (G); *see also* 42 C.F.R. § 412.92 (special treatment for sole community hospitals); *id*. § 412.79 (hospital-specific rate for Medicare-dependent, small rural hospitals).

27. The statute also grants the Secretary authority to establish other appropriate adjustments and exceptions by regulations. 42 U.S.C. § 1395ww(d)(5)(I). Congress enacted that provision to permit additional adjustments and exceptions, like the adjustments and exceptions delineated in the statute, for special cases or discrete types of hospitals with special circumstances to ensure payment equity under the inpatient prospective payment system. See H.R. Rep. No. 98-47, 195 (1983) (Conf. Rep.), reprinted in 1983 U.S.C.C.A.N. 404, 485.

E. Prospective Payment for Capital-Related Costs

28. Congress mandated that the Secretary establish a prospective payment system for payment on a per-discharge basis for the capital-related costs of inpatient hospital services furnished. 42 U.S.C. § 1395ww(g); see 42 C.F.R. §§ 412.304(c), 412.308. Like for operating costs, the statute prescribes adjustments to the standard rate for capital-related costs, including adjustments to address special circumstances (including, e.g., the "relative costs of capital and construction for ... different types of facilities" and "occupancy rate"), and the statute also permits the Secretary to adopt additional adjustments. See 42 U.S.C. § 1395ww(g)(1)(B)(ii)-(iv). Under the implementing regulations, the standard "Federal rate" for capital related costs, like the "standardized amount" for inpatient operating costs, is updated yearly to account for inflation. See 42 C.F.R. § 412.308(c)(1)(ii). As under the prospective payment system for operating costs, the Secretary has adopted additional adjustments and exceptions for the capital Federal rate for special cases and unique hospital circumstances. Id. §§ 412.308(c)(2), (c)(3).

For example, the regulations provide for adjustments and exceptions for extraordinarily costly cases (outliers), id. §§ 412.308(c)(2), 412.312(c), for hospitals that treat a disproportionate share of low-income patients, id. § 412.312(b)(3), and for hospitals that incur costs for medical education, id. § 412.312(b)(4).

F. Review of Rate Determinations Under the Prospective Payment System

29. A hospital may appeal a final determination of the Secretary as to the amount of payment under the prospective payment system for inpatient hospital services to an administrative tribunal called the Provider Reimbursement Review Board ("PRRB" or "Board"). 42 U.S.C. § 1395oo(a).

30. The PRRB is bound by the agency rules setting the prospective payment rates. See 42 C.F.R. § 405.1867 (the Board is bound by CMS regulations issued under Title XVIII of the Act); *Sarasota Mem'l Hosp. v. Shalala*, 60 F.3d 1507, 1509 (11th Cir. 1995) (noting the Board's recognition that "it is bound by Medicare regulations, including the . . . wage index published by the Secretary [for the prospective payment system]"); *Hunterdon/Somerset 2001 Wage Index Group v. Riverbend Gov't Benefits Administrator*, PRRB Dec. No. 2004-D13 (Apr. 14, 2004) (granting expedited judicial review where the Board was without power to change the Secretary's policies used to calculate the wage indexes used to calculate payments under the prospective payment system).

31. The Medicare statute authorizes the PRRB, acting either on its own motion or at the request of a hospital, to determine that it is without authority to decide a question of law or regulation relevant to the matter in controversy. 42 U.S.C. § 1395oo(f)(1). If the PRRB makes that determination, then the hospital may commence a civil action in this Court within 60 days of the date on which the hospital receives notification of the Board's determination. *Id.*

G. Medicare Administrative Contractors

32. The Secretary contracts with private organizations (usually insurance companies) to process claims and make payments for covered services under Part A of the Medicare program. *See* Medicare Claims Processing Manual, ch. 1, § 10.2. These organizations are commonly referred to as "fiscal intermediaries" or, more recently, "Medicare Administrative Contractors."

H. The Two Midnight Rule and The 0.2% IPPS Reduction

33. Since the beginning of Medicare, CMS and its predecessors defined an inpatient as a patient "formally admitted as inpatient with the expectation that he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight." Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapter 1, §10. In doing so, CMS acknowledged that the decision to admit a patient as an inpatient is a "complex medical judgment which can be made only after the physician has considered a number of factors." *Id*.

34. CMS determined that the inpatient admission guidelines required clarification, and developed a new standard in the FFY 2014 rulemaking. Under the new rule, there is a presumption that inpatient admissions (which are paid under Medicare Part A) are reasonable and necessary for Medicare beneficiaries who require more than one Medicare utilization day, defined as crossing two midnights of medically necessary inpatient hospital services. This is referred to as the "two-midnight" policy. 78 Fed. Reg. at 50944-49; 42 C.F.R. §412.3(e)(1). Under the two-midnight policy, hospital services spanning less than two midnights are considered outpatient services (which are paid under Medicare Part B) unless: (1) the medical record contains clear documentation supporting the physician's order and expectation that the

beneficiary would require care beyond two midnights but that two-midnight stay is not realized, (2) the services are designated by CMS as "inpatient only," or (3) unspecified "rare and unusual circumstances" when second night stay is not expected, but is appropriate for inpatient admission. 78 Fed. Reg. at 50946; 42 C.F.R. §412.3(e)(1).

35. The FFY 2014 IPPS Proposed Rule (the "2014 Proposed Rule") stated that CMS actuaries estimated that the two-midnight policy would shift 400,000 encounters from outpatient to inpatient, and 360,000 encounters from inpatient to outpatient, for a net shift (increase) of 40,000 inpatient admissions. 78 Fed. Reg. 27486, 27649 (May 10, 2013). CMS estimated that the shift would cost the Medicare program an additional $220,000,000. Id. To offset the predicted increase, the Secretary used his alleged "exceptions and adjustments authority" under 42 U.S.C. §1395ww(d)(5)(I)(i) to institute a 0.2% reduction for the standardized amount, the hospital-specific rates, and the Puerto Rico-specific standardized amount for all IPPS hospitals. Id. In the Proposed Rule, CMS provided no data, calculations, or even a description of the method its actuaries used to make these estimates.

36. Following the 2014 Proposed Rule, more than 630 comments were submitted regarding the 2014 Proposed Rule, a number of which involved the 0.2% IPPS Reduction. The commenters opposed the 0.2% IPPS Reduction. Some disputed the findings based on their own calculations, noting that CMS refused to release any actuarial data to support its prediction of increased payments to providers, despite requests for such information. In fact, some commenters described models showing that the result of the new "two-midnight" policy produced a net increase in outpatient encounters, which would lead to a net decrease in payment to providers, the exact opposite of CMS's predictions.

37. In the 2014 Final Rule, CMS adopted the 0.2% IPPS Reduction. 78 Fed. Reg. at 50952-54. In the 2014 Final Rule, CMS acknowledged that commenters opposed the 0.2% IPPS Reduction, and complained about the lack of actuarial data and methodologies. 78 Fed. Reg. at 50953. CMS summarily dismissed these comments as unfounded, while continuing to withhold the data, calculations, and methodology used by its actuaries, explaining their estimates only in vague terms. 78 Fed. Reg. at 50953-54. Of minor detail CMS publishrf, CMS explained that in determining the estimate of the number of encounters that would shift from outpatient to inpatient, their actuaries examined outpatient claims for observation and major procedures, while in determining the estimate of the number of encounters that would shift from inpatient to outpatient, their actuaries examined inpatient claims containing surgical MS-DRGs, but not non-surgical MS-DRGs. 78 Fed. Reg. at 50953. Non-surgical cases outnumber surgical cases by two to one. Neither the proposed or final 2014 rule explains why a trend in surgical cases moving from the outpatient to the inpatient category could be applied to non-surgical cases.

38. Since adopting the 2014 Final Rule, CMS issued numerous clarifications on the two-midnight policy, including "Frequently Asked Questions" ("FAQs"), alerts, bulletins, "open door forums," and other sub-regulatory guidance. Confusion over the two-midnight policy has been so great that CMS instructed its Medicare administrative contractors to perform "probe and educate" audits for compliance with the two-midnight policy for the first 18 months the policy was in effect, and also instructed its recovery audit contractors to not conduct pre-payment patient status reviews for compliance with the two-midnight policy for the first 18 months the policy was in effect. As recently as July 2015, CMS announced additional changes to its education and enforcement policy for the two-midnight policy.

39. In the FFY 2015 IPPS Proposed Rule (the "2015 Proposed Rule"), CMS failed to eliminate or even address the 0.2% IPPS Reduction. 79 Fed. Reg. 27,978 (May 15, 2014). In response to the 2015 Proposed Rule, a number of comments were submitted requesting that CMS provide any data supporting the adjustment, identify the assumptions underlying the adjustment or in the absence of either supporting data and the identification of underlying assumptions, withdraw the reduction. In the 2015 Final Rule, the Secretary once again did not address the 0.2% IPPS Reduction, nor any of the comments submitted regarding the reduction. See 79 Fed. Reg. at 50,381-83. Thus, despite the concerns raised by commenters in the rulemaking process, the Secretary completely ignored these comments. FFY 2015 Final Rule, 79 Fed. Reg. at 50147 ("We thank commenters for the many comments submitted on this issue, and we will take these into account in any potential future rulemaking."). He instead continued to implement his 0.2 percent reduction to IPPS payment rates for FFY 2015 without engaging in any reasoned analysis. *Id*. at 49995.

40. Because the Secretary did not reverse the 0.2% IPPS Reduction, the reduction therefore carried forward to IPPS rates for FFY 2015. See Id.; see also Cape Cod Hosp., 630 F.3d at 213-14.

41. The 0.2% IPPS Reduction continued for FY 2016 See 80 Fed. Reg. 49341, 49593-49594 (August 17, 2015) (the "2016 Final Rule").

42. In an action challenging the 0.2% IPPS Reduction for FFY 2014, this Court ruled that the rulemaking promulgating the reduction had serious procedural flaws in violation of the APA. *Shands Jacksonville Medical Center v. Burwell*, No. 14-cv-00263, Mem. Op. at 33 (D.D.C. Sept. 21, 2015). Specifically, this Court found that the Secretary deprived the public of an opportunity for meaningful notice and comment on the 0.2% IPPS Reduction by failing to

disclose critical aspects and assumptions of the methodology that CMS used to calculate the expected net increase in the number of inpatient admissions until after the comment period. Id. at 36. This Court in *Shands* remanded the FFY 2014 rulemaking to CMS, and ordered that "the Secretary shall publish a notice in the Federal Register by December 1, 2015; that the Secretary shall afford interested parties an opportunity to submit comments regarding this notice on or before February 2, 2016; and that the Secretary shall publish a further notice in the Federal Register by March 18, 2016." *Shands*, Order at 2 (D.D.C. Oct. 6, 2015). This Court further ordered that "should the Secretary issue a notice of proposed rulemaking and notice of final rule on remand, the Secretary shall publish the notice of proposed rulemaking by December 16, 2015; shall afford interested parties an opportunity to submit comments regarding this notice on or before February 17, 2016; and shall publish a further notice in the Federal Register by April 18, 2016." Id. at 2-3.

I. The FY 2017 Rule

43. The Secretary apparently issued what was in effect its proposed final notice in compliance with this Court's order in *Shands* in the Proposed Rule for the FFY 2017 Hospital Inpatient Prospective Payment System and Long Term Acute Care Hospital (the "FY 2017 Proposed Rule"). The Secretary stated in relevant part:

> We still believe the assumptions underlying the 0.2 percent reduction to the rates put in place beginning in FY 2014 were reasonable at the time we made them in 2013. Nevertheless, taking all the foregoing factors into account, in the context of this case, we believe it would be appropriate to use our authority under sections 1886(d)(5)(I)(i) and 1886(g) of the Act to prospectively remove, beginning in FY 2017, the 0.2 percent reduction to the rates put in place beginning in FY 2014. (Display Copy, Page 793.)

44. The FY 2017 Proposed Rule proposed the following remedial action:

> In summary, for the reasons described above, we are proposing to include a permanent factor of (1/0.998) and a temporary one-time factor of (1.006) in the calculation of the FY 2017 standardized amount, the hospital-specific payment

> rates, and the national capital Federal rate. We also are proposing to include a factor of (1/1.006) in the calculation of the FY 2018 standardized amount, the hospital-specific payment rates, and the national capital Federal rate to remove the temporary one-time factor of 1.006. (Display Copy, Page 794.)

45. The Secretary ultimately issued the FFY 2017 Final IPPS Rule in which, as noted, the Secretary rescinded the 0.2% IPPS Reduction for FFY 2017 and subsequent years, and provided for a one-time upward adjustment to Medicare payment rates for FY 2017 of 0.6 percent (the "2017 0.6% IPPS Increase") for the purpose of addressing the effect of the 0.2% IPPS Reduction to the payment rates for FY 2014, FY 2015, and FY 2016. *See* 81 Fed. Reg. 56,762, 57058-57060 (August 22, 2016) (the "FY 2017 Final Rule").

J. The Medicare Appeals Process

46. A hospital is entitled to a Provider Reimbursement Review Board ("PRRB") hearing if the hospital is dissatisfied with a final determination as to the amount of the payment under subsections (b) or (d) of 42 U.S.C. §1395ww, and meets the other requirements set forth in 42 U.S.C §1395oo(a). The publication of the PPS rates in the Federal Register constitutes a final determination that may be appealed to the Board under this authority. *See Washington Hospital Center v. Bowen*, 795 F.2d 139, 146 (D.C. Cir. 1986) (finding that "a year-end cost report is *not* a report which is necessary in order for the Secretary to make PPS payments, and the appeals provision applicable to PPS recipients cannot be read to require hospitals to file cost reports and await NPRs prior to filing a PRRB appeal.") (emphasis in original, footnote omitted). The CMS Administrator subsequently found that the holding in *Washington Hospital Center* was not limited to appeals of the specific issue in *Washington Hospital Center*, but rather, applies to general notices published in the Federal Register that determine the Federal rate. *See* Health Law Rulings and Other Documents, MED-GUIDE 1993-1 MED-GUIDE-TB ¶41,025, *District of Columbia Hospital Association Wage Index Group Appeal*, HCFA Administrator's Decision,

Centers for Medicare and Medicaid Services (Jan. 15, 1993). The 2015 Final Rule, continuing the 0.2% IPPS Reduction, is such a final determination that may be appealed under 42 U.S.C §1395oo.

47. If a hospital's jurisdictionally-proper appeal involves a question of law that the PRRB is without authority to decide, the PRRB may, through its own motion or upon the request of the hospital, grant expedited judicial review ("EJR") of the appeal. 42 U.S.C §1395oo(f)(1). If EJR is granted, a hospital may seek judicial review of the final determination without a PRRB hearing. 42 U.S.C §1395oo(f)(1).

48. Under 42 C.F.R. §405.1867, the PRRB is required to comply with all policies issued by the Secretary under the Social Security Act. *See Sarasota Memorial Hosp. v. Shalala*, 60 F.3d 1507, 1509-10 (11th Cir. 1995) (noting the PRRB's recognition that EJR was granted because the Board is bound by Medicare regulations as well as IPPS rate adjustment factors).

K. The Administrative Procedure Act

49. Under the APA, a "reviewing court shall ... hold unlawful and set aside agency action, findings, and conclusions found to be ... arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. §706(2)(A). Furthermore, a "reviewing court shall ... hold unlawful and set aside agency action, findings, and conclusions found to be ... in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. §706(2)(C).

50. Additionally, a "reviewing court shall ... hold unlawful and set aside agency action, findings, and conclusions found to be ... without observance of procedure required by law." 5 U.S.C. §706(2)(D). The APA dictates rulemaking procedural requirements, specifically the requirement that the agency provides notice of proposed rulemaking, that the agency affords

interested parties an opportunity to comment on the proposed rulemaking, and that the agency considers the relevant matters presented. 5 U.S.C. §553.

V. PROCEDURAL HISTORY

51. The Hospitals filed appeals, which are pending before this Court, challenging the 0.2% IPPS Reduction for fiscal years 2014 and 2016.[1]

52. The Hospitals timely filed group appeals to the PRRB challenging the Secretary's FY 2017 Final Rule on the basis that the 2007 0.6% IPPS Increase would not offset in its entirety the 0.2% IPPS Reduction the Hospitals experienced in the FFYs 2014, 2015 and 2016 IPPS. The PRRB assigned the appeals case numbers 17-1159GC, 17-0941GC and 17-1010GC.

53. Each of the group appeals stated an amount in controversy in excess of $50,000.

54. By letter dated March 19, 2018, the PRRB, at the requests of the Hospitals, found that it had jurisdiction over the Hospitals' appeals and ordered expedited judicial review ("EJR"). (Exhibit 1.)

55. The PRRB's EJR decision is the final decisions over which this Court possesses jurisdiction. 42 U.S.C.§ 1395oo(f)(1).

56. This Complaint is filed within 60 days of the Hospitals' representative receipt of the PRRB's EJR decision.[2]

VI. THE HOSPITALS' CHALLENGE TO THE 0.2% IPPS REDUCTION

57. Although at issue here is the FY 2017 Final Rule, the Secretary has not vacated the FYs 2014-2016 Rules which imposed the 0.2% IPPS Reduction.

58. The 0.2% IPPS Reduction was invalid because it: (a) is inconsistent with, and unauthorized by, the governing Medicare statute, regulations, and manual provisions, (b) is

[1] 1:14-cv-00976-EGS; 1:15-cv-01800-RDM; 1:16-cv-01544-RDM.

[2] March 19, 2018.

arbitrary, capricious, and not based on substantial evidence, (c) was improperly promulgated under the APA, and (d) is otherwise defective both procedurally and substantively.

59. The Hospitals have filed appeals in this Court challenging the validity of the FYs 2014-2016 Rules which imposed the 0.2% IPPS Reduction.

60. In addition to their challenge to the 0.2% IPPS Reduction, pending before this Court,[3] the Hospitals challenge the 2017 0.6% IPPS Increase because it fails to compensate them fully for the payment reduction imposed by the 0.2% IPPS Reduction.

VII. THE INVALIDITY OF THE SECRETARY'S POSITION REGARDING THE 2017 FINAL RULE

61. The Secretary has provided no evidence that the 2017 0.6% IPPS Increase will make the Hospitals whole, *i.e.*, that the 2017 0.6% IPPS Increase will be at least equal to the aggregate 0.2% IPPS Reduction for FFYs 2014-2016.

62. No documents in the rule making record contain any prediction of how the aggregate total of dollars paid under the 2017 0.6% IPPS Increase will relate to the aggregate total of dollars taken from Hospitals under the 0.2% IPPS reduction for FFYs 2014-2016.

63. The 2017 Final Rule was issued prior to the beginning of FFY 2017 and, therefore, there was no available data regarding FFY 2017 discharges. The Secretary, at most, could have made only a prediction based on assumptions regarding the aggregate number of discharges that *might* occur in FFY 2017 and how the 2017 0.6% IPPS Increase for a predicted number of discharges *might* offset the 0.2% IPPS Reduction for FFYs 2014-2016.

64. CMS has conceded that the 2017 0.6% IPPS Increase will not necessarily offset the aggregate 0.2% IPPS Reduction in FFYs 2014-2016, but has stated that CMS will not redress the problem:

---

[3] *See supra*, n.1.

> Comment: Some commenters stated the multiplicative effect of the FY 2017 0.6 percent adjustment would not fully compensate hospitals for the effect of the -0.2 percent adjustment for FYs 2014 through FY 2016 for reasons that included the recent trend of a decline in inpatient admissions.
>
> Response: We recognize that our proposed method of a prospective 1.006 adjustment for FY 2017 generally may have a differential *positive or negative* impact on an individual hospital relative to an attempt to estimate hospital by hospital the impact of the 2-midnight adjustment for FYs 2014, 2015, and 2016. As stated in the prior response, we generally believe that, given the prospective nature of our method and our goal to adopt a transparent, expedient, and administratively feasible approach, these differential impacts are an appropriate consequence. We also note that attempts to make prospective adjustments to the 1.006 factor would need to rely on estimates of factors that have been objected to by commenters in the prior rulemaking related to the -0.2 percent adjustment, such as estimates regarding projected inpatient utilization levels.

81 Fed. Reg. 56,762, 57060 (August 22, 2016).

65. In promulgating the FFY 2017 Rule, the Secretary explained that the 2017 0.6% IPPS Increase was meant to only "address" the 0.2% IPPS Reduction. 81 Fed. Reg. at 57,059; *see also* FY 2017 IPPS Proposed Rule, 81 Fed. Reg. 24,946, 24,956 (Apr. 27, 2016). The Secretary's use of "address" evidences recognition that the 2017 0.6% IPPS Increase was not intended to, and in fact did not, fully eliminate the effects of the 0.2% IPPS Reduction.

66. The promulgation of the FFY 2007 Rule did not, in and of itself, vacate the FFY 2014, 2015 and 2016 Rules. *See e.g., United States v. Nixon*, 418 U.S. 683, 693-96 (1974) (A legislative rule has the force and effect of law and agencies cannot simply choose to ignore their own rules when convenient to do so.). Until a rule has been formally amended by the agency or vacated by a court of competent jurisdiction, it remains in effect. *See, e.g, C.F. Communs. Corp. v. FCC*, 128 F.3d 735, 739 (D.C. Cir. 1997) (in order to amend its rule, agency was required to comply with notice and comment procedures of the APA); *United States Lines, Inc. v. Federal Maritime Com.*, 584 F.2d 519, 527 n. 20 (D.C. Cir. 1978) (although it is within the power of the

agency to amend or repeal its own regulations, the agency is not free to ignore those regulations while they remain in effect).

VIII. CAUSES OF ACTION

COUNT I:
Violation of the Medicare Act and the Administrative Procedure Act
(The Secretary Lacked the Statutory Authority to Apply the 2017 0.6% IPPS Increase As a Means of Offsetting the 0.2% IPPS Reduction Occurring in FFYs 2014-2016.)

67. The Hospitals repeat and reallege paragraphs 1-66 as if set forth fully herein.

68. The APA prohibits the Secretary from implementing the Medicare Act through actions, findings or conclusions that are in excess of statutory jurisdiction, authority, or limitations, or short of statutory right. 5 U.S.C. §706(2).

69. The Secretary lacks the statutory authority to apply the 2017 0.6% IPPS Increase as a means of offsetting the 0.2% IPPS Reduction occurring in FFYs 2014-2016. The Medicare Act and regulations prescribe precise payment methodologies under IPPS.

70. The exception contained within 42 U.S.C. §1395ww(d)(5)(I)(i) does not provide sweeping authority for the Secretary to apply an across-the-board 2017 0.6% IPPS Increase as a means of offsetting the 0.2% IPPS Reduction occurring in FFYs 2014-2016.

71. The basic structure and policy of IPPS does not allow for the application of a "budget neutrality" adjustment to a policy-induced volume increase.

72. The 2017 0.6% IPPS Increase does not allow CMS or its Medicare administrative contractors to correct or adjust the rate reduction, either on a hospital level or program-wide level basis, in case the predictions are incorrect. The structure of IPPS, and the potential unreasonable consequences of the 2017 0.6% IPPS Increase, show that §1395ww(d)(5)(I)(i) was not intended to be used to make global adjustments to account for estimated changes in volume. Therefore, in

implementing and continuing the 2017 0.6% IPPS Increase, the Secretary exceeded his statutory authority or otherwise violated the Medicare Act.

COUNT II:
Violation of the Administrative Procedure Act
(The 2017 0.6% IPPS Increase is Arbitrary and Capricious Because the Secretary Failed to Provide Pertinent Data and Methodologies to Demonstrate that the 2017 0.6% IPPS Increase Would Offset the 0.2% IPPS Reduction Occurring in FFYs 2014-2016)

73. Plaintiffs repeat and reallege paragraphs 1-72 as if set forth fully herein.

74. The APA prohibits the Secretary from implementing the Medicare Act through actions, findings or conclusions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. §706(2).

75. In the 2014 Proposed Rule, CMS failed to provide the data, actuary studies, assumptions and calculations that led to the conclusion that the two-midnight policy would increase IPPS expenditures due to net increased inpatient admissions.

76. Despite requests for such information, and comments criticizing the failure to publish this information in the 2014 Final Rule, CMS continued to withhold the data, actuary studies, assumptions and calculations that led to the conclusion that the two-midnight policy would increase IPPS expenditures due to net increased inpatient admissions.

77. In the 2015 Proposed and Final Rules, and the 2016 Final Rule, CMS once again failed to provide any data, actuarial studies or calculations, or even the assumptions used to support the 0.2% IPPS Decrease, despite commenters' request for such information.

78. Similarly, in the FY 2017 Rule, the Secretary failed to provide any data, actuarial studies or calculations, or even the assumptions used to support the 2017 0.6% IPPS Increase.

79. Without properly explaining the data, actuary studies, assumptions and calculations that led to the conclusion that the 2017 0.6% IPPS Increase would offset the 0.2%

IPPS Decrease in FFYs 2014-2016, the policy is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.

COUNT III:
Violation of the Medicare Act and the Administrative Procedure Act
(The 2017 0.6% IPPS Increase is Arbitrary and Capricious Because There is No Mechanism to Adjust the Payment Increase if the Secretary's Assumptions Upon Which it is Based Prove to be Inaccurate)

80. Plaintiffs repeat and reallege paragraphs 1-79 as if set forth fully herein.

81. The APA prohibits the Secretary from implementing the Medicare Act through actions, findings or conclusions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. §706(2).

82. The 2017 0.6% IPPS Increase does not allow CMS or its Medicare administrative contractors to correct or adjust the increase, either on a hospital level or program-wide level basis, in case the predictions are incorrect. It is arbitrary, capricious and an abuse of discretion for CMS to implement a 2017 0.6% IPPS Increase based on flimsy predictions, and not incorporate a mechanism to adjust the reduction should the predictions not be accurate.

COUNT IV:
Violation of the Administrative Procedure Act
(The Secretary Failed to Comply with Notice and Comment Procedures)

83. Plaintiffs repeat and reallege paragraphs 1-82 as if set forth fully herein.

84. The APA requires the Secretary to observe procedure required by law, and to follow proper rulemaking procedures, including notice and comment requirements. 5 U.S.C. §706(2)(D); 5 U.S.C. §553.

85. In the 2014 Proposed Rule, CMS failed to provide the data, actuary studies, assumptions, calculations or specific methodologies that led to the conclusion that the two-midnight policy would increase IPPS expenditures due to net increased inpatient admissions. Some commenters stated that they could not recreate CMS's predictions, and some commenters

noted that they requested such information during the comment period, and were denied. Without providing such data and methodologies in the Proposed Rule, the Secretary did not provide meaningful notice to the public, and therefore denied interested parties an opportunity for meaningful comment. This error was carried forward by not rescinding the reduction for FFY 2015, and not addressing these concerns in the 2015 Proposed or Final Rules and the 2016 Final Rule.

86. Similarly, in the 2017 Rule, the Secretary failed to provide the data, actuary studies, assumptions, calculations or specific methodologies that would support the conclusion that the 2017 0.6% IPPS Increase would offset the aggregate 0.2% IPPS Decrease in FYs 2014-2016.

COUNT V:
Violation of the Administrative Procedure Act
(The Secretary Exceeded Statutory Authority Because the 2017 0.6% IPPS Increase was Not Promulgated as a Regulation)

87. Plaintiffs repeat and reallege paragraphs 1-86 as if set forth fully herein.

88. The APA prohibits the Secretary from implementing the Medicare Act through actions, findings or conclusions that in excess of statutory jurisdiction, authority, or limitations, or short of statutory right. 5 U.S.C. §706(2).

89. 42 U.S.C. §1395ww(d)(5)(I)(i) requires adjustments made under this exception to be "provide[d] by regulation." Similarly, 42 U.S.C. §1395hh(a) prohibits any rule or policy that establishes or changes a substantive legal standard governing the payment for service, unless it is promulgated by the Secretary by regulation.

90. The Secretary did not promulgate a regulation to effectuate the 2017 0.6% IPPS Increase, but merely applied it as a rate adjustment as published in the preamble to the 2017

Final Rule. Accordingly, the 0.6% IPPS Increase violates the express terms of 42 U.S.C. §1395ww(d)(5)(I)(i) and 42 U.S.C. §1395hh(a), thereby violating the APA.

COUNT VI:
Mandamus

91. Plaintiffs repeat and reallege paragraphs 1-90 as if set forth fully herein.

92. The Secretary has the non-discretionary duty to reimburse the Hospitals fully at the amounts to which they are entitled under the law. The 2017 0.6% IPPS Increase violates the Medicare Act and APA. Under the Court's authority pursuant to 28 U.S.C. §1361, the Hospitals are entitled to issuance of a writ of mandamus under the Medicare Act and other authority requiring the Secretary to order the Hospitals' Medicare administrative contractors, or their successors in interest, to pay to the Hospitals the difference between the aggregate 0.2% IPPS Decrease suffered in FFYs 2014-2016 and the 2017 0.6% IPPS Increase for FY 2017.

COUNT VII:
All Writs Act

93. Plaintiffs repeat and reallege paragraphs 1-92 as if set forth fully herein.

94. The Secretary has violated the Medicare Act and APA in implementing the 0.6% IPPS Increase. The Providers are entitled to receive the difference between the aggregate 0.2% IPPS Decrease suffered in FFYs 2014-2016 and the 2017 0.6% IPPS Increase for FFY 2017. Under the All Writs Act, 28 U.S.C. §1651, and other authority, the Providers are entitled to issuance of an order requiring the Secretary to order the Providers' Medicare administrative contractors, or their successors in interest, to make new determinations for the fiscal years at issue in this case.

RELIEF REQUESTED

The Hospitals ask this Court to enter an Order:

1. That the 2017 0.6% IPPS Increase is factually invalid because it fails to pay to the Hospitals the aggregate 0.2% IPPS Decrease suffered in FFYs 2014-2016;

2. That the 2017 0.6% IPPS Increase is lawfully invalid for the reasons stated in this Complaint;

3. Requiring the Secretary to recalculate the appropriate increase in the standardized amount and the capital standard federal payment rates for FFYs 2014-2016 in order to offset the aggregate decrease in IPPS payments resulting from adoption of the two-midnight rule (*i.e.*, the 0.2% IPPS Reduction and the resulting shift in classification of patients thereby lowering IPPS aggregate payments) and pay the Hospitals the additional sums due them as a result of such recalculation, over and above what the 2017 0.6% IPPS Increase provides, or alternatively, vacating the FFY 2014–2016 Final Rules, restoring the .02% payment reductions for each of FFYs 2014–2016, and paying to the Hospitals additional amounts due to the shift in patient classifications resulting from the two-midnight policy.

4. Exercising jurisdiction under the Medicare Act (42 U.S.C. § 1395oo(f)(1)), mandamus (28 U.S.C. §1361) and/or the All Writs Ac (28 U.S.C. §1651), that the Secretary make payment to the Hospitals in the amount that is equal to the difference between the aggregate 0.2% IPPS Decrease suffered in FFYs 2014-2016 and the 2017 0.6% IPPS Increase;

5. Awarding the Hospitals interest on the amount that is equal to the difference between the aggregate 0.2% IPPS Decrease suffered in FFYs 2014-2016 and the

2017 0.6% IPPS Increase calculated in accordance with 42 U.S.C. § 1395oo(f)(2);

6. Awarding the costs of suit incurred by the Hospitals; and

7. Providing such other relief as the Court deems proper.

Respectfully submitted,

Kenneth R. Marcus
DC Bar No. MI-0016
HONIGMAN MILLER SCHWARTZ AND COHN LLP
660 Woodward Avenue, Suite 2290
Detroit, Michigan 48226-3506
Phone: (313) 465-7470
Fax: (313) 465-7471
kmarcus@honigman.com
Legal Counsel For Plaintiffs

Dated: May 10, 2018