UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SHANDS JACKSONVILLE MEDICAL CENTER, INC., *et al.*	)	
Plaintiffs,	)	
v.	)	**Case No. CIV-14-263-EGS**
SYLVIA M. BURWELL,	)	
Defendant.	)	

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT, MOTION TO DISMISS, AND OPPOSITION TO PLAINTIFFS' MOTIONS FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiffs, various hospitals that participate in the Medicare program, challenge one aspect of the complex annual rulemaking process through which the Secretary of Health and Human Services ("the Secretary"), through the Centers for Medicare & Medicaid Services ("CMS"), establishes the following year's rates under the Inpatient Prospective Payment System ("IPPS"), which pays hospitals for providing inpatient services to eligible Medicare beneficiaries. Specifically, Plaintiffs challenge the Secretary's adoption of a .2 percent reduction to federal fiscal year ("FFY") 2014 IPPS rates pursuant to her statutory authority to promulgate exceptions and adjustments to such rates "as the Secretary deems appropriate." 42 U.S.C. § 1395ww(d)(5)(I)(i).

The Secretary's use of that authority was occasioned here to offset the expected increase in IPPS expenditures resulting from her establishment during the same rulemaking process of a policy intended to address a long-standing issue concerning which services to bill as inpatient services under Medicare Part A (for which Medicare payments are generally higher) as opposed to outpatient services under Medicare Part B. While the Medicare statute does not define "inpatient," Medicare guidance has defined that term as a person who has been formally admitted as an inpatient with such admission guided by a "benchmark" that a physician should order inpatient admission when the patient is expected to need hospital care for a period of at least twenty-four hours. A disturbing trend has attended that policy: In many instances, hospitals apparently have elected to treat Medicare beneficiaries as outpatients, rather than inpatients, because of the significant financial risk of admitting Medicare beneficiaries for inpatient stays and having the claims for those services denied. Thus, in an attempt to clarify the circumstances in which hospital care appropriately is furnished on an inpatient basis, the

Secretary last year proposed and ultimately adopted new inpatient hospital admissions guidance called the "two-midnight rule."

Under that rule, surgical procedures, diagnostic tests, and other treatments generally are appropriate for inpatient hospital payment under Medicare Part A when the physician expects the patient to require medically necessary hospital care that crosses at least two midnights and admits the patient based on that expectation. The rule includes a presumption that those inpatient admissions that span more than two midnights are appropriate and generally will not be subject to further review absent evidence that the hospital is gaming the system. Under the Secretary's prior practice, all inpatient admissions were subject to potential review and disallowance. Because the Secretary determined that her new policy would result in increased IPPS expenditures not attributable to changes in the types of benefits offered, the Medicare beneficiary population, or the number or intensity of services, she used her statutory authority to establish the challenged .2 percent reduction to IPPS rates to offset that increase.

Plaintiffs here challenge the Secretary's .2 percent reduction for a host of reasons – all unavailing. First, despite the unambiguous statutory language providing that she could establish exceptions and reductions to the IPPS rates as she deemed appropriate, Plaintiffs contend that the Secretary lacked authority to do so. *See* 42 U.S.C. § 1395ww(d)(5)(I)(i). Although the Court need not look beyond the statutory language itself to uphold the .2 percent reduction, Plaintiffs invoke canons of statutory construction, the legislative history, and the Secretary's past uses of that authority in an effort to persuade the Court otherwise. Even if the Court considers such, the record demonstrates that the Secretary's interpretation of her authority to adjust IPPS rates is reasonable and thus entitled to deference.

Plaintiffs alternatively urge the Court to invalidate the .2 percent reduction under the Medicare statute and Administrative Procedure Act's ("APA") deferential arbitrary-and-capricious standard. Under that standard, Plaintiffs bear a heavy burden clearly not met here as to either the procedural or substantive challenges leveled against the .2 percent reduction. The rulemaking record[1] on which this Court's decision should be based demonstrates that Plaintiffs had adequate notice of the terms and technical basis for the .2 percent reduction to permit public comment thereon. Moreover, in response to comments requesting further details about the actuarial study on which her reduction was based, the Secretary provided them in the Final Rule. However, after addressing the objections of Plaintiffs and like-minded public commenters, the Secretary finalized the .2 percent reduction. The rulemaking record reflects her reasoned basis for doing so, which is all the APA requires. Plaintiffs' apparent disagreement with that decision does not somehow transform it into arbitrary-and-capricious agency action.

Finally, in a last-ditch effort to invalidate the Secretary's reduction, Plaintiffs contend that it was not promulgated "by regulation" as required by the Medicare statute. That contention is based on Plaintiffs' erroneous belief that publication in the *Code of Federal Regulations* is a condition precedent for agency regulations. The law in the D.C. Circuit is otherwise. Because the Secretary subjected her .2 percent reduction to notice-and-comment rulemaking, she thereby complied with the statutory requirement that the adjustment be issued by regulation. Accordingly, the Court should uphold the Secretary's .2 percent reduction, grant this cross-motion, deny Plaintiffs' motions, and enter judgment in her favor.

STATUTORY BACKGROUND

Title XVIII of the Social Security Act, commonly known as the Medicare statute, establishes a program of federally-supported health insurance for the elderly and disabled. 42

[1] References to the rulemaking record are cited herein as "A.R. ___."

U.S.C. §§ 1395, et seq. Medicare sets out a "complex statutory and regulatory regime," *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 404 (1993), under which hospitals can obtain payment from the Medicare program for services that they provide to Medicare beneficiaries. Among other things, Medicare Part A makes payments to hospitals for inpatient care. 42 U.S.C. §§ 1395c-1395i-5. Responsibility for determining the amount of these payments has been entrusted by Congress to the Secretary, who has delegated it to CMS. CMS, in turn, hires Medicare contractors, to engage in much of the direct interaction with hospitals related to the processing of claims for payment and the collection of data to support CMS's administration of the Medicare program. Among other things, the Medicare contractors make determinations regarding whether hospitals have properly accounted for and reported their services to CMS. Hospitals dissatisfied with determinations regarding Medicare payment, in accordance with the Medicare statute, may challenge those determinations before the Provider Reimbursement Review Board ("PRRB"), (42 U.S.C. § 1395oo(a)), and seek judicial review, as here, of final agency decisions, (42 U.S.C. § 1395oo(f)).

A. The Medicare Hospital Inpatient Prospective Payment System ("IPPS")

The Medicare program generally does not reimburse hospitals for the actual operating costs that they incur in providing inpatient care. Instead, most hospitals are paid fixed rates under a scheme known as the "Prospective Payment System." *See County of Los Angeles v. Shalala*, 192 F.3d 1005, 1008 (D.C. Cir. 1999); 42 U.S.C. § 1395ww(d). The "IPPS" refers to the prospective payment system for inpatient hospitalizations.

Payment under the IPPS is governed by a complex statutory and regulatory regime. In general, IPPS pays hospitals based on the patients they discharge from inpatient care, and based on the specific patient's primary diagnosis at that time. *See* 42 U.S.C. § 1395ww(d)(3)(D)(iii).

Each patient diagnosis has a corresponding Diagnosis-Related Group ("DRG") "to which CMS has assigned a numeric weight reflecting the amount of resources needed, on average, to treat a patient with the corresponding diagnosis," relative to other diagnoses. *State of Florida v. Tenet Healthcare Corp.*, 420 F. Supp. 2d 1288, 1293 (S.D. Fla. 2005); *see* 42 U.S.C. § 1395ww(d)(4); 42 C.F.R. § 412.60.

Most IPPS hospitals are paid what the regulations call the "federal rate," (42 C.F.R. § 412.64), and the statute calls the "national adjusted [diagnosis related group] payment rate," (42 U.S.C. § 1395ww(d)(1)(A)(iii)(I)), for each Medicare beneficiary they discharge. The methodology for calculating the federal rate is the same across hospitals paid under this method, but the final amount a given hospital receives varies. The starting point in calculating a hospital's payment under the federal rate is the "average standardized amount" for the current year. *See* 42 U.S.C. § 1395ww(d)(3)(A). The standardized amount is "based on the average resources used to treat cases in all DRGs," (*State of Fla.*, 420 F. Supp. 2d at 1294), and is adjusted each year for inflation based on the percentage increase in the hospital "market basket," which is a price index used by the Secretary to measure the costs of hospital goods and services. *National Hospice & Palliative Care Org. v. Weems*, 587 F. Supp. 2d 184, 188 n.3 (D.D.C. 2008); *Hospital San Rafael, Inc. v. Sullivan*, 784 F. Supp. 927, 930 n.4 (D.P.R. 1991); *see* 42 U.S.C. § 1395ww(b)(3)(B)(ii)(VIII), (iii), (d)(3)(A); 42 C.F.R. § 412.64(d). The DRG budget neutrality adjustment for the current year is then applied, (*see* 42 U.S.C. § 1395ww(d)(4)(c)(iii)),[2] together with other statutory adjustments, (*see* 42 U.S.C. § 1395ww(d)(3)(B)-(C), (E)). As relevant here,

[2] This factor requires that any adjustments the Secretary makes to DRG classifications and weighting attributable to "changes in treatment patterns, technology . . . and other factors which may change the relative use of hospital resources" be "made in a manner that assures that the aggregate payments under this subsection for discharges in the fiscal year are not greater or less than those that would have been made for discharges in the year without such adjustment." 42 U.S.C. § 1395ww(d)(4)(c)(i), (iii).

the statute also authorizes the Secretary to "provide by regulation for such other exceptions and adjustments . . . as the Secretary deems appropriate." 42 U.S.C. §1395ww(d)(5)(I)(i).

To calculate the payment amount for a particular discharged beneficiary, the amount following such adjustments is further adjusted to reflect the average resources associated with treating that beneficiary, using the applicable DRG weighting factor. *See* 42 U.S.C. § 1395ww(d)(3)(D). The final product of that calculation is the hospital's federal rate payment for the beneficiary.[3]

B. Policies and Practices Related to Differentiating Between Inpatient and Outpatient Hospital Admissions.

Congress designed the IPPS to hold down costs, eliminate incentives for hospitals to provide unduly long or costly inpatient stays, and encourage efficiency by prescribing in advance an inflation-adjusted amount that Medicare will pay for different diagnostic categories of cases. *Compare* H.R. Rep. No. 98-25(I) at 132 (1983), *reprinted in* 1983 U.S.C.C.A.N. 219, 351 *with* S. Rep. No. 98-23 at 47 (1983), *reprinted in* 1983 U.S.C.C.A.N. 143, 187; *see also County of Los Angeles*, 192 F.3d at 1008. Despite such intentions, the system in practice has not always operated as efficiently as anticipated. One such area for which that is true relates to providers' differentiation between inpatient and outpatient (or observation) admissions.

Medicare guidance has long recognized that the appropriateness of inpatient treatment does not depend "solely on the basis of the length of time the patient actually spends in the hospital." A.R. 1451. Rather, the decision whether to admit a patient is a "complex medical judgment" that depends on a number of factors including, "the patient's medical history and current medical needs, the types of facilities available to inpatients and outpatients, the hospital's

[3] The Secretary also calculates a "hospital-specific rate" and "Puerto Rico-specific rate" that is particular to a specific hospital (and based on the historical per-patient operating costs at the particular hospital) or to hospitals located in Puerto Rico. *See* 42 U.S.C. § 1395ww(b)(3), (d)(5)(D)(i)(I); 42 C.F.R. §§ 412.92(d), 412.108(c); 42 C.F.R. §§ 412.370, 412.374.

by-laws and admissions policies, and the relative appropriateness of treatment in each setting." *Id*. "Factors to be considered when making the decision to admit include such things as:

- The severity of the signs and symptoms exhibited by the patient;
- The medical predictability of something adverse happening to the patient;
- The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and
- The availability of diagnostic procedures at the time when and at the location where the patient presents."

Id. The Medicare Benefit Policy Manual additionally advised that "[g]enerally, 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 not actually use a hospital bed overnight." A.R. 1450. Notwithstanding such guidance, hospital providers have expressed confusion regarding correctly identifying which of their services are appropriate for inpatient hospitalization. *See, e.g.*, A.R. 3509 (public commenter) (noting that "[d]ifferentiating inpatient admission from outpatient observation has presented a major challenge for hospitals and has been the source of a great deal of lost revenue when Medicare auditors retrospectively determined that some patients admitted as inpatients could have been safely treated with outpatient observation"). In 2012, for example, the Comprehensive Error Rate Testing ("CERT") "contractor found that inpatient hospital admissions for 1-day stays or less had a Part A improper payment rate of 36.1 percent." A.R. 728. "The improper payment rates decrease[d] significantly for 2-day or 3-day stays, which had improper payment rates of 13.2 percent and 13.1 percent respectively." *Id.* Medicare

recovery auditors moreover "have recovered more than $1.6 billion in improper payments because of inappropriate beneficiary patient status." *Id.*

In response to such "financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review," hospitals apparently have "elect[ed] to treat beneficiaries as outpatients receiving observations services, often for longer periods of time, rather than admit them." A.R. 96.

These trends "demonstrate[d] that the appropriate determination of a beneficiary's patient status is a systemic and widespread issue and is not isolated to a few hospitals." A.R. 728.

C. CMS' Efforts to Improve Guidance Related to Inpatient Hospitalization Determinations and the Two-Midnight Rule and Benchmark.

In 2012, CMS solicited public comments on "[p]otential policy changes [it] could make to improve clarity and consensus among providers, Medicare, and other stakeholders regarding the relationship between admission decisions and appropriate Medicare payment." A.R. 95. Numerous commenters "applaud[ed] CMS' efforts to better define how patient status is determined – inpatient or outpatient with observation." A.R. 3526; *see also generally* A.R. 3503-3526. It was not until the IPPS rulemaking for FY 2014, however, that CMS took action on this issue. In the proposed rule, CMS proposed "inpatient hospital admission guidance under which a physician or other practitioner should order admission if he or she expects that the beneficiary's length of stay will exceed a 2-midnight threshold or if the beneficiary requires a procedure specified as inpatient-only under 42 CFR 419.22." A.R. 727. Thus, "in addition to services designated by CMS as inpatient only, surgical procedures, di[a]gnostic tests, and other treatments would be generally appropriate for inpatient hospital payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation." *Id.* "Conversely, when a patient

enters a hospital for a surgical procedure not specified by Medicare as inpatient only under § 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the patient in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A." *Id.* CMS contemplated that under this proposed policy "physicians w[ould] make the decision to keep a beneficiary in the hospital when clinically warranted and w[ould] order all appropriate treatments and care in the appropriate location based on the beneficiary's individual medical needs." A.R. 1356.

After consideration of the public comments received, the Secretary finalized "two distinct, though related, medical review polices, a 2-midnight *presumption* and a 2-midnight *benchmark*." A.R. 1357. Under the former, "inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order will be presumed generally appropriate for Part A payment and will not be the focus of medical review efforts absent evidence of systemic gaming, abuse or delays in the provision of care in an attempt to qualify for the 2-midnight presumption." *Id.* "If the physician admits the beneficiary as an inpatient but the beneficiary is in the hospital for less than 2 midnights after the order is written, CMS and its medical review contractors will not presume that the inpatient hospital status was reasonable and necessary for payment purposes, but may instead evaluate the claim pursuant to the 2-midnight benchmark." *Id.* In applying that benchmark, Medicare review contractors "will (a) evaluate the physician order for inpatient admission to the hospital, along with other required elements of the physician certification, (b) the medical documentation supporting the expectation that care would span at least 2 midnights, and (c) the medical documentation supporting a

decision that it was reasonable and necessary to keep the patient at the hospital to receive such care, in order to determine whether payment under Part A is appropriate." *Id.*

D. The Secretary Invokes Her Authority Under Subsection (d)(5)(I)(i) to Adjust IPPS Rates to Offset Anticipated Increased Expenditures as a Result of the Two-Midnight Policy.

The Secretary determined that her new two-midnight policy had significant attendant costs. Specifically, her actuaries estimated that the "policy that medical review of inpatient admissions will include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 'midnights') in the hospital receiving medically necessary services . . . would increase IPPS expenditures by approximately $220 million." A.R. 728. Her actuaries further calculated that a .2 percent reduction in the IPPS rates would offset that expected increase. *Id.* Based on an examination of FY 2009 through FY 2011 Medicare claims data for extended hospital outpatient encounters and shorter stay hospital inpatient encounters, the actuaries "estimated that approximately 400,000 encounters would shift from outpatient to inpatient and approximately 360,000 encounters would shift from inpatient to outpatient, causing a net shift of 40,000 encounters." *Id.*

To offset the expected $220 million in increased expenditures, the Secretary invoked her catchall exceptions and adjustment authority and proposed, in conjunction with the two-midnight rule, that a .2 percent adjustment be applied to the IPPS rates. *See* 42 U.S.C. § 1395ww(d)(5)(I)(i). The Secretary explained that "[i]n light of the widespread impact of the proposed [two-midnight rule] . . . and the systemic nature of the issue . . . it is appropriate to propose to use our exceptions and adjustment authority . . . authoriz[ing her] to provide 'for such other exceptions and adjustments to [IPPS] payment amounts . . . as the Secretary deems

appropriate.'" A.R. 729. The .2 percent adjustment proposal was submitted for public notice and comment. *See* A.R. 3642-5894.

Hospital "[c]ommenters generally did not support the proposed -0.2 percent payment adjustment." A.R. 1361. The criticisms ranged from the "actuaries' estimated increase in IPPS expenditures . . . was unsupported" to "CMS did not provide sufficient rationale for the use of [the] exceptions and adjustments authority." *Id.* Other commenters requested additional details about the actuaries' analysis that supported the .2 percent calculation. *See id.* The Secretary responded to that request by explaining that

> In determining the estimate of the number of encounters that would shift from outpatient to inpatient, our actuaries examined outpatient claims for observation or a major procedure. Claims not containing observation or a major procedure were excluded. The number of claims spanning 2 or more midnights based on the dates of service that were expected to become inpatient was approximately 400,000. This estimate did not include any assumption about outpatient encounters shorter than 2 midnights potentially becoming inpatient encounters.
>
> In determining the estimate of the number of encounters that would shift from inpatient to outpatient, our actuaries examined inpatient claims containing a surgical MS-DRG. Claims containing medical MS-DRGs were excluded. The number of claims spanning less than 2 midnights based on the length of stay that were expected to become outpatient, after excluding encounters that resulted in death or transfers, was approximately 360,000.

Id. The Secretary advised the public that these estimates, which necessarily had a certain "degree of uncertainty" surrounding them, "should not be construed as absolute statements about every individual encounter." *Id.*

In the end, after considering the public comments received, and because her actuaries "continue[d] to estimate" that there would be approximately $220 million in additional expenditures resulting from the two-midnight rule, the Secretary finalized the .2 percent reduction. A.R. 1362.

STATEMENT OF FACTS

Plaintiffs in this consolidated action are various hospitals that participate as service providers under the Medicare program. *See* Compl. for Declaratory & Inj. Relief & for Sums Due Under the Medicare Act ("Shands Compl.") ¶ 4 in *Shands v. Sebelius*, Case No. 14-263-EGS, Feb. 20, 2014, ECF No. 1; Compl. ("Athens Compl.") ¶ 5 in *Athens Regional Med. Ctr., Inc. v. Sebelius*, Case No. 14-503-RBW, Mar. 25, 2014, ECF No. 1; Compl. for Declaratory & Inj. Relief & for Sums Due Under the Medicare Act ("Dignity Health Compl.") ¶ 5 in *Dignity Health v. Sebelius*, Case No. 14-536-EGS, Mar. 31, 2014, ECF No. 1; Compl. ("AHA Compl.") in *American Hosp. Ass'n v. Sebelius*, Case No. 14-607-RBW, Apr. 14, 2014, ECF No. 1; Compl. for Judicial Review of Final Adverse Agency Decisions on Medicare Reimbursement ("Bakersfield Compl.") ¶¶ 4-14 in *Bakersfield Heart Hosp. v. Burwell*, Case No. 14-976, June 9, 2014, ECF No. 1; Compl. for Judicial Review of Agency Action Under Medicare Act ("St. Helena Compl.") ¶ 10 in *St. Helena Hosp. v. Burwell*, Case No. 14-1477-EGS, Aug. 27, 2014, ECF No. 1. Following the Secretary's promulgation of the challenged .2 percent reduction, Plaintiffs appealed her decision to the PRRB, which granted expedited review in their appeals. *See* Shands Compl. ¶¶ 39-41; Athens Compl. ¶¶ 23-26; Dignity Health Compl. ¶¶ 39-42; AHA Compl. ¶¶ 69-88; Bakersfield Compl. ¶¶ 26-28; St. Helena Compl. ¶¶ 30-21; *see also* 42 U.S.C. § 1395oo(f)(1).[4]

[4] Shands Plaintiffs appealed to the PRRB on January 23, 2014, and expedited judicial review was granted on February 19, 2014; Athens Plaintiffs appealed to the PRRB on January 28, 2014, and expedited judicial review was granted on March 12, 2014; AHA Plaintiffs appealed to the PRRB on January 23, 2014, and expedited judicial review was granted on March 20, 2014; Bakersfield Plaintiffs appealed to the PRRB on January 28, 2014, and expedited judicial review was granted on April 14 and 17, 2014; and St. Helena Plaintiffs filed a consolidated expedited judicial review request that was granted on August 7, 2014.

Plaintiffs thereafter filed five separate actions in the United States District Court for the District of Columbia over the period February 20, 2014 through August 27, 2014. *See generally* Shands Compl.; Athens Compl.; Dignity Health Compl.; AHA Compl.; Bakersfield Compl.; St. Helena Compl. The Court sua sponte consolidated all fives actions in this Court and issued a consolidated briefing schedule for dispositive motions. *See* Minute Order, May 23, 2014 (consolidating *Shands* with *Dignity Health*); Minute Order, July 23, 2014 (consolidating *Athens Regional*, *AHA*, and *Bakersfield* with *Shands*/*Dignity Health*); Order, Aug. 13, 2014 (establishing consolidated briefing schedule for motions for summary judgment); Minute Order, Sept. 9, 2014 (consolidating *St. Helena* with consolidated *Shands*). Plaintiffs filed their motions for summary judgment between September 12 and September 15, 2014. *See* Bakersfield Pls.' Mem. of Points & Auths. in Supp. of Mot. for Summ. J. ("Bakersfield MSJ"), Sept. 12, 2014, ECF No. 15; Am. Hosp. Ass'n Pls.' Mem. of Points & Auths. in Supp. of Mot. for Summ. J. ("AHA MSJ"), Sept. 15, 2014, ECF No. 16; Shands Pls.' Mem. of Points & Auths. in Supp. of Mot. for Summ. J. ("Shands MSJ"), Sept. 15, 2014, ECF No. 17-1; Mem. of Points & Auths. in Supp. of Pls.' St. Helena Hosp. et al.'s Mot. for Summ. J. ("St. Helena MSJ"), Sept. 15, 2014, ECF No. 18-1; Mem. in Supp. of Pls.' Athens Regional et al.'s Mot. for Summ. J. ("Athens Regional MSJ"), Sept. 15, 2014, ECF No. 19-1.

The Secretary now opposes Plaintiffs' motions and cross-moves for dismissal and summary judgment.

ARGUMENT

I. THE SECRETARY HAS STATUTORY AUTHORITY TO IMPOSE THE .2 PERCENT REDUCTION TO MEDICARE'S IPPS PAYMENT RATES.

Despite clear statutory language to the contrary, Plaintiffs contend that the Secretary was not statutorily authorized to apply the challenged .2 percent adjustment across the IPPS

standardized amount, the hospital-specific rates, and the Puerto Rico-specific standardized amount.[5] *See* St. Helena MSJ at 11-19; Shands MSJ at 11-24; Bakersfield MSJ at 29-30. Specifically, Plaintiffs complain that the Secretary's invocation of 42 U.S.C. § 1395ww(d)(5)(I)(i) as authorizing the challenged .2 percent reduction is inconsistent with the statutory structure, the Secretary's prior interpretations of that provision, and the legislative history. Plaintiffs also claim that the reduction itself contravenes Medicare's per-discharge payment system by effectively denying them payment for approximately 40,000 inpatient hospitalizations. *See, e.g.*, St. Helena MSJ at 11-19; Shands MSJ at 11-24; Bakersfield MSJ at 30. All of these arguments are without merit.

The challenged .2 percent reduction is within the Secretary's statutory authority. In determining whether an agency has "acted within the bounds of its authority," this Court "looks to the agency's enabling statute and subsequent legislation." *Adirondack Med. Ctr. v. Sebelius*, 891 F. Supp. 2d 36, 43 (D.D.C. 2012) (upholding adjustment under Subsection (d)(5)(I)(i)). The well-established two-step *Chevron* analysis applies to the agency's interpretation of its enabling statute. *See id.*; *see also Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984).[6] "First, the court determines whether 'Congress has directly spoken to the precise question at issue" and, if so, the court must 'give effect to the unambiguously expressed intent of Congress.'" *Adirondack*, 891 F. Supp. 2d at 43 (quoting *Chevron*, 467 U.S. at 842-43). "If, on the other hand, the statute is ambiguous or silent on [the] issue, the court proceeds to the second

[5] The analysis that follows applies equally to Plaintiffs' challenge to the Secretary's reduction for capital-related costs. *See* St. Helena MSJ at 18-19.

[6] St. Helena Plaintiffs contend that this Court's analysis should instead be pursuant to *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), as opposed to *Chevron*. *See* St. Helena MSJ at 24-25. Even if true (and it is not), under the circumstances here, that distinction is immaterial. In cases involving Medicare or Medicaid, "in which CMS, 'a highly expert agency[,] administers a large complex regulatory scheme in cooperation with many other institutional actors, the various possible standards for deference' – namely, *Chevron* and *Skidmore* – 'begin to converge.'" *Landers v. Leavitt*, 545 F.3d 98, 107 (2d Cir. 2009) (quoting *Community Health Ctr. v. Wilson-Coker*, 311 F.3d 132, 138 (2d Cir. 2002)).

step of the *Chevron* analysis and determines whether the agency's interpretation is based on a permissible construction of the statute." *Adirondack*, 891 F. Supp. 2d at 43 (quoting *Chevron*, 467 U.S. at 843). Whether under the first or second step of *Chevron*, the Secretary's .2 percent adjustment should be upheld.

A. The Secretary's .2 Percent Reduction Should Be Upheld Under *Chevron* Step One.

This Court need look no further than the statutory language of Subsection (d)(5)(I)(i) to uphold the Secretary's interpretation of her adjustment authority. *See* 42 U.S.C. § 1395ww(d)(5)(I)(i). The resolution of any dispute over the meaning of that provision "begins where all such inquiries must begin: with the language of the statute itself." *United States v. Ron Pair Enter., Inc.*, 489 U.S. 235, 241 (1989). Where, as here, that meaning is clear, the statutory language "is also where the inquiry should end." *Id.*; *see also Adirondack*, 891 F. Supp. 2d at 43 ("When the statute is not ambiguous, the text controls . . . ."). Congress, in broad terms, authorized – indeed required – the Secretary to adjust, as she did here, the IPPS payments rates as she deems appropriate. *See* 42 U.S.C. § 1395ww(d)(5)(I)(i). Specifically, Subsection (d)(5)(I)(i) provides that "[t]he Secretary *shall provide* by regulation for such other exceptions and adjustments to such payment amounts under this subsection *as the Secretary deems appropriate*." 42 U.S.C. § 1395ww(d)(5)(I)(i) (emphasis added). Courts have regarded this provision as a "catch-all provision for adjustments," (*Episcopal Hosp. v. Sullivan*, No. 89-1716, 1991 WL 330924, at *5 (D.D.C. Nov. 12, 1991); *Board of Trustees of Knox Cnty. v. Sullivan*, 965 F.2d 558, 563 (7th Cir. 1992)), that encompasses "a broad delegation of discretion to the Secretary either to modify the [IPPS] regulation or to grant an exception," (*Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1224 (D.C. Cir. 1993)). *See also Adirondack*, 891 F. Supp. 2d at 44-45 (concluding that "§ (d)(5)(I)(i) plainly grants broad authority to the

Secretary to provide 'for such other exceptions and adjustments to [IPPS] payment amounts . . . as the Secretary deems appropriate'"); *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 699 (D.C. Cir. 2014). The term "'as appropriate' [] ordinarily denotes the giving of discretion to the decisionmaker." *Consumer Fed'n of Am. v. Department of Health & Human Servs.*, 906 F. Supp. 657, 665 (D.D.C. 1995), *rev'd on other grounds*, 83 F.3d 1497 (D.C. Cir. 1996). Plaintiffs' characterizations of Subsection (d)(5)(I)(i) are plainly at odds with these of the courts.

Here, it is undisputed that the Secretary regarded the .2 percent reduction to the IPPS rates as appropriate. *See* A.R. 729 (explaining in the Final Rule preamble that "we believe it is appropriate to propose to use our exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act [42 U.S.C. § 1395ww(d)(5)(I)(i)] to offset the estimated $220 million in additional IPPS expenditures associated with this proposed policy"). Although Plaintiffs suggest that the .2 percent reduction effects a "fundamental" change to the Medicare system by "overrid[ing]" its "per-discharge" payment basis, specifically, by "den[ying] payment for 40,000 projected new inpatient cases for 2014," (*see* St. Helena MSJ at 13-14; Shands MSJ at 11-12), the Secretary's reduction is one of numerous adjustments provided for by the statute itself and applied to the standardized rate before that rate is applied *per qualified discharge* to determine the inpatient hospital service payment. *See* 42 U.S.C. § 1395ww(d)(1)(A)(iii) (providing that "the amount of the payment with respect to the operating costs of inpatient hospital services . . . of a subsection (d) hospital . . . for inpatient hospital discharges in a cost reporting period or in a fiscal year . . . beginning on or after April 1, 1988, is equal to [] the national adjusted DRG prospective payment rate determined under paragraph (3) for such discharges"). Thus, Medicare's per-discharge payment basis is not disturbed by the Secretary's addition of an

adjustment beyond those already specified by the Medicare statute. Indeed, Subsection (d)(5)(I)(i) specifically authorizes the Secretary to create new adjustments.

Moreover, as evident from its size, the .2 percent reduction is not a "substantial departure from the default amounts" that would "occasion [this Court] to engage in line drawing to determine when 'adjustments' cease being 'adjustments.'"[7] *Amgen Inc. v. Smith*, 357 F.3d 103, 117 (D.C. Cir. 2004). Rather, it is an "alteration" or "modification" to those rates as contemplated by the ordinary meaning of "adjustment." *See* OXFORD ENGLISH DICTIONARY (3d ed. 2011) *available at* www.oed.com (defining "adjustment" as "[t]he action or process of adjusting something (in various senses). Also: an instance of this; an alteration, a modification.").[8] For these reasons, the Secretary's .2 percent reduction should be upheld under a plain-language analysis of 42 U.S.C. § 1395ww(d)(5)(I)(i). *See id.* (authorizing the Secretary to provide for "such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate").

B. The Secretary's .2 Percent Reduction Should Be Upheld Under *Chevron* Step Two.

Notwithstanding the clear language of Subsection (d)(5)(I)(i) authorizing – indeed requiring – the Secretary to implement those adjustments she deems appropriate, Plaintiffs contend that this Court should resort to various rules of statutory construction to discern that provision's meaning. *See, e.g.*, Shands MSJ at 14-15 (invoking canon of *ejusdem generis*); St. Helena MSJ at 15 (same); Shands MSJ at 16-17 (invoking legislative history). Such rules of statutory interpretation are only employed if the statutory language is ambiguous, and here it is

[7] The adjustment at issue and upheld by the court in *Adirondack* – an approximately 2.9% reduction – was much larger than the adjustment challenged here. *See Adirondack*, 740 F.3d at 700; 75 Fed. Reg. 50,042, 50,063 (Aug. 16, 2010).

[8] The Supreme Court has noted that the OXFORD ENGLISH DICTIONARY is "one of the most authoritative." *Taniguchi v. Kan Pac. Saipan, Ltd.*, 132 S. Ct. 1997, 1999 (2012).

not. As the Supreme Court has admonished "time and again [] courts must presume that a legislature says in a statute what it means and means in a statute what it says there. When the words of a statute are unambiguous, then, this first canon is also the last: judicial inquiry is complete." *Connecticut Nat'l Bank v. Germain*, 503 U.S. 249, 253-54 (1992). Otherwise, "canons of construction are no more than rules of thumb that help courts determine the meaning of legislation." *Id.* at 253. If the Court were to conclude that Subsection (d)(5)(I)(i) is ambiguous, then whether or not such canons are employed, the Secretary's interpretation of that provision should be upheld under *Chevron* step two.

At that step, the Court "determines whether the agency's interpretation is based on a permissible construction of the statute." *Adirondack*, 891 F. Supp. 2d at 43. In doing so, the Court must heed another Supreme Court admonishment "that '[if an] agency regulation is not in conflict with the plain language of the statute, a reviewing court should give deference to the agency's interpretation of the statute.'" *Clinton Mem'l Hosp. v. Sullivan*, 783 F. Supp. 1429, 1437 (D.D.C. 1992) (quoting *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 292 (1988)). "And here, 'the tremendous complexity of the Medicare program enhances the deference due the Secretary's decision.'" *Adirondack*, 891 F. Supp. 2d at 43 (quoting *Community Care Found. v. Thompson*, 318 F.3d 219, 225 (D.C. Cir. 2003)). Thus, the Court "need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." *Chevron*, 467 U.S. at 843 n.11. Rather, the Court "need only determine 'whether the agency's answer is based on a permissible construction of the statute.'" *Episcopal Hosp. v. Shalala*, 994 F.2d 879, 884 (D.C. Cir. 1993) (quoting *Chevron*, 467 U.S. at 843); *see also Good Samaritan Hosp.*, 508 U.S. at 417 (noting that "where the agency's

interpretation of a statute is at least as plausible as competing ones, there is little, if any, reason not to defer to its construction").

The Secretary in this case determined that the "widespread impact" of the proposed two-midnight rule and "the systemic nature of the issue" warranted her use of the "exceptions and adjustments authority under section1886(d)(5)(I)(i) of the Act [42 U.S.C. § 1395ww(d)(5)(I)(i)] to offset the estimated $220 million in additional IPPS expenditures associated with this proposed policy." A.R. 729. As interpreted by the Secretary, that "special exceptions and adjustment authority authorizes [her] to provide 'for such other exceptions and adjustments to [IPPS] payment amounts . . . as . . . [she] deems appropriate.'" *Id.* Plaintiffs can only prevail at *Chevron* step two by "show[ing] that the statutory language 'cannot bear the interpretation adopted by the Secretary.'" *Adirondack*, 891 F. Supp. 2d at 43 (quoting *Sullivan v. Everhart*, 494 U.S. 83, 91-92 (1990)). On the record here, Plaintiffs clearly have not made that showing. *See* Shands MSJ at 11-24; St. Helena MSJ at 11-19; Bakersfield MSJ at 29-30.

1. The Statutory Structure Supports the Secretary's Construction of Subsection (d)(5)(I)(i).

Plaintiffs erroneously contend that the statutory structure supports their preferred narrow construction of Subsection (d)(5)(I)(i) as authorizing the Secretary to address "only . . . discrete payment inequities," (Shands MSJ at 14; *see also* St. Helena MSJ at 14) – notwithstanding that such a limitation appears nowhere in the statute. That contention according to Plaintiffs is supported by the *ejusdem generis* canon of construction. *See id.* at 15; Shands MSJ at 14-15. The canon of *ejusdem generis* provides that "where general words follow specific words, the general words are construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words." *Williams v. District of Columbia*, 825 F. Supp. 2d 88, 99 (D.D.C. 2011); *see also United States v. Espy*, 145 F.3d 1369, 1370-71 (D.C. Cir. 1998)

("Where a general term follows a list of specific terms, the rule of *ejusdem generis* limits the general term as referring only to items of the same category."). "*Ejusdem generis* only comes into play when the general term in the list is so broad that it creates ambiguity." *Id.* at 1371. Here, that canon should not come into play at all.

The Secretary's authority to establish "other exceptions and adjustments," (42 U.S.C. § 1395ww(d)(5)(I)(i)), does not follow a list of specific terms as contemplated by the rule of *ejusdem generis*. *See, e.g.*, *Espy*, 145 F.3d at 1370 (interpreting statutory provision that forbid "any inspector, deputy inspector, chief inspector, or *other officer or employee of the United States authorized to perform any of the duties prescribed by this subchapter*"); *Williams*, 825 F. Supp. 2d at 99 (interpreting D.C. Code § 1-615.52(a)(5)(A) (2010), a statutory provision defining a "prohibited personnel action" as a "recommended, threatened, or actual termination, demotion, suspension, or reprimand; involuntary transfer, reassignment, or detail; referral for psychiatric or psychological counseling; failure to promote or hire or take other favorable personnel action; or retaliating in any *other manner against an employee* because that employee makes a protected disclosure or refuses to comply with an illegal order" (emphasis added)). Rather, the Secretary's catchall authority appears in a self-contained statutory provision. The structure of the statute therefore does not lend itself to the application of the *ejusdem generis* canon. Indeed, that the Secretary's catchall authority is within a self-contained provision suggests that the authority is independent of any exceptions authority appearing elsewhere in the statute. *See, e.g.*, *Episcopal Hosp.*, 1991 WL 330924, at *5 (regarding Subsection (d)(5)(I)(i) as a "catch-all provision for adjustments"). Regardless, Plaintiffs' invocation of the *ejusdem generis* canon falls far short of their required showing to prevail here, i.e., that the language of Subsection (d)(5)(I)(i) "cannot bear the interpretation adopted by the Secretary." *Sullivan*, 494 U.S. at 92.

2. The Legislative History Does not Support Plaintiffs' Narrow Interpretation of Subsection (d)(5)(I)(i).

Plaintiffs' invocation of the legislative history fares no better. *See* Shands MSJ at 16-17. At best, the legislative history is equivocal. As enacted, the catchall provision authorized the Secretary to "provide by regulation for such other exceptions and adjustments to such payment amounts . . . as the Secretary deems appropriate (including exceptions and adjustments that may be appropriate with respect to hospitals involved extensively in treatment for and research on cancer)." *Id.* at 17 (quoting Social Security Amendments of 1983, Pub. L. No. 98-21, § 601, 97 Stat. 65, 158). Relying entirely on conference and committee reports from 1983, Plaintiffs contend that the Secretary's then-new "exceptions and adjustments authority was consistent with the Secretary's then-governing authority to provide exceptions 'to take into account the special needs of' particular types of hospitals." Shands MSJ at 17. Plaintiffs neglect to mention, however, that a subsequent Congress removed the parenthetical language concerning cancer hospitals, thereby leaving the general grant of authority to provide for exceptions and adjustment "as the Secretary deems appropriate," (42 U.S.C. § 1395ww(d)(5)(I)(i)). *See* Omnibus Reconciliation Act of 1989, Pub. L. No. 101-239 § 6004 (Dec. 19, 1989). To the extent the 1983 Congress contemplated a narrow exceptions and adjustment authority, a subsequent Congress expanded that authority through the removal of the parenthetical language. *See Garcia v. United States*, 88 F.3d 318, 332 (5th Cir. 1996) (noting that, in analyzing legislative history, "a court should begin with the most recent statement of authority"). Under those circumstances, the Court could not appropriately interpret the current statutory language by reference to the legislative history predating the enactment of the challenged provision. *See e.g., Exxon Mobil Corp. v. Allapattah Servs. Inc.*, 545 U.S. 546, 568 (2005) (favorably mentioning the view that legislative-history analyses are akin to "looking over a crowd and picking out your friends"). The

legislative history therefore does not support Plaintiffs' claim that the Secretary's interpretation of Subsection (d)(5)(I)(i) is invalid under *Chevron* step two.

3. The Secretary's Interpretation Is not in Conflict with Authority Provided Elsewhere in the Medicare Statute.

Plaintiffs alternatively, but erroneously, contend that specific authority provided elsewhere in the Medicare statute requires that Subsection (d)(5)(I)(i) be construed narrowly so that those other provisions are not rendered superfluous. *See* St. Helena MSJ at 15 (contending that "[i]f the adjustments authority under subsection (d)(5)(I)(i) encompasses the authority to enact across-the-board adjustments to standardized amounts, subsection (d)(5)(I)(ii) would be superfluous and unnecessary"); Bakersfield MSJ at 30 (contending that "the suggestion that Congress gave CMS the authority to make across-the-board cuts is inconsistent with Congress's reserved power to set the annual update to the base payments under the IPPS and in conflict with the statutorily prescribed market basket update 'for all hospitals in all areas'"). The canon of construction regarding superfluities "is not a mandate" and "merely provides that 'if possible' a court should construe a statute to give effect to every word and clause and should avoid a construction that renders a word or clause surplusage." *Adirondack*, 891 F. Supp. 2d at 46-47 (quoting *Public Citizen, Inc. v. Rubber Mfrs. Ass'n*, 533 F.3d 810, 816-17 (D.C. Cir. 2008)). "Redundancies across statutes[, however,] are not unusual events in drafting, and so long as there is no 'positive repugnancy' between two laws, a court must give effect to both." *Connecticut Nat'l Bank*, 503 U.S. at 253.

> It is an old and familiar rule that where there is, in the same statute, a particular enactment, and also a general one, which, in its most comprehensive sense, would include what is embraced in the former, the particular enactment must be operative, and the general enactment must be taken to affect only such cases within its general language as are not within the provisions of the particular enactment.

United States v. Chase, 135 U.S. 255, 260 (1890); *see also DeNaples v. Office of Comptroller of Currency*, 706 F.3d 481, 487 (D.C. Cir. 2013) ("That there is overlap among the various enforcement provisions is not surprising . . . . Congress could reasonably hand the agencies a palette sufficiently sophisticated to capture the full spectrum of enforcement possibility."); *Shook v. District of Columbia Fin. Responsibility & Mgmt. Assistance Auth.*, 132 F.3d 775, 782 (D.C. Cir. 1998) (noting that Congress "sometimes drafts statutory provisions that appear preclusive of other unmentioned possibilities – just as it sometimes drafts provisions that appear duplicative of others – simply in Macbeth's words, 'to make assurance double sure'").

Thus, for example, in *Adirondack Med. Ctr. v. Sebelius*, the district court upheld the Secretary's interpretation of Subsection (d)(5)(I)(i) as authorizing an across-the-board reduction in the hospital specific rate to offset an artificial rate increase caused by changes in MS-DRG coding that were unrelated to the severity of patient illness notwithstanding that "Congress *expressly* authorized the Secretary to make such a downward adjustment for other types of hospitals without similarly providing for such an adjustment for rural and community hospitals." *Adirondack*, 891 F. Supp. 2d at 39. The plaintiffs in that case suggested that "the Secretary's express authority to adjust the federal rate under § 1395ww(d)(3)(A)(vi) . . . must mean that the Secretary does *not* have similar authority to adjust the hospital-specific rate" under Subsection (d)(5)(I)(i). *Adirondack*, 891 F. Supp. 2d at 42. In other words, according to the plaintiffs, "the statute's silence on the topic of the hospital-specific rate work[ed] to revoke the Secretary's authority under § (d)(5)(I)(i) to make such adjustments." *Id.* at 45. The district court and the D.C. Circuit rejected that suggestion. As the D.C. Circuit explained, Section 1394ww(d)(3)(A)(vi) says "nothing about adjusting the hospital-specific rate; therefore the broad grant of authority (and the Secretary's use thereof) fills a space that the specific provisions do not

occupy. Such an arrangement does not run afoul of [any statutory] canon." *Adirondack*, 740 F.3d at 699. The general catchall authority "operates to the extent that [specific authorities elsewhere] are silent." *Id.*

So too here, because Plaintiffs have not identified any statutory provision that prohibits the Secretary's invocation of her authority to address the anticipated widespread impact of the two-midnight rule on IPPS expenditures, any perceived redundant statutory provisions and Subsection (d)(5)(I)(i) must be given effect. *See Connecticut Nat'l Bank*, 503 U.S. at 253 (noting that "so long as there is no 'positive repugnancy' between two laws, a court must give effect to both"). Thus, notwithstanding any potential redundancies (as opposed to repugnancies) that Plaintiffs identify, the Court should deem reasonable and permissible the Secretary's determination that Subsection (d)(5)(I)(i) authorizes her to adjust the IPPS rates to address the two-midnight rule's impact on IPPS expenditures. *See*, *e.g.*, *Adirondack*, 891 F. Supp. 2d at 48 ("Since § (d)(3)(A)(vi) and § 7 of the TMA are silent on the issue of adjustment to the hospital-specific rate, the Secretary's determination that she has the authority to adjust th[at] rate under § (d)(5)(I)(i) is reasonable and permissible."); *Amgen, Inc. v. Smith*, 357 F.3d 103, 106 (D.C. Cir. 2004) (rejecting plaintiff's assertion that more specific provisions of Medicare statute establishing particular calculations of payment amounts should be read to limit the Secretary's broad authority to make "other adjustments as determined to be necessary" to Outpatient Prospective Payment System rates).

4. The Secretary's Interpretation Is not in Conflict with Prior Interpretations of Subsection (d)(5)(I)(i).

Plaintiffs finally suggest that the Secretary's challenged interpretation of Subsection (d)(5)(I)(i) is unreasonable and thus not entitled to deference because it departs from her prior interpretations construing that authority as more limited. *See* Shands MSJ at 20 (alleging that

"the Secretary had previously interpreted that clause to preclude the type of system wide payment reduction the Secretary adopted here"); St. Helena MSJ at 16 (alleging that "[i]n other instances, the Secretary has used or considered using the exceptions and adjustment authority to address unique circumstances that arise for particular types of hospitals or hospital stays"). Less deference is generally owed to the "Secretary's interpretation that is inconsistent with earlier and later pronouncements, because 'the [Secretary's] expertise . . . to which we normally defer becomes dubious when the expert cannot make up its own mind.'" *Centra Health, Inc. v. Shalala*, 102 F. Supp. 2d 654, 659 (W.D. Va. 2000) (quoting *New York City Health & Hosps. Corp. v. Perales*, 954 F.2d 854, 861-62 (2d Cir. 1992)). This case does not present that type of situation. *See, e.g., Centra Health*, 102 F. Supp. 2d at 659 (concluding that the "Secretary's prior exclusion of CVTC data [from the wage index calculation] – as recently as 1996 – undermine[d] her argument that it [wa]s infeasible to exclude it for 1997").

Because the Secretary invokes her authority under Subsection (d)(5)(I)(i) to make adjustments "as she deems appropriate," her past invocations, as here, have arisen in different and unique circumstances. *See, e.g.*, St. Helena MSJ at 16 ("For example, in 2007, the Secretary adjusted payments for surgical procedures to replace certain medical devices where the device is provided at a reduced or no cost to the hospital."); *id.* at 16-17 ("In 2004, the Secretary addressed 'unique and temporary circumstances' that would have placed certain small community hospitals in sparsely populated states at a 'temporary, but serious, disadvantage.'"); *Adirondack*, 891 F. Supp. 2d at 41 (Because she "viewed payments to sole community and rural hospitals as artificially inflated by the new MS-DRG," the Secretary "determined in 2011 that she had authority under a 'special exceptions and adjustments' provision to adjust the hospital-specific rate."); A.R. 1362 ("finalizing a reduction to the standardized amount, the hospital-specific rates,

and the Puerto Rico-specific standardized amount of -0.2 percent to offset the additional $220 million in expenditures"). To attempt to generalize the reach of the broad authority conferred in Subsection (d)(5)(I)(i) from these prior examples, as Plaintiffs have here, is futile. *See* St. Helena MSJ at 16-18; Shands MSJ at 20-22. Indeed earlier this year, the D.C. Circuit referred to that provision as "the once-obscure grant of authority." *Adirondack*, 740 F.3d at 696.

Plaintiffs also urge the Court to conclude from past occasions when the Secretary declined to use her authority under Subsection (d)(5)(I)(i) that she determined that she lacked the authority to do so. *See* Shands MSJ at 21. None of the examples cited in Plaintiffs' briefs, however, bear out that conclusion. *Compare* Shands MSJ at 21 ("In 1994, for example, the Secretary declined to make a payment policy change for patients transferred from one hospital to another because the proposed change would have increased aggregate payments. 59 Fed. Reg. at 45,366.") *with id.* (merely expressing that "we do not feel it would be appropriate to change the transfer payment methodology absent an offsetting savings provision"); *compare* Shands MSJ at 21 ("[W]hen the agency sought to implement changes that would refine the diagnosis-related groups ('DRGs') to better adjust for severity of illness, the Secretary declined to do so unless Congress granted specific legislative authority to offset any aggregate payment increase. *See* 65 Fed. Reg. at 47,103") *with id.* (expressing desire to wait for "specific legislative authority to offset, through adjustments to the standardized amounts, any *significant anticipated increase* in payments attributable to changes in coding practices by *significant changes* to the DRG classification system" (emphasis added)). Because these examples are *sui generis*, they do not speak to whether the Secretary's determination here to invoke her authority under Subsection (d)(5)(I)(i) is inconsistent with her past practices. *Cf. Plyler v. Doe*, 457 U.S. 202, 247 n.8 (1982) (noting with respect to a string of "quotations drawn from cases addressing such diverse

matters as the right of individuals under the Due Process Clause to learn a foreign language, the First Amendment prohibition against state-mandated religious exercises in the public schools, and state impingements upon the free exercise of religion," that "not every isolated utterance of this Court retains force when wrested from the context in which it was made" (citations omitted)). Plaintiffs moreover have proffered no express prior interpretation by the Secretary of the reach of Subsection (d)(5)(I)(i). Therefore, their contention that, in this case, the Secretary has *sub silentio* departed from a past policy and thus is not entitled to deference fails. For these reasons, the Secretary's interpretation of Subsection (d)(5)(I)(i) as authorizing the challenged reduction to the IPPS rates that she determined was appropriate under the circumstances presented here is reasonable and should be upheld under *Chevron* step two.

II. THE SECRETARY'S .2 PERCENT REDUCTION WITHSTANDS PLAINTIFFS' PROCEDURAL AND SUBSTANTIVE CHALLENGES UNDER THE MEDICARE STATUTE AND APA.

All Plaintiffs contend that the Secretary's .2 percent reduction is arbitrary and capricious under the Medicare statute and APA and thus, on that alternative basis, should be invalidated. *See* Shands MSJ at 24-30; St. Helena MSJ at 19-30; Bakersfield MSJ at 9-30; AHA MSJ at 13-24; Athens Regional MSJ at 12-27. Judicial review of the challenged rulemaking is provided for under 42 U.S.C. § 1395oo(f)(1), which incorporates the APA's deferential arbitrary-and-capricious standard of review. *See id.* (providing for judicial review "in the District Court for the District of Columbia and . . . pursuant to the applicable provisions under chapter 7 of Title 5"). It is well established that the scope of that review "is narrow and [the C]ourt 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). The Court instead "presumes the validity of agency action." *National Ass'n of Clean Air Agencies v. EPA*, 489 F.3d 1221, 1228 (D.C. Cir. 2007). It is a "heavy burden indeed" – not met here by Plaintiffs – to demonstrate that agency action should be

declared arbitrary and capricious. *Village of Bensenville v. FAA*, 457 F.3d 52, 70 (D.C. Cir. 2006).

A. The Secretary's Promulgation of the .2 Percent Reduction Did Not Violate the APA's Notice Requirement.

Plaintiffs contend that the Secretary's .2 percent reduction is procedurally invalid because it was inadequately noticed in her proposed rule in violation of the APA. The APA requires an agency to describe "either the terms or the substance of a proposed rule or a description of the subjects and issue involved," (5 U.S.C. § 553(b)(3)), and to "give interested persons an opportunity to participate in the rule making through the submission of written data, views, or arguments," (5 U.S.C. § 553(c)). "The purpose of the comment period is to allow interested members of the public to communicate information, concerns, and criticisms to the agency during the rule-making process." *Connecticut Light & Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 530 (D.C. Cir. 1982). "If the notice of proposed rule-making fails to provide an accurate picture of the reasoning that has led the agency to the proposed rule, interested parties will not be able to comment meaningfully upon the agency's proposals." *Id.* Consequently, "the agency may operate with a one-sided or mistaken picture of the issues at stake in a rule-making." *Id.* "In order to allow for useful criticism, it is especially important for the agency to identify and make available technical studies and data that it has employed in reaching the decisions to propose particular rules." *Id.* Thus, an agency "commits serious procedural error when it fails to reveal portions of the technical basis for a proposed rule in time to allow for meaningful commentary." *Id.* at 530-31. Here, it is undisputed that, in compliance with the APA, the Secretary's proposed rule contained the terms and substance of the .2 percent reduction. Plaintiffs instead challenge the adequacy of notice as to the technical basis for that adjustment. In that respect too, the Secretary's notice was sufficient under the APA.

The D.C. Circuit's decision in *Connecticut Light & Power v. Nuclear Regulatory Comm'n* makes that plain. In the wake of a fire at the Browns Ferry Nuclear Power Plant, the Commission issued a report ("Browns Ferry Report") recommending improved fire safety at nuclear power plants and establishing guidelines for evaluating fire safety at such plants. For several years thereafter, the Commission evaluated fire safety at nuclear power plants on a plant-by-plant basis. The Commission eventually decided to establish through notice-and-comment rulemaking certain fire-safety requirements across all such plants. Connecticut Light & Power challenged the rulemaking on notice grounds. The public notice proposing the challenged requirements "made little reference to technical material." *Id.* at 531. However, the Browns Ferry Report that the Commission had issued earlier was widely circulated. The Commission also "relied on the utilities' common knowledge of problems that had recurred in plant after plant and on reports that had been publicly filed." *Id.* at 531-32. Finally, "the Commission did rely on some technical studies that were not mentioned in the notice of proposed rule-making." *Id.* at 532. Although acknowledging that "it would have been better practice for the NRC to have identified these technical materials specifically in the notice of proposed rule-making," the D.C. Circuit nonetheless upheld the challenged rule. *Id.* Given that the rulemaking had occurred against a background of the Commission's extensive exploration of safety proposals in a public forum, that court concluded that the "technical background of the rules was sufficiently identified to allow for meaningful comment during the rule-making process." *Id.*

Likewise, here, the Secretary's .2 percent reduction was promulgated in a context where the technical background, including the inpatient and outpatient data sources used and the underlying assumptions, was adequately identified and made accessible to the public to permit meaningful comment during the rulemaking process. For years, CMS has studied hospitals' use

of observation and short inpatient stays and the concerns raised by hospitals about determining those hospitals services appropriate for inpatient hospitalization. "When a Medicare beneficiary presents to a hospital in need of medical or surgical care, the physician or other qualified practitioner must decide whether to admit the beneficiary for inpatient care or treat him or her as an outpatient." A.R. 95. "In some cases, when the physician admits the beneficiary and the hospital provides inpatient care," Medicare Administrative Contractors "determine[] that inpatient care was not reasonable and necessary . . . and den[y] the hospital inpatient claim for payment." *Id.* The denied hospital can appeal the denial or rebill certain of the provided services under Part B of Medicare.[9] CMS "heard from various stakeholders that hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review, by electing to treat beneficiaries as outpatients receiving observation services, often for longer periods of time, rather than admit them." A.R. 96. Because of such concerns, the agency in July 2012, solicited public comments on potential policy changes, including time-based criteria for inpatient admission, that could be implemented "to improve clarity and consensus among providers, Medicare, and other stakeholders regarding the relationship between admission decisions and appropriate Medicare payment, such as when a Medicare beneficiary is appropriately admitted to the hospital as an inpatient and the cost to hospitals associated with making this decision." A.R. 95. The varied public responses were published in the *Federal Register* in November 2012. A.R. 394-95. That same year, Medicare contractors also "found that inpatient hospital admissions for 1-day stays or less had a Part A improper payment rate of 36.1 percent." A.R. 728. That rate decreased significantly for 2-day

[9] The inpatient vs outpatient determination also has significant impact on Medicare beneficiaries. "[H]ospital inpatients have significantly different Medicare benefits and liabilities than hospital outpatients, notably coverage of self-administered drugs and, for patients who are admitted to the hospital for 3 or more consecutive calendar days, coverage of postacute SNF [skilled-nursing facility] care." A.R. 95.

or 3-day stays. *See id.* Based on these data, the Secretary concluded that the "appropriate determination of a beneficiary's patient status [wa]s a systemic and widespread issue." *Id.*

The following year, in the rulemaking challenged here, the Secretary proposed "inpatient hospital admission guidance under which a physician or other practitioner should order admission if he or she expects that the beneficiary's length of stay will exceed a 2-midnight threshold [i.e., the 2-midnight rule] or if the beneficiary requires a procedure specified as inpatient only under 42 CFR 419.22." A.R. 727. That guidance clarified that

> in addition to services designated by CMS as inpatient only, surgical procedures, di[a]gnostic tests, and other treatments would be generally appropriate for inpatient hospital payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient to the hospital based upon that expectation. Conversely, when a patient enters a hospital for a surgical procedure not specified by Medicare as inpatient only . . . a diagnostic test, or any other treatment, and the physician expects to keep the patient in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A.[10]

A.R. 727.

The Secretary's actuaries estimated that the proposed policy that "medical review of inpatient admissions w[ould] include a presumption that hospital inpatient admissions are reasonable and necessary for beneficiaries who require more than 1 Medicare utilization day (defined by encounters crossing 2 'midnights') in the hospital receiving medically necessary services . . . would increase IPPS expenditures by approximately $220 million." A.R. 728. That additional expenditure was explained as resulting "from an expected net increase in hospital inpatient encounters due to some encounters spanning more than 2 midnights moving to the IPPS from the OPPS, and some encounters of less than 2 midnights moving from the IPPS to OPPS."

[10] CMS noted in the proposed rule that "[t]here are certain types of cases for which a hospital inpatient admission is rarely appropriate," e.g., a minor surgical procedure. A.R. 727.

Id. Specifically, and as explained in the proposed rule, the actuaries, based on an examination of publicly available "FY 2009 through FY 2011 Medicare claims data for extended hospital outpatient encounters and shorter stay hospital inpatient encounters," estimated that "approximately 400,000 encounters would shift from outpatient to inpatient and approximately 360,000 encounters would shift from inpatient to outpatient, causing a net shift of 40,000 encounters," representing "an increase of approximately 1.2 percent in the number of shorter stay hospital inpatient encounters paid under the IPPS." *Id.* The additional expenditure is "partially offset by reduced expenditures from the shift of shorter stay hospital inpatient encounters to hospital outpatient encounters." *Id*. The actuaries estimated that "on average the per encounter payments for these hospital outpatient encounters would be approximately 30 percent of the per encounter payments for the hospital inpatient encounters." *Id*.

Moreover, during the public notice-and-comment period for the proposed rule, the Office of Inspector General published a report on hospitals' use of observation stays and short inpatient stays in 2012, which it noted the then-proposed two-midnight policy sought to address. The results of the report indicated that, under that proposed policy, "the number of short inpatients stays would be significantly reduced; however, the number of observation and long outpatient stays may not be reduced if outpatient nights are not counted towards the 2-night presumption." A.R. 1974. The results further indicated that "some hospitals would likely follow the provisions and continue to bill these as outpatient stays; other hospitals – given strong financial incentives and few barriers – would likely not follow the provisions and would admit beneficiaries as inpatients as soon as possible to meet the 2-night presumption." *Id.*

Based on the foregoing analyses, her public study of the systemic nature of the issue of hospital inpatient determinations, and public comments related thereto, the Secretary determined to use her exceptions and adjustment authority to offset the estimated $220 million in additional IPPS expenditures associated with her two-midnight policy. A.R. 1362; *see also Wisconsin Power & Light Co. v. Federal Energy Regulatory Comm'n*, 363 F.3d 453, 463 (D.C. Cir. 2004) (noting that the Secretary could properly "take official notice of matters of common knowledge, of evidence available to her from other proceedings, and of matters known to the agency through its cumulative experience and consequent expertise"). The Secretary's public study of the systemic issue with hospitals' inpatient determinations together with the proposed rule's explanation that her actuaries examined "FY 2009 through FY 2011 Medicare claims data for extended hospital outpatient encounters and shorter stay hospital inpatient encounters and estimated that approximately 400,000 encounters would shift from outpatient to inpatient and approximately 360,00 encounters would shift from inpatient to outpatient, causing a net shift of 40,000 encounters" supplied sufficient notice of the technical basis for the Secretary's proposed .2 percent reduction to permit public comment thereon. A.R. 728.

Evidently, Plaintiffs would prefer that this estimate were an accounting exercise, where an examination of historical data alone yields a single inescapable conclusion. But such an exercise is not possible in this situation, where it was difficult to predict the behavioral consequences of hospitals confronted with new or clarified rules. If it were possible for the Secretary to have examined only historical data, the Secretary could have relied on CMS' accountants to reach a conclusion. But because there are multiple variables and consequently multiple potential consequences, the Secretary reasonably relied on her actuaries' analysis.[11]

[11] "Actuarial science is an applied science based on concepts and observations distilled from the experience of practitioners and from other sciences." Mark Allaben et al., *Principles Underlying Actuarial Science* at 5, *Actuarial*

That analysis was a reasonable estimate of potential future experience that encompassed an examination of historical data *and* the exercise of actuarial judgment relating to potential responses to the proposed policy. The Secretary provided all of the underlying inpatient and outpatient utilization data to the public in conjunction with the rulemaking, explicitly stated her actuaries' estimate regarding the net number of additional cases for FY 2015 that would be inpatient if the policy were adopted, and clearly articulated the underlying actuarial assumptions regarding the shifts between the inpatient and outpatient hospital settings. The public was capable of using those same publicly available historical data sources to comment meaningfully on the estimate and assumptions. As noted in the Final Rule, "[i]n addition to the opportunity to comment on the estimate, any component of the estimate, or the methodology, commenters had an opportunity to provide alternative estimates for us to consider." A.R. 1361.

Indeed, commenters using this supplied information and the publicly available inpatient and outpatient utilization data performed their own analysis of the proposed rule's impact on hospitalizations. One such commenter "performed an analysis to determine whether [it] could duplicate CMS's conclusions on the number of encounters that would move from inpatient status to outpatient status and *vice versa* should the two-midnight medical review standard be adopted." A.R. 4653-54. In contrast to the Secretary's analysis, that commenter's analysis "show[ed] that the anticipated decrease in inpatient stays lasting two days or less (that is, cases moving from IPPS to OPPS) is far greater in volume than the anticipated cases of outpatient encounters that would be paid under IPPS."[12] A.R. 4654. Another commenter, using tables "furnished with the

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Practice Forum (July 2008), avail. at https://www.soa.org/search.aspx?searchterm=principles%20underlying%20actuarial%20science. "Actuarial practice, in turn, is concerned with the assessment of the economic consequences associated with phenomena that are subject to uncertainty." *Id.*

[12] In contrast to this commenter, other commenters opined that, under the two-midnight rule (and its presumption of appropriateness for inpatient treatment of hospitalizations that crossed two midnights), hospitals would have the

rule" and cases assigned to particular MS-DRGs, determined that there was "a potential of 530,000 cases that could change to outpatient status from inpatient." A.R. 5010. Other commenters could have performed similar analyses. Yet, the majority merely expressed general disagreement with the actuaries' estimates and did not offer any counter-analysis specifying what the "correct" estimate should be.[13] *See, e.g.*, A.R. 3714, A.R. 3743, A.R. 3803, A.R. 3981, A.R. 4053, A.R. 4090, A.R. 4137, A.R. 4265, A.R. 4365, A.R. 4487, A.R. 4496, A.R. 4527, A.R. 4617, A.R. 4713, A.R. 4997, A.R. 5312, A.R. 5472. Taken in context, therefore, the technical background for the .2 percent reduction (including the underlying publicly available inpatient and outpatient hospital utilization data) was adequately identified to allow meaningful comment during the rulemaking process, and the .2 percent reduction accordingly withstands Plaintiffs' claim to the contrary.[14] *See Connecticut Light & Power*, 673 F.2d at 532.

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incentive to hold patients specifically for the purpose of meeting the 2-midnight presumption – a response that would be reflected by significant movement from OPPS to IPPS. *See, e.g.*, A.R. 3846; A.R. 4033; A.R. 5178.

[13] The Supreme Court has "emphatically instructed," (*Thompson v. Clark*, 741 F.2d 401, 408 (D.C. Cir. 1984), that

> Administrative proceedings should not be a game or a forum to engage in unjustified obstructionism by making cryptic and obscure reference to matters that "ought to be" considered and then, after failing to do more, to bring the matter to the agency's attention, seeking to have that agency determination vacated on the ground that the agency failed to consider matters "forcefully presented."

Vermont Yankee Nuclear Power Corp. v. NRCD, 435 U.S. 519, 553-54 (1978).

[14] Athens Regional Plaintiffs in their motion for summary judgment includes an extensive data analysis in support of its claim that the Secretary's analysis was "counter to the Secretary's own data." *See* Athens Regional MSJ at 17-21. For purposes here, that analysis is irrelevant because it was not before the Secretary when she promulgated the .2 percent reduction. Under the APA, the "focal point" for this Court's review "should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973); *see also Walter O. Boswell Mem'l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) ("If a court is to review an agency's action fairly, it should have before it neither more nor less information than did the agency when it made its decision.").

Athens Regional Plaintiffs' data analysis, in any event, is flawed in several respects and in no sense undercuts the reasonableness of the Secretary's analysis. First, Plaintiffs claim that the baseline figure to be used as the "cost per case of inpatient stays under two days" is $6,552, not the $7,250 calculated by CMS. Athens Regional MSJ at 19. The $6,552 figure, however, represents the 1-Day figure in the Per Discharge column of Table 5.9; but for actuarial purposes, CMS calculates 1 Day as zero days. Thus, the proper figure for the baseline should have been the 2-Day figure or $6,623. Plaintiffs' second error is their failure to factor in case-mix in their impact analysis. That factor accounts for payment increases resulting from changes in the mix of cases. Over a given period of time, health conditions become more complex and thus the case mix (and attendant expenses) changes. Plaintiffs' failure

That result alternatively follows under the rule of prejudicial error. In making the determination whether to set aside agency action as arbitrary or capricious, the APA requires the Court to take "due account . . . of the rule of prejudicial error." 5 U.S.C. § 706(2)(F); *see also Owner-Operator Indep. Drivers Ass'n, Inc. v. Federal Motor Carrier Safety Admin.*, 494 F.3d 188, 202 (D.C. Cir. 2007) (noting that "before we may vacate an agency action [for procedural error] during the notice-and-comment period, we must take 'due account . . . of the rule of prejudicial error.'"). To show prejudicial error, a plaintiff "'must indicate with reasonable specificity,' the aspect of the rule to which it objects and 'how it might have responded if given the opportunity.'" *Miami-Dade County v. EPA*, 529 F.3d 1049, 1061 (11th Cir. 2008) (quoting *Owner-Operator*, 494 F.3d at 202). Plaintiffs must "[a]t base . . . demonstrate that 'on remand, [they] can mount a credible challenge . . . and [were] thus prejudiced by the absence of an opportunity to do so before the agency." *Miami-Dade County*, 529 F.3d at 1061 (quoting *Owner-Operator*, 494 F.3d at 202).

As evident from the comments submitted, the Secretary's alleged failure to disclose additional details about her actuaries' estimates did not preclude the submission of comments – including by Plaintiffs here – on her actuaries' estimates. *See, e.g.*, A.R. 4653-54, A.R. 3743. Moreover, the Final Rule clearly demonstrates that the Secretary considered such criticisms, (A.R. 1361-62), but proceeded with implementation of her reduction as proposed. "It follows that when a party's claims were considered," as here, "even if notice was inadequate, the challenging party may not have been prejudiced." *United States v. Johnson*, 632 F.3d 912, 931 (5th Cir. 2011); *see also id.* at 932 (noting that, under the harmless error analysis, "that the final

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to account for this fluctuation in the case-mix also contributed to the differences between Plaintiffs' calculations and those of the Secretary. The third error in Plaintiffs' analysis is their oversight of changes in the future number of cases handled by hospitals and the consequential increase in the overall discharge numbers. Such errors render the Athens Regional analysis deficient.

rulemaking process with full APA comment did not change the Attorney General's decision cannot be ignored"). Thus, the Secretary's alleged failure to provide sufficient detail about her actuaries' data analysis in the proposed rule should not occasion invalidation of the .2 percent reduction.

B. The Secretary Adequately Responded to Comments.

Plaintiffs complain that the Secretary failed to respond to comments questioning the data analysis underlying her .2 percent reduction. *See, e.g.,* Athens Regional MSJ at 21-24 (alleging that "the Secretary ignored significant criticisms of her methodology during the rulemaking process"); AHA MSJ at 19-20 (alleging that "[t]he agency failed to respond to major criticisms raised during the rulemaking process"). "An agency need not address every comment, but it must respond in a reasoned manner," depending on "the nature of the comments received" and address those properly submitted comments "that raise significant problems." *Reytblatt v. United States Nuclear Regulatory Comm'n*, 105 F.3d 715, 722 (D.C. Cir. 1997). In the particular context here (i.e., Medicare's annual IPPS rulemaking), the Secretary has a limited amount of time statutorily to give "such consideration" to submitted comments. 42 U.S.C. § 1395ww(e)(5)(B). "Nevertheless, '"[t]he failure to respond to comments is significant only insofar as it demonstrates that the agency's decision was not based on a consideration of the relevant factors."'" *City of Waukesha v. EPA*, 320 F.3d 228, 257 (D.C. Cir. 2003) (quoting *Texas Mun. Power Agency v. EPA*, 89 F.3d 858, 876 (D.C. Cir. 1996)); *see also Thompson*, 741 F.2d at 409 (same). The record here does not support that conclusion.

As evident from the Final Rule, the Secretary did address significant comments critical of her proposal. After acknowledging that "[c]ommenters generally did not support the proposed 0.2 percent payment adjustment," and enumerating the specific criticisms leveled, the Secretary indicated that she "disagree[d] with commenters who indicated that [her] actuaries' estimated

increase in IPPS expenditures of $220 million was unsupported and insufficiently explained to allow for meaningful comment." A.R. 1361. The Secretary then reiterated the detail she had provided in the proposed rule, which in her estimation afforded "the opportunity to comment on the estimate, any component of the estimate, or the methodology" as well as provide "an opportunity to provide alternative estimates for [her] to consider." *Id*.

In response to comments requesting additional detail about her actuaries' analysis, the Secretary explained

> In determining the estimate of the number of encounters that would shift from outpatient to inpatient, our actuaries examined outpatient claims for observation or a major procedure. Claims not containing observation or a major procedure were excluded. The number of claims spanning 2 or more midnights based on the dates of service that were expected to become inpatient was approximately 400,000. This estimate did not include any assumption about outpatient encounters shorter than 2 midnights potentially becoming inpatient encounters.
>
> In determining the estimate of the number of encounters that would shift from inpatient to outpatient, our actuaries examined inpatient claims containing a surgical MS-DRG. Claims containing medical MS-DRGs were excluded. The number of claims spanning less than 2 midnights based on the length of stay that were expected to become outpatient, after excluding encounters that resulted in death or transfers, was approximately 360,000.

Id. The Secretary further explained that none of these estimates should "be construed as absolute statements about every individual encounter. For example, we fully expect that not every single surgical MS-DRG encounter spanning less than 2 midnights will shift to outpatient and that not every single outpatient observation stay or major surgical encounter spanning more than 2 midnights will shift to inpatient."[15] *Id.* Nevertheless, "after consideration of the comments [] received," the Secretary finalized the .2 percent reduction because her "actuaries *continue to*

[15] Despite that warning, Bakersfield Plaintiffs in their motion for summary judgment erroneously treat the Secretary's estimates as absolute statements. *See, e.g.*, Bakersfield Plaintiffs MSJ at 23 (arguing the unremarkable proposition that "[h]ospitals will not bill all stays spanning two midnights as inpatient").

estimate there will be approximately $220 million in additional expenditures resulting from our 2-midnight presumption medical review policies." A.R. 1362 (emphasis added); *see also* A.R. 2046-48 (Memorandum summarizing the Office of the Actuary's financial estimate for clarifying inpatient vs. outpatient hospital services when all stays which span two midnights will be presumed to be inpatient). In effect, Plaintiffs take issue with the Secretary's decision to implement her proposal over their objections. That, however, is not sufficient basis to invalidate the challenged .2 percent reduction. *See Sierra Club v. Dombeck*, 161 F. Supp. 2d 1052, 1070 (D. Ariz. 2001) ("Mere disagreement with an agency's policies, methodologies, and conclusions does not render the decision arbitrary and capricious.").

C. The Secretary Provided a Reasoned Basis for Her .2 Percent Reduction.

Plaintiffs also level substantive challenges to the .2 percent reduction because the Secretary's actuaries allegedly did not have a reasoned basis for their analysis and relied on indefensible assumptions.[16] *See, e.g.*, AHA MSJ at 20-24; Shands MSJ at 27-30; St. Helena MSJ at 25-30. Plaintiffs fundamentally disagree that the two-midnight policy will result in a net increase in inpatient hospitalizations. *See* St. Helena MSJ at 26 (alleging that "the entire premise for the Reduction is counterintuitive and arguably illogical from the outset"); *see also, e.g.*, AHA

[16] Bakersfield Plaintiffs fault the actuaries' attempt to estimate hospital behavior under the two-midnight policy because the policy itself is "so confused and internally inconsistent that the actuaries could not have possibly formed a basis for making a reliable prediction." Bakersfield MSJ at 13; *see also id.* at 13-22. It is obvious that what Plaintiffs wanted was a policy that led only to an increase in inpatient admissions with no corresponding benchmark as to when very short-stay inpatient admissions would likely be inappropriate. But any challenge to the two-midnight policy itself is not properly before this Court because such a claim was not pleaded, and Plaintiffs cannot amend their complaint through their motions for summary judgment. *See Hajjar-Nejad v. George Washington University*, 2014 WL 1280228, at *38 (D.D.C. Mar. 31, 2014); *Sharp v. Rosa Mexicano, D.C., LLC*, 496 F. Supp. 2d 93, 97 n. 3 (D.D.C.2007) ("[P]laintiff may not, through summary judgment briefs, raise the new claims . . . because plaintiff did not raise them in his complaint, and did not file an amended complaint."); *see also* Bakersfield Compl. at 29-30 (requesting as relief an order "[d]eclaring invalid and setting aside the Final Rule's 0.2 percent payment decrease to the operating and capital IPPS rates, and requiring the Secretary to recalculate the appropriate increase in the standardized amount and the capital standard federal payment rates for FY 2014 in order to offset the aggregate decrease in IPPS payments resulting from adoption of the two-midnight rule"). To the extent Bakersfield Plaintiffs complain that, in estimating the financial impact of the two-midnight policy, the actuaries considered that policy, Bakersfield Plaintiffs' complaint makes little sense.

MSJ at 20-24; Shands MSJ at 27-30. At a more granular level, Plaintiffs question the actuaries' consideration of surgical MS-DRGs (to the exclusion of medical MS-DRGs) in estimating the shift from inpatient to outpatient, (*see, e.g.*, AHA MSJ at 21; Bakersfield MSJ at 29), and consideration of observation cases (to the exclusion of other MS-DRGs) in estimating the shift from outpatient to inpatient, (*see, e.g.*, Bakersfield MSJ at 29). *But see Universal Health Servs. of McAllen, Inc. v. Sullivan*, 770 F. Supp. 704, 718 (D.D.C. 1991) (noting that "[a]s with any line-drawing exercise, certain entities will be outside of the class or category created by the lawmakers" but "[s]uch inequalities do not necessarily make the Secretary's decision *arbitrary and capricious*"). Rather, if "an agency's decision to which deference is afforded may be supported on *any* rational basis, [the court] must uphold it." *Friends of Boundary Waters Wilderness v. Bosworth*, 437 F.3d 815, 822 (8th Cir. 2006) (emphasis added). That standard is "particularly deferential" when, as here, an agency takes action based on predictive judgments about future events or developments. *Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1105 (D.C. Cir. 2009) ("The 'arbitrary and capricious' standard is particularly deferential in matters implicating predictive judgments . . . . [W]hen an agency's decision is primarily predictive, our role is limited; we require only that the agency acknowledge factual uncertainties and identify the considerations it found persuasive."); *see also Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 565 (D.C. Cir. 2002) ("We may reject an agency's choice of a scientific model 'only when the model bears no rational relationship to the characteristics of the data to which it is applied.'"); *BNSF Ry. Co. v. Surface Transp. Bd.*, 526 F.3d 770, 781 (D.C. Cir. 2008) (rejecting complaints by shippers and railroads about a rate-setting board's methods for forecasting a hypothetical railroad's future operating expenses and "declin[ing] to enter this hyper-technical fray"); *In re Core Commc'ns, Inc.*, 455 F.3d 267, 282 (D.C. Cir. 2006) (rejecting challenges to the FCC's

predictions about declining dialup Internet usage and noting that "[u]nder the arbitrary and capricious standard of review, an agency's predictive judgments about areas that are within the agency's field of discretion and expertise are entitled to particularly deferential review, as long as they are reasonable" (alteration in original) (internal quotation marks omitted)); *St. John's United Church of Christ v. FAA*, 550 F.3d 1168, 1172 (D.C. Cir. 2008) (noting that the FAA is entitled to deference when it acts based on forecasts of capacity and demand at an airport); *North Carolina v. FERC*, 112 F.3d 1175, 1190 (D.C. Cir. 1997) ("Projections of any kind . . . are necessarily speculative, inexact, and riddled with uncertainty."); *West Virginia v. EPA*, 362 F.3d 861, 871 (D.C. Cir. 2004) ("[W]e will give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise. Furthermore, we must defer to the agency's decision on how to balance the cost and complexity of a more elaborate model against the oversimplification of a simpler model. We will reverse only if the model is so oversimplified that the agency's conclusions from it are unreasonable." (citations omitted) (internal quotation marks omitted)); *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994) (finding that "the tremendous complexity of the Medicare statute" "adds to the deference which is due to the Secretary's decision").

Because Plaintiffs assume that the two-midnight policy makes it "*more difficult* to claim a hospital stay on an inpatient basis," (Shands MSJ at 28), they predict – to the exclusion of all other possibilities – that the policy will result in a net increase in outpatient hospitalizations. The Secretary, however, reasonably could have concluded otherwise based on the information before her. *See, e.g.*, A.R. 1354 (noting that "the decision to admit *becomes easier* as the time approaches the second midnight" (emphasis added)); A.R. 395 (noting that "[s]ome in the hospital community have indicated that it may be helpful for the agency to establish more

specific criteria for patient status in terms of how many hours the beneficiary is in the hospital"); *id.* (noting that "[s]ome commenters representing the hospital community believed that patients who have been actively monitored for more than 24 to 48 hours as outpatients under observation and cannot be safely discharged are likely sufficiently complex cases that would benefit from being admitted as an inpatient"). Thus, for APA purposes, there was a reasoned basis for the Secretary's belief that the time-based criterion of the two-midnight rule would result in a net increase in inpatient hospitalizations. *See* A.R. 1354 ("While previous guidance provided a 24-hour benchmark to be used in making inpatient admission decisions, we now specify that the 24 hours relevant to inpatient admission decisions are those encapsulated by 2 midnights.").

Likewise, there was a reasoned basis for the Secretary's actuaries' consideration of surgical MS-DRGs in estimating the movement from inpatient to outpatient and long observation cases in estimating the movement from outpatient to inpatient. *See, e.g.*, A.R. 96 ("We have heard from various stakeholders that hospitals appear to be responding to the financial risk of admitting Medicare beneficiaries for inpatient stays that may later be denied upon contractor review, by electing to treat beneficiaries as outpatients receiving observations services, often for longer periods of time, rather than admit them."); A.R. 727 ("We have stated in our existing Medicare manual that when a beneficiary receives a minor surgical procedure or other treatment in the hospital that is expected to keep him or her in the hospital for only a few hours (less than 24), the services should be provided as outpatient services . . . ."); A.R. 1962 ("CMS and others also have raised concerns about short inpatient stays," and CMS has "found that a significant portion of payments for these stays were improper because the services should have been provided in the outpatient setting."); *id.* ("CMS expected these policy changes to reduce the number of observation stays lasting 2 nights or longer and to reduce the number of short

inpatient stays."); A.R. 1354 ("The potential increase in very short (less than 2 midnights) observations stays should be balanced by a significant decrease in long (2 midnights or more) observations stays."); *id.* ("[W]e expect that this revision should virtually eliminate the use of extended observation . . . ."). Plaintiffs' contrary views notwithstanding, the APA does not require more here. *See Episcopal Hosp.*, 994 F.2d at 884.

The D.C. Circuit's observations in *Episcopal Hosp. v. Shalala*, thus are apt as applied to the Secretary's .2 percent reduction:

> A review of the Secretary's official explanation of the final rules reveals that the Secretary responded to comments that were in fact submitted. She revealed her goals and reasoning. She gave [the Court] a record which "will enable us to see what major issues of policy were ventilated by the . . . proceedings and why the agency reacted to them as it did.' She did, in short, all that the APA required.

Id. at 884. Accordingly, the Court should uphold the Secretary's .2 percent reduction under the Medicare statute and APA.

III. THE SECRETARY ISSUED THE .2 PERCENT REDUCTION BY REGULATION.

Plaintiffs contend that the "by regulation" requirement of 42 U.S.C. § 1395hh(a)(2) and § 1395ww(d)(5)(I)(i) were violated "because [the Secretary] did not codify the cut in the Code of Federal Regulations [and] only discussed the 0.2 Percent Payment Cut in the preamble to the IPPS Final Rule." AHA MSJ at 25; *see also* 42 U.S.C. § 1395ww(d)(5)(I)(i) ("The Secretary shall provide *by regulation* for such other exceptions and adjustments to such payment amounts under this subsection as the Secretary deems appropriate." (emphasis added)). In support of that erroneous contention, Plaintiffs cobble together out-of-context statements from inapposite cases in an effort to establish publication in the *Code of Federal Regulations* as a condition precedent for promulgation "by regulation." *See* AHA MSJ at 25 (relying on *Utah Power & Light Co. v. Sec'y of Labor*, 897 F.2d 447, 450 (10th Cir. 1990); *Hawaii v. Office of Hawaiian Affairs*, 556

U.S. 163, 175 (2009); *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 68 Fed. Appx. 205, 206 (D.C. Cir. 2003); *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 569-70 (D.C. Cir. 2002)). Codification in the *Code of Federal Regulations*, however, is not dispositive here. Rather, the Court's determination turns on "three factors: (1) the [a]gency's own characterization of the action; (2) whether the action was published in the Federal Register or the Code of Federal Regulations;[17] and (3) whether the action has binding effects on private parties or on the agency." *Wilderness Soc. v. Norton*, 434 F.3d 584, 595 (D.C. Cir. 2006) (citing *Molycorp, Inc. v. EPA*, 197 F.3d 543, 545 (D.C.Cir.1999)). All three factors demonstrate that the .2 percent reduction is a regulation.

As to the first factor, the Secretary clearly regards the .2 percent reduction as a final and binding regulation. *See* A.R. 1362 ("[W]e are finalizing a reduction to the standardized amount, the hospital-specific rates, and the Puerto Rico-specific standardized amount of -0.2 percent to offset the additional $220 million in expenditures."); *see also* A.R. 4137 (acknowledgment by public commenter that "the agency proposes to offset this additional expenditure by permanently and prospectively reducing the operating PPS standardized amount."). The second factor also should be resolved in the Secretary's favor because the .2 percent reduction was published in the *Federal Register*. *See* A.R. 728-29 (78 Fed. Reg. 27,649-50 (May 10, 2013)); A.R. 1360-62 (78 Fed. Reg. 50,952-54 (Aug. 19, 2013)). Finally, the first two factors "serve to illuminate the third, for the ultimate focus of the inquiry is whether the agency action partakes of the fundamental characteristic of a regulation, i.e., that it has the force of law." *Molycorp*, 197 F.3d at 545; *see also CropLife America v. EPA*, 329 F.3d 876, 883 (D.C. Cir. 2003); *General Electric Co. v. EPA*, 290 F.3d 377, 382-83 (D.C. Cir. 2002). It is well established that "advance notice and public

[17] Plaintiffs apparently misinterpret dicta in *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 539 (D.C. Cir. 1986), as mandating publication in both the *Code of Federal Regulations* and the *Federal Register*. *See* St. Helena MSJ at 23.

participation are required for those actions that carry the force of law." *Batterton v. Marshall*, 648 F.2d 694, 701 (D.C. Cir. 1980); *GCI Health Care Centers, Inc. v. Thompson*, 209 F. Supp. 2d 63, 68 (D.D.C. 2002) (distinguishing interpretative rule as "not subject to the formal rulemaking process"). Plaintiffs do not – and indeed cannot – dispute that the .2 percent reduction was subject to public notice and comment. *See* A.R. 728-29 (proposed .2 percent reduction); A.R. 1360-62 (final .2 percent reduction); A.R. 3642-5894 (Public comments received in response to FY 2014 IPPS/LTCH PPS Proposed Rule, CMS-1599-P). Therefore, notwithstanding that it was not published in the *Code of Federal Regulations*, that adjustment was issued by regulation as required by the statute.

CONCLUSION

For the foregoing reasons, the Secretary respectfully requests that the Court grant her cross-motion, deny Plaintiffs' motions, and enter judgment in her favor.

Dated: October 15, 2014

Respectfully submitted,

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SHANDS JACKSONVILLE MEDICAL CENTER, INC., *et al.*	)	
Plaintiffs,	)	
v.	)	**Case No. CIV-14-263-EGS**
SYLVIA M. BURWELL,	)	
Defendant.	)	

PROPOSED ORDER

Upon consideration of the Secretary's Motion for Summary Judgment and Motion to Dismiss, the oppositions thereto, and the complete record in the case, it is hereby

ORDERED that the Secretary's motions are GRANTED. Judgment is entered in favor of Secretary Burwell.

SO ORDERED.

Date: _____

_____
United States District Court Judge