

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

SHANDS JACKSONVILLE)
MEDICAL CENTER, INC., et al.)
)
Plaintiffs,)
)
v.)
)
SYLVIA M. BURWELL,)
)
Defendant.)
_____)

Case No. CIV-14-263-EGS

**REPLY IN SUPPORT OF SECRETARY BURWELL’S CROSS-MOTION FOR
SUMMARY JUDGMENT AND MOTION TO DISMISS**

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INTRODUCTION

As the Secretary demonstrated in her opening brief, the challenged .2 percent reduction to the current Fiscal Year's Inpatient Prospective Payment System ("IPPS") rates stemmed from her decision to address a longstanding issue – that Plaintiffs acknowledge – related to correct identification of which hospital services are appropriate for inpatient hospitalization and thus payment under the IPPS. Because of confusion related thereto, many Medicare providers apparently 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 upon further review. In an effort to clarify existing guidance on the inpatient admission decision, the Centers for Medicare & Medicaid Services ("CMS") last year adopted the two-midnight rule. "While previous guidance provided a 24-hour benchmark to be used in making inpatient admission decisions," CMS has now specified "that the 24 hours relevant to inpatient admission decisions are those encapsulated by 2 midnights." A.R. 1354. An expected outcome of providing that additional clarification was elimination of the disturbing trend that had been observed under the prior policy. Hospitals would not be incented to treat as outpatients (sometimes in long observation stays), Medicare beneficiaries whose care was expected to cross two midnights.

CMS actuaries predicted that, under the two-midnight rule, there would be a net increase in inpatient hospitalizations, and calculated the cost of the new rule as \$220 million. The Secretary determined to spread that cost across hospitals participating in the IPPS by applying a .2 percent reduction to all IPPS rates pursuant to her broad statutory authority under Subsection (d)(5)(I)(i) to make adjustments and exceptions to the IPPS rates as she deems appropriate. Notwithstanding the reasonableness of that decision and the underlying assumptions about provider behavior under the clearer guidance on the inpatient admission decision, Plaintiff

hospital providers characterize both as arbitrary and capricious and unlawful under the Medicare statute and Administrative Procedure Act (“APA”). Yet, Plaintiffs have fallen short of satisfying the legal standard to overturn the challenged .2 percent reduction. Instead, their Oppositions continue to reflect their vehement disagreement with the Secretary’s decision. But that clearly is no basis to vacate her regulation. Accordingly, the Court should see their challenge for what it is – a difference of opinion – and grant the Secretary’s motion and enter judgment in her favor.

ARGUMENT

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

The Secretary’s interpretation of her authority under Subsection (d)(5)(I)(i) is reasonable and thus entitled to deference under *Chevron*. See Mem. of Pts. & Auths. in Supp. of Def.’s Cross-Mot. for Summ. J., Mot. to Dismiss & Opp’n to Pls.’ Mots. for Summ. J. (“Sec’y MSJ”) at 18-19, Oct. 15, 2014, ECF No. 23-1. If the Court’s determination “begins where all such inquires must begin: with the language of the statute itself,” (*United States v. Ron Pair Enter., Inc.*, 489 U.S. 235, 241 (1989)), that provision clearly gives the Secretary the broad authority to provide for any adjustment or exception that she deems appropriate. See 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.”); see also *Adirondack Med. Ctr. v. Sebelius*, 891 F. Supp. 2d 36, 44-45 (D.D.C. 2012) (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’” (emphasis added)). Plaintiffs, however, urge the Court to look beyond the statutory language to adopt their preferred, more limited interpretation of Subsection (d)(5)(I)(i). See Pls.’ Opp’n to Def.’s Mot. to Dismiss & for Summ. J. & Reply in Supp. of Pls.’ Mot. for

Summ. J. (“Shands Opp’n”) at 1-16, Oct. 31, 2014, ECF No. 27; Bakersfield Pls.’ Consol. Reply in Supp. of Bakersfield Pls.’ Mot. for Summ. J. & Opp’n to Def.’s Mot. to Dismiss & Mot. for Summ. J. (“Bakersfield Opp’n”) at 11-14, Oct. 31, 2014, ECF No. 32; Reply Mem. of Pts. & Auths. in Supp. of Pls. St. Helena Hosp. et al.’s Mot. for Summ. J. & Opp’n to Def.’s Mot. to Dismiss & Mot. for Summ. J. (“St. Helena Opp’n”) at 1-6, Oct. 30, 2014, ECF No. 26.

As the Secretary demonstrated, and none of Plaintiffs dispute, to prevail on their claim, they must demonstrate that “the statutory language ‘cannot bear the interpretation adopted by the Secretary.’” *Adirondack*, 891 F. Supp. 2d at 43 (emphasis added); *see also* Sec’y MSJ at 19. Evaluated under that standard, Plaintiffs’ arguments in support of their statutory claim fall short.¹

1. The Secretary’s Construction of Subsection (d)(5)(I)(i) Is Not Contrary to Congressional Intent.

Plaintiffs originally claimed that the Secretary’s .2 percent reduction violated the Medicare statute’s per-discharge payment scheme but now concede that the reduction does no such thing. *See* St. Helena Opp’n at 2 (conceding that “the Reduction may be applied on a per-discharge basis”).² Now their arguments claiming the reduction violates the catchall adjustment authority provision and congressional intent turn on its “across-the-board” application. *See* Shands Opp’n at 11 (contending that an “across-the-board rate reduction . . . is no ‘adjustment’”); St. Helena Opp’n at 3 (contending that “an across-the-board payment reduction

¹ It is not even necessary here for the Court to “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 U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 n.11 (1984). 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. v. Shalala*, 508 U.S. 402, 417 (1993) (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”).

² The Shands Plaintiffs persist in their erroneous suggestion that the .2 percent reduction “denies payment” for 40,000 inpatient hospitalizations. *See* Shands Opp’n at 10. As the Secretary explained, the .2 percent reduction is one of several adjustments applied to the standardized rate before it is applied per qualified discharge. *See* Sec’y MSJ at 16.

impacting every IPPS hospital and applying to every discharge” is not within “the bounds of the Secretary’s adjustment authority”). Plaintiffs’ concern about the reduction’s breadth of application is misplaced as nothing in the statute precludes the Secretary from making an across-the-board adjustment. The ordinary meaning of “adjustment” is a modification, which implies a small or moderate change. *See* OXFORD ENGLISH DICTIONARY (3d ed. 2011)³ *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.”); AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 1130 (4th ed. 2000) (defining “modification” as “[a] small alteration, adjustment, or limitation”); *see also* *MCI Telecomm. v. American Tel. & Tel.*, 512 U.S. 218, 225 (1994) (“Virtually every dictionary we are aware of says that ‘to modify’ means to change moderately or in minor fashion.”). Thus, contrary to Plaintiffs’ suggestion, (*see* St. Helena Opp’n at 1), the term “adjustment” necessitates consideration of the size of the modification. *See* *MCI Telecomm.*, 512 U.S. at 225. Here, the challenged adjustment was .2 percent, which is significantly smaller than the adjustment at issue and upheld by the court in *Adirondack* – 2.9% reduction in FY 2011 and a further 2.0% reduction in FY 2012. *See* *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692, 700 (D.C. Cir. 2014); 75 Fed. Reg. 50,042, 50,063 (Aug. 16, 2010). Moreover, there is nothing in the statute (or legislative history) indicating that the adjustment authority may only be used to adjust an individual provider’s or small group of providers’ claims. The Court appropriately should consider the size of the reduction – .2 percent – and uphold it under Subsection (d)(5)(I)(i)’s plain language. *See* *Estate of Doe v. Islamic Republic of Iran*, 808 F. Supp. 2d 1, 18 (D.D.C. 2011) (“The plain meaning of legislation should be conclusive”); *see also* *Bennett v. Islamic Republic of Iran*, 618 F.3d

³ The Supreme Court has noted that the OXFORD ENGLISH DICTIONARY is “one of the most authoritative.” *Taniguchi v. Kansas Pac. Saipan, Ltd.*, 132 S. Ct. 1997, 1999 (2012).

19, 22 (D.C. Cir. 2010) (assuming that “the ordinary meaning of th[e] language accurately expresses the legislative purpose”).

2. The Canon of *Ejusdem Generis* Should Not Inform the Court’s Determination.

Although Subsection (d)(5)(I)(i) plainly does not follow a list of specific terms, Plaintiffs inexplicably contend that the interpretation of that provision is informed by the canon of *ejusdem generis*. See Shands Opp’n at 11; St. Helena Opp’n at 5. That canon 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.”). Subsection (d)(5)(I)(i), which is a standalone provision among many under 42 U.S.C. § 1395ww(d), is preceded by Subsection (d)(5)(H) that authorizes adjustments “to take into account the unique circumstances of hospitals located in Alaska and Hawaii,” (42 U.S.C. § 1395ww(d)(5)(H)), and followed by Subsection (d)(5)(J)(i) that requires the Secretary to “treat the term ‘transfer case’ . . . as including the case of a qualified discharge . . . which is classified within a diagnosis-related group described in clause (iii), and which occurs on or after October 1, 1998,” (42 U.S.C. § 1395ww(d)(5)(J)(i)). That structure does not lend itself to application of the *ejusdem generis* canon. The sole authority on which Plaintiffs rely for their argument to the contrary makes that plain. See Shands Opp’n at 11 (citing *Cement Kiln Recycling Coal v. EPA*, 493 F.3d 207 (D.C. Cir. 2007), in support of the claim that the canon “applies to items in a statutory list even if the items are set forth in separate subparagraphs of a single paragraph of the

statute”). The allegedly comparably structured regulation at issue in *Cement Kiln Recycling Coal* provided as follows:

(1) The Director shall base the evaluation of whether compliance with the standards of 40 CFR part 63, subpart EEE alone is protective of human health or the environment on factors relevant to the potential risk from a hazardous waste combustion unit, including, as appropriate, any of the following factors:

- (i) Particular site-specific considerations such as proximity to receptors (such as schools, hospitals, nursing homes, day care centers, parks, community activity centers, or other potentially sensitive receptors), unique dispersion patterns, etc.;
- (ii) Identities and quantities of emissions of persistent, bioaccumulative or toxic pollutants considering enforceable controls in place to limit those pollutants;
- (iii) Identities and quantities of nondioxin products of incomplete combustion most likely to be emitted and to pose significant risk based on known toxicities (confirmation of which should be made through emissions testing);
- (iv) Identities and quantities of other off-site sources of pollutants in proximity of the facility that significantly influence interpretation of a facility-specific risk assessment;
- (v) Presence of significant ecological considerations, such as the proximity of a particularly sensitive ecological area;
- (vi) Volume and types of wastes, for example wastes containing highly toxic constituents;
- (vii) Other on-site sources of hazardous air pollutants that significantly influence interpretation of the risk posed by the operation of the source in question;
- (viii) Adequacy of any previously conducted risk assessment, given any subsequent changes in conditions likely to affect risk; and
- (ix) Such other factors as may be appropriate.

40 C.F.R. § 270.10(1)(1); *see also Cement Kiln Recycling Coal*, 493 F.3d at 218-19. Any resemblance between the structure of that regulation and Subsection (d)(5)(I)(i) is imagined. The canon of *ejusdem generis* clearly should not inform the Court’s determination here.

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

In their Opposition, Plaintiffs again invoke the legislative history in support of their narrow statutory interpretation but still have identified nothing in that history that speaks to the scope of the Secretary's authority under Subsection (d)(5)(I)(i). *See* Shands Opp'n at 13-14. Instead of relying entirely on conference and committee reports from 1983 as before, (*see* Sec'y MSJ at 21), Plaintiffs now invoke as support the legislative history surrounding "[t]he most recent amendment to the other adjustments clause." Shands Opp'n at 14 (citing "103 [sic] Cong. Rec. S15935 (daily ed. Nov. 17, 1993)" and "Social Security Act Amendments of 1994, Pub. L. No. 103-432, § 109, 108 Stat. 4398, 4408"). These most recent legislative statements only explain that the then-newly enacted Subsection (d)(5)(I)(ii) "authorize[s the Secretary] to make future revisions to transfer payment policy in a budget neutral manner." 139 Cong. Rec. S15935 (daily ed. Nov. 17, 1993). Nothing in those statements, however, addresses the reach of the Secretary's catchall adjustments authority under Subsection (d)(5)(I)(i) – the issue before the Court. Plaintiffs' invocation of the legislative history of *a different statutory provision*, therefore, is unavailing.

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

Because Plaintiffs perceive a redundancy between, on the one hand, Subsection (d)(5)(I)(i) as interpreted by the Secretary and, on the other hand, her authority under Subsection (d)(5)(I)(ii) and the statutory adjustments provided under 42 U.S.C. § 1395ww(d)(3), Plaintiffs contend that Congress could not have authorized the type of adjustment challenged here. *See* Bakersfield Opp'n at 12-14; St. Helena Opp'n at 4-5; Shands Opp'n at 12. "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 v.*

Germain, 503 U.S. 249, 253 (1992). The D.C. Circuit’s decision in *Adirondack* is instructive. Similar to the arguments Plaintiffs here make, the plaintiffs in *Adirondack* contended that Section 1395ww(d)(3)(A)(vi)’s express authorization to adjust the average standardized amounts to eliminate the effect of diagnosis-related group (“DRG”) coding or classification changes precluded the Secretary from invoking her authority under Subsection (d)(5)(I)(i) to adjust the hospital-specific rates to offset increased future payments that otherwise would stem from such changes. Prior to the enactment of Section 1395ww(d)(3)(A)(vi), the Secretary had “expressed doubts about [her] ability to correct the potential for anomalously-high payments resulting from changes to how hospital cases were classified;” Congress responded by enacting Section 1395ww(d)(3)(A)(vi). *Adirondack*, 740 F.3d at 698. The D.C. Circuit inferred from that sequence of events “that Congress intended to *clarify and complement the Secretary’s existing authority* – i.e., ‘to make assurance double sure,’ not to extinguish or eliminate it.” *Id.* (emphasis added; citation omitted). “[N]othing unambiguously suggest[ed] Congress intended to strip the Secretary of her broad grant of authority under § 1395ww(d)(5)(I)(i).” *Id.* at 697. The same is true here.

Plaintiffs contend that the specific grant of authority in Subsection (d)(5)(I)(ii) to make adjustments for transfer cases “to each of the average standardized amounts . . . to assure that the aggregate payments made under this subsection for such fiscal year are not greater or lesser than those that would have otherwise been made in such fiscal year” impliedly limits the authority granted in Subsection (d)(5)(I)(i). *See St. Helena Opp’n* at 4; *see also Bakersfield Opp’n* at 13-14 (making similar argument as to the specific authorizations under Subsections 1395ww(d)(5)(C) and 1395ww(d)(5)(H)). Other than stating that proposition, Plaintiffs proffer nothing to suggest that *Congress* unambiguously had that intent as opposed to the intent

recognized in *Adirondack* – “to make assurance double sure.” *Adirondack*, 740 F.3d at 698 (quoting *Shook v. District of Columbia Fin. Responsibility & Mgmt. Assistance Corp.*, 132 F.3d 775, 782 (D.C. Cir. 1998) (“Sometimes Congress 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.” That is, Congress means to clarify what might be doubtful – that the mentioned item is covered – without meaning to exclude the unmentioned ones.”)). Thus, Plaintiffs’ preferred interpretation is not grounds to overturn the reasonable, alternative interpretation of the Secretary.

Plaintiffs also contend that the provisions under 42 U.S.C. § 1395ww(d)(3) authorizing “adjustments to the base rate for all hospitals that are unrelated to specific hospital characteristics or case types” delimit the Secretary’s authority under Subsection (d)(5)(I)(i) to “special types of hospitals.” *Shands Opp’n* at 12. The Secretary, however, did not purport to use that authority for any of the purposes covered by the adjustments enumerated in Section 1395ww(d)(3). *See* 42 U.S.C. § 1395ww(d)(3)(A) (updating previous standardized amounts); 42 U.S.C. § 1395ww(d)(3)(B) (reducing for value of outlier payments); 42 U.S.C. § 1395ww(d)(3)(C) (maintaining budget neutrality); 42 U.S.C. § 1395ww(d)(3)(D) (computing DRG-specific rates for hospitals); 42 U.S.C. § 1395ww(d)(3)(E) (adjusting for different area wage levels). Rather, the Secretary invoked her broad adjustments authority to offset the impact of the policy change set forth in the two-midnight rule. *See* A.R. 1361-62 (“Policy clarifications such as this do not usually result in utilization shifts of sufficient magnitude and breadth to significantly impact the IPPS . . . it would be inappropriate to ignore such a utilization shift in the development of the IPPS payment rates.”); *see also* A.R. 2047 (characterizing the actuaries’ analysis as “estimat[ing] the financial impact of this policy change”). Thus, under the circumstances here, there is no

repugnancy between the Secretary's interpretation of Subsection (d)(5)(I)(i) and any of the statutory provisions Plaintiffs identified, and that interpretation should be upheld as reasonable. *See Connecticut Nat'l Bank*, 503 U.S. at 253 (“[S]o long as there is no ‘positive repugnancy’ between two laws, a court must give effect to both.” (citation omitted)).

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

Despite Plaintiffs' suggestions to the contrary, the Secretary has not issued an interpretation of the scope of her exceptions and adjustments authority under Subsection (d)(5)(I)(i). *See* Sec'y MSJ at 27. Plaintiffs, however, urge the Court to accept as the only permissible reach of that authority their unreliable inferences from one or two instances when that authority was used – or more inexplicably, not used – by the Secretary. *See* St. Helena Opp'n at 3 (suggesting that Subsection (d)(5)(I)(i) authorizes adjustments to combat “artificial,” not real, increases in payment amounts); Shands Opp'n at 5 (contending that the Secretary on two occasions determined that Subsection (d)(5)(I)(i) “did not authorize the agency to effect an across-the-board rate reduction”). It is a well-established principle in statistics that conclusions drawn from a small sample generally are not meaningful. *See Massachusetts Med. Soc'y v. Dukakis*, 637 F. Supp. 684, 695 (D. Mass. 1986) (concluding that “no reliable inferences . . . can be drawn from . . . [a] sample too small . . . [that] is quite obviously neither random nor representative”); *see also Schmid v. Frosch*, 680 F.2d 248, 249 n.4 (D.C. Cir. 1982) (“Small samples tend to be less reliable than large samples because of instability and variability caused by [their] unrepresentative[ness] . . .”). Moreover, as the Secretary demonstrated, and Plaintiffs do not dispute, her past invocations of her authority under Subsection (d)(5)(I)(i) have arisen in different and unique circumstances. *See* Sec'y MSJ at 25-26. Thus Plaintiffs' attempt to make generalities from isolated (and, in this case, distinguishable) instances is inherently meaningless

and certainly does not demonstrate that the Secretary's invocation of her Subsection (d)(5)(I)(i) authority under the circumstances here was unreasonable.

6. The Secretary's Interpretation of Her Authority to Adjust Capital Rates Under 42 U.S.C. § 1395ww(g) Should be Upheld.

Plaintiffs contend without elaboration that the Secretary exceeded her authority under Subsection 1395ww(g) by applying a .2 percent reduction to the capital rates.⁴ *See* Bakersfield Opp'n at 14 (contending that the "plain meaning of th[at] section is that the Secretary has the authority to except certain hospitals of the Secretary's choosing from capital PPS or one or more of the requirements under capital PPS, and does not mean that the Secretary can uniformly adjust capital PPS rates for all hospitals"); *see also* St. Helena Opp'n at 6. Subsection 1395ww(g) authorizes the Secretary to provide for (i) a payment and appropriate weighting of that payment "as relates to the classification of the discharge," (42 U.S.C. 1395ww(g)(B)(i)); (ii) "an adjustment to take into account variations in the relative costs of capital and construction for the different types of facilities or areas in which they are located," (42 U.S.C. 1395ww(g)(B)(ii)); (iii) "such exceptions . . . as the Secretary determines to be appropriate," (42 U.S.C. 1395ww(g)(B)(iii)); and (iv) "suitable adjustment to reflect hospital occupancy rate," (42 U.S.C. 1395ww(g)(B)(iv)). Invoking that authority, the Secretary decided to reduce the national capital federal rate and Puerto Rico-specific capital rate by .2 percent. She explained that "[b]ecause hospitals receive an operating IPPS payment and also a capital IPPS payment for each discharge . . . it would be appropriate to reduce payments under both the operating and capital IPPS to fully

⁴ Section 1886(g) of the Medicare statute requires the Secretary to pay for the capital-related costs of inpatient acute hospital services "in accordance with a prospective payment system established by the Secretary." 42 U.S.C. § 1395ww(1)(A). Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. "The basic methodology for determining capital prospective payments is set forth in [] regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs. The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR Part 412, Subparts A through M." A.R. 578.

offset the projected increases in expenditures associated with these inpatient discharges.” A.R. 1154. As with Plaintiffs’ challenge to the Secretary’s interpretation of Subsection (d)(5)(I)(i), to prevail on their challenge to her interpretation of Subsection 1395ww(g), Plaintiffs must demonstrate that the statutory language cannot bear the Secretary’s interpretation as authorizing the .2 percent reduction to the capital rates. *See Adirondack*, 891 F. Supp. 2d at 43; *Sullivan v. Everhart*, 494 U.S. 83, 91-92 (1990); *see also* Sec’y MSJ at 14 n.5 (noting that the analysis applicable to Plaintiffs’ challenge to the Secretary’s interpretation of Subsection (d)(5)(I)(i) “applies equally to Plaintiffs’ challenge to the Secretary’s reduction for capital-related costs”). Because Plaintiffs did not attempt to make that showing, their statutory challenge to the capital rates reduction also fails.

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

A. The Secretary Promulgated the .2 Percent Reduction in Compliance with the APA.

Plaintiffs erroneously contend that the Secretary’s .2 percent reduction should be invalidated because the Secretary provided insufficient notice of the actuaries’ analysis on which she relied and she failed to respond to comments critical of her proposed reduction set forth in the Notice of Proposed Rulemaking. *See* Shands Opp’n at 16-18; Bakersfield Opp’n at 3-11; St. Helena Opp’n at 6-18; Pls.’ Athens Reg’l et al.’s Reply in Supp. of Pls.’ Mot. for Summ. J. & Opp’n to Sec’y’s Mot. to Dismiss & Mot. for Summ. J. (“Athens Opp’n”) at 3-18, Oct. 31, 2014, ECF No. 34; Am. Hosp. Ass’n Pls.’ Reply in Supp. of Their Mot. for Summ. J. & Opp’n to Def.’s Cross-Mot for Summ. J. & Mot. to Dismiss (“AHA Opp’n”) at 2-18, Oct. 31, 2014, ECF No. 29. There is a “heavy burden” to demonstrate that the Secretary’s decision was arbitrary and capricious. *See Village of Bensenville v. FAA*, 457 F.3d 52, 70 (D.C. Cir. 2006). As the

Secretary demonstrated, that burden is not met on the record here. The D.C. Circuit's decision in *Connecticut Light & Power Co. v. Nuclear Regulatory Comm'n*, 673 F.2d 525, 530 (D.C. Cir. 1982), is instructive. In that case, the plaintiffs contended that "[s]ome technical papers relied upon by the Commission . . . were either not public or were not identified as relevant by the Commission until long after the comment period had closed." *Id.* at 531. During oral argument in the case, counsel for the government represented that "the experience accumulated during the plant by plant evaluations, together with the Sandia tests results [which had been subjected to widespread public comment] were the most important bases of the rule as proposed." *Id.* at 531 n.7. Based on that representation, the court considered whether the bases counsel identified as well as two other publicly available reports and the comments submitted to the agency "provide[d] adequate justification for the rules as finally adopted by the Commission." *Id.* Although the court concluded that it "would have been better practice for the NRC to have identified [its] technical materials specifically in the notice of proposed rule-making," the D.C. Circuit "conclude[d] that the technical background of the rules was sufficiently identified to allow for meaningful comment during the rule-making process." *Id.* at 532. Plaintiffs here miss the point of *Connecticut Light's* relevance with their observations that the Secretary did not rely on publicly available reports. *See* Bakersfield Opp'n at 5; St. Helena Opp'n at 7. Rather, that decision is instructive in demonstrating that the .2 percent reduction can and should be upheld notwithstanding the absence from the record of certain details of the actuaries' analysis and all of the data on which they relied.

Although Plaintiffs dismiss as "irrelevant" the context in which the Secretary promulgated both the two-midnight policy and the .2 percent reduction to offset that policy change, (*see, e.g.*, Athens Opp'n at 8; AHA Opp'n at 3; Bakersfield Opp'n at 4), that context

informs why her actuaries assumed that her policy change would have a greater impact on observation stays and long outpatient hospitalizations. *See, e.g.*, A.R. 96 (noting that under the prior policy, hospitals apparently were “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”). The Secretary additionally disclosed during the notice-and-comment period that, 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,” her 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,” representing “an increase of approximately 1.2 percent in the number of shorter stay hospital inpatient encounters paid under the IPPS.”⁵ A.R. 728. Even after consideration of public comments submitted, her actuaries “continue[d] to estimate” that the two-midnight rule would have that financial impact. A.R. 1362. All together this publicly available information was sufficient to “allow for useful criticism” – as the record before the Court clearly reflects. *Connecticut Light*, 673 F.2d at 530 (“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.”); *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.

⁵ Although it is clear from the record that the actuaries’ analysis considered behavioral response under the two-midnight rule, Athens Plaintiffs inexplicably contend in their Opposition that before this Court “is the first time the Secretary has suggested that she adjusted her claims numbers to account for ‘behavior consequences.’” Athens Opp’n at 10.

Plaintiffs claim entitlement under the APA to every last detail and all granular considerations of the actuaries' calculations. Indeed, Plaintiffs complain of their inability to replicate the actuaries' analysis. *See Athens Opp'n* at 16 (alleging that "the rate reduction violates the APA because the Notice of Proposed Rulemaking failed to give sufficient information for the public to replicate the Secretary's methodology"); *AHA Opp'n* at 5 (alleging that the fact that commenters "*could not*, despite their best efforts, duplicate CMS's analysis . . . only underscores that CMS's explanation of its methodology and identification of the data it used were insufficient"). That some commenters claimed they could not replicate the Secretary's calculations based on their review of public data is irrelevant to the adequacy of public notice and the reasonableness of the regulation itself. "There is no general requirement that the [Secretary] include in the record the data underlying each factor' considered in [her] decision." *District Hosp. Partners v. Sebelius*, 971 F. Supp. 2d 15, 24 (D.D.C. 2013) (concluding that "plaintiffs' bare desire to replicate each calculation contained within the Secretary's analysis – without more – will not suffice to justify supplementation [of the administrative record]"); *cf. Banner Health v. Sebelius*, 945 F. Supp. 2d 1, 28 (D.D.C. 2013) (same). In the Employee Retirement Income Security Act ("ERISA") context, where reliance on actuarial assumptions is commonplace in calculating liability for withdrawal from a pension benefit plan, Congress created a statutory presumption to guard against what plainly is afoot here: "endless disputes over technical actuarial matters with respect to which there are often several equally 'correct approaches.'" *Combs v. Classic Coal Corp.*, 931 F.2d 96, 99-100 (D.C. Cir. 1991) (internal quotations omitted). "In the absence of th[at] presumption, 'employers could effectively nullify their obligation by refusing to pay and forcing the plan sponsor to prove every element involved in making an actuarial determination.'" *Id.* at 100. The Secretary should prevail here, even

absent such a statutory presumption, because the APA does not impose on the Secretary the obligation to explain every element of her actuaries' analysis. It is undisputed that the top-level assumptions of that analysis were provided and, under the APA, that was sufficient notice for the public to proffer its views about the proposed .2 percent reduction.⁶ *See Connecticut Light*, 673 F.2d at 530 (“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.”).

Plaintiffs' complaints about the Secretary's response to public comments are in a similar vein – she failed to provide all of the details Plaintiffs wanted.⁷ *See, e.g.,* AHA Opp'n at 9-11; Athens Opp'n at 17-18. “[A]n agency's failure to address a particular comment or category of comments is not an APA violation per se.” *Sherley v. Sebelius*, 689 F.3d 776, 784 (D.C. Cir. 2012). Such a failure is significant “only insofar as it demonstrates that the agency's decision was not based on a consideration of the relevant factors.” *Id.* The record before the Court demonstrates that the Secretary indeed considered the relevant factors but, in the end, disagreed

⁶ As the Secretary noted in her opening brief, also in the rulemaking record is a report of the Office of Inspector General (“OIG”) that her brief mistakenly characterized as published “during the public notice-and-comment period,” (Sec’y MSJ at 32). Plaintiffs contend that they were deprived of the opportunity to comment on this supposed additional basis for the Secretary's .2 percent reduction. *See* Athens Opp'n at 12-13. As described in the Secretary's opening brief, the OIG report is further evidence of her very “public study of the systemic nature of the issue of hospital inpatient determinations,” (Sec’y MSJ at 33), which under *Connecticut Light & Power*, should factor into the Court's decision here.

⁷ Plaintiffs' complaints primarily relate to the Secretary's failure to provide more explanation about her actuaries' decision to exclude medical MS-DRGs in estimating “the number of encounters that would shift from inpatient to outpatient.” A.R. 1361. Plaintiffs erroneously regard that decision as a failure to consider a relevant factor. *See* Bakersfield Opp'n at 8; St. Helena Opp'n at 15; AHA Opp'n at 11-12; Athens Opp'n at 3-5. On the contrary, as explained in the actuaries' memorandum, the exclusion of medical MS-DRGs was not an oversight; the actuaries “assumed that these cases would be unaffected by the policy change.” A.R. 2047. That assumption is bolstered by the fact that “[i]npatient hospital short-stay claim errors are frequently related to minor surgical procedures or diagnostic tests. In such situations, the beneficiary is typically admitted as a hospital inpatient after the procedure is completed on an outpatient basis, monitored overnight as an inpatient, and discharged from the hospital in the morning. Medicare review contractors typically find that while the underlying services provided were reasonable and necessary, the inpatient hospitalization following the procedure was not (that is, the services following the procedure should have been provided on an outpatient basis).” 78 Fed. Reg. 27,486, 27,647 (May 10, 2013).

with commenters' criticisms about the .2 percent reduction. *See* A.R. 1361-62. Under the APA, her decision to implement that reduction over Plaintiffs' objections is not sufficient basis to invalidate the .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.").

B. The Prejudicial Error Doctrine Is Applicable to the APA Deficiency Alleged by Plaintiffs.

The Secretary's .2 percent reduction alternatively should be upheld under the prejudicial-error doctrine. Plaintiffs contend that this doctrine does not apply because the D.C. Circuit in *Allina Health Servs. v. Sebelius*, 746 F.3d 1102 (D.C. Cir. 2014), observed that "the Medicare statute has no harmless error exception." *See id.* at 1109; *see also* St. Helena Opp'n at 12 (contending that the "Court should reject the Secretary's harmless-error argument, because the rulemaking requirements imposed by the Medicare Act contain no harmless-error exception" (citation omitted)). That observation was based on Section 1395hh(a)(4), which provides that

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

42 U.S.C. § 1395hh(a)(4). Thus, in context, it is clear that the D.C. Circuit was not addressing the type of error alleged here. It is undisputed that the Secretary's proposed reduction was the same as that adopted. *See* Sec'y MSJ at 28 (explaining "that, in compliance with the APA, the Secretary's proposed rule contained the terms and substance of the .2 percent reduction.").

Although there is not a harmless-error provision in the Medicare statute, there is such a provision in the APA. *See* 5 U.S.C. § 706 (providing that "due account shall be taken of the rule of prejudicial error"). Where, as here, the alleged error turns on the level of details disclosed

about the technical basis for the Secretary's decision, the D.C. Circuit acknowledged that it "examine[s] whether a failure to disclose such material actually harmed a petitioner." *Allina Health*, 746 F.3d at 1110. Actual harm is demonstrated when the plaintiff demonstrates "that an opportunity to comment regarding an agency's important information created 'enough uncertainty' as to its possible affect on the agency's disposition." *Id.*

Here, the record reflects that the public did comment – despite Plaintiffs' contention that they were deprived of the opportunity to do so – that the migration of cases from inpatient to outpatient was greater than the Secretary's actuaries estimated. *See, e.g.*, A.R. 4654 (commenter's analysis "show[ed] that the anticipated decrease in inpatient stays lasting two days or less (that is, case moving from IPPS to OPSS) is far greater in volume than the anticipated cases of outpatient encounters that would be paid under IPPS"); A.R. 5010 (commenter's analysis determined that there was "a potential of 530,000 cases that could change to outpatient status from inpatient"). Nevertheless, her actuaries continued to reach the same conclusion about the financial impact of the two-midnight rule. *See* A.R. 1362; *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"). "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 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 is not reversible error under the APA's prejudicial-error doctrine.

C. The Proper Remedy Is Remand and Not Invalidation of the .2 Percent Reduction.

Even if the Court determines that the Secretary's explanation of her actuaries' analysis was deficient, the appropriate remedy is remand, not invalidation of the .2 percent reduction. Plaintiffs have not substantiated their request for vacation of the .2 percent reduction. *See generally* Shands Opp'n; St. Helena Opp'n; AHA Opp'n; Athens Opp'n; Bakersfield Opp'n. It "is simply not the law" that if an agency violates the APA, "its actions must be vacated." *Sugar Cane Growers Cooperative of Fla. v. Veneman*, 289 F.3d 89, 98 (D.C. Cir. 2002). Rather, "under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with correct legal standards." *Palisades v. General Hosp. Inc. v. Leavitt*, 426 F.3d 400, 404 (D.C. Cir. 2005). The D.C. Circuit has "commonly remanded without vacating an agency's rule or order" where "the failure lay in lack of reasoned decisionmaking," (*International Union, United Mine Workers v. Federal Mine Safety & Health Admin.*, 920 F.2d 960, 966-67 (D.C. Cir. 1990)), and where "the agency failed to follow notice-and-comment procedures," (*Sugar Cane Growers*, 289 F.3d at 98). Remand thus would be appropriate here. *See Lilliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1314 (D.C. Cir. 2014) (suggesting that remand without vacatur is appropriate where it is "plausible that [the agency] can redress its failure of explanation on remand while reaching the same result"); *Massachusetts v. NRC*, 924 F.2d 311, 336 (D.C. Cir. 1991) ("In appropriate cases, we will remand without vacating an agency's order where the reason for the remand is a lack of reasoned decisionmaking."); *Bush-Quayle '92 Primary Comm., Inc. v. Federal Election Comm'n*, 104 F.3d 448, 455 (D.C. Cir. 1997) ("Remand will permit the

[agency] to justify its approach.”). Accordingly, if the Court were to find an APA violation, it should deny Plaintiffs’ request for vacatur and instead remand to the Secretary.

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

It is undisputed that the Secretary intended the .2 percent reduction to have binding legal effect, that the reduction was subjected to notice-and-comment rulemaking, and that the final reduction was published in the *Federal Register*. See Sec’y MSJ at 43-45; A.R. 728-29; A.R. 1360-62; AHA Opp’n at 17. Yet Plaintiffs still contend that the reduction was not promulgated by regulation because it was not also published in the *Code of Federal Regulations* (“CFR”). See St. Helena Opp’n at 9-12; AHA Opp’n at 16-18. Their attempt to read into Subsection (d)(5)(I)(i) and 42 U.S.C. § Section 1395hh(a)(2) the requirement of publication in the CFR fails as a matter of statutory interpretation. See 42 U.S.C. § 1395ww(d)(5)(I)(i) (authorizing the Secretary to “provide by regulation for such other exceptions and adjustments . . . as the Secretary deems appropriate”); 42 U.S.C. § 395hh(a)(2) (providing that “[n]o rule, requirement, or other statement of policy . . . under this subchapter shall take effect unless it is promulgated by the Secretary by regulation”); see also *Health Ins. Ass’n of Am., Inc. v. Shalala*, 23 F.3d 412, 423 (D.C. Cir. 1994) (publication in the CFR is only a “snippet of evidence of agency intent” to promulgate a substantive rule). Clearly nothing in the language of either provision bears out Plaintiffs’ claim. See St. Helena Opp’n at 9 (erroneously contending that the Secretary violated “the plain language of subsection (d)(5)(I)(i)”). Statutory construction “must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose.” *Bennett*, 618 F.3d at 22 (quoting *Engine Mfrs. Ass’n v. South Coast Quality Mgmt. Dist.*, 541 U.S. 246, 252 (2004)). Here, the ordinary

meaning of the terms “regulation” and “promulgate” make plain that the Secretary’s .2 percent reduction was established by binding regulation as required by statute.

Neither the Medicare statute nor the APA defines the term “regulation.” In normal parlance, that term means “[a] rule or order, having legal force, issued by an administrative agency or a local government.” BLACK’S LAW DICTIONARY 1289 (7th ed. 1999); *see also* WEBSTER’S THIRD NEW INT’L DICTIONARY 1913 (1993) (same); AM. HERITAGE DICTIONARY 1471 (4th ed. 2006) (defining “regulation” as “[a] principle, rule, or law designed to control or govern conduct” and “[a] governmental order having the force of law”). “Promulgate” means “[t]o declare or announce publicly.” BLACK’S LAW DICTIONARY at 1231; *see also* WEBSTER’S THIRD INT’L DICTIONARY at 1816 (defining “promulgate” as “to make public as having the force of law”); AM. HERITAGE DICTIONARY at 1403 (defining “promulgate” as “[t]o put (a law) into effect by formal public announcement”). The record clearly establishes that the Secretary promulgated the .2 percent reduction as a binding regulation through its publication in the *Federal Register* after notice-and-comment rulemaking. *See* A.R. 1362 (declaring in the *Federal Register* that “we are finalizing the reduction to the standardized amount, the hospital-specific rates, and the Puerto Rico-specific standardized amount of -0.2 percent”); *see also Kennecott Utah Copper Corp. v. United States Dep’t of Interior*, 88 F.3d 1191, 1212 (D.C. Cir. 1996) (“While there may be uncertainty about the precise date upon which a regulation is promulgated, it is surely either the date of issuance or other formal announcement by the agency, the date of filing with the Office of the Federal Register, or the date of publication in the Federal Register.”); *Environmental Def. Fund., Inc. v. Gorsuch*, 713 F.2d 802, 813 (D.C. Cir. 1983) (concluding that the EPA had complied with a court order “to promulgate regulations” when it “made a formal announcement in the *Federal Register* of its issuance of the regulations”).

Moreover, that the .2 percent reduction was subjected to notice-and-comment rulemaking is further indication that it has binding legal effect under the Medicare statute. *See Queen City Home Health Care Co. v. Sullivan*, 978 F.2d 236, 242 (6th Cir. 1992) (concluding that the Secretary's inherently reasonable allowance (IRA) determination was properly treated as a reimbursement decision and not a regulation because "an IRA determination is not subject to the same rule making requirements to which regulations are subject, such as notice and comment").

Plaintiffs' claims to the contrary are based on misplaced reliance on out-of-context statements from inapposite cases. *See* St. Helena Opp'n at 10 (relying on dicta from *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533 (D.C. Cir. 1986));⁸ AHA Opp'n at 17 (same); St. Helena Opp'n at 11 (relying on dicta from *Rhode Island Hosp. v. Leavitt*, 548 F.3d 29 (1st Cir. 2008)).⁹ Indeed, one of the cases on which Plaintiffs rely for their contention that publication in the CFR is required for a regulation, *Natural Resources Defense Council v. EPA*, 559 F.3d 561, 565 (D.C. Cir. 2009), actually belies that erroneous claim. *See* AHA Opp'n at 16 (relying on

⁸ In *Brock*, the Secretary of Labor contended that his "Enforcement Policy and Guidelines for Independent Contractors," notwithstanding its publication in the *Federal Register*, was a general statement of policy and not legally binding. The court agreed. Although the fact that the guidelines had not been published in the CFR was noted, the court upheld the Secretary's judgment because "[t]he language of the guidelines is replete with indications that the Secretary retained his discretion to cite production-operators as he saw fit." *Brock*, 796 F.2d at 538. As the court explained: "While the agency's characterization of an official statement as binding or nonbinding has been given some weight, of far greater importance is the language used in the statement itself." *Id.* at 537-38 (citations omitted). Thus, even under *Brock*, the challenged .2 percent reduction would be upheld as legally binding. *See* A.R. 1362 ("finalizing a reduction to the standardized amount, the hospital-specific rates, and the Puerto Rico-specific standards amount of -0.2 percent").

⁹ Plaintiffs contend that in *Rhode Island Hosp. v. Leavitt*, the Secretary took that position "that in order to be a 'regulation,' a statement must be codified in the [CFR]." St. Helena Hosp. Opp'n at 11. To the contrary, in that case, the Secretary contended that no "regulations" governing the indirect medical education ("IME") adjustment were in effect as of January 1, 1983, notwithstanding his publication of notices in the *Federal Register*. *See Rhode Island Hosp.*, 548 F.3d at 40; *see also* 46 Fed. Reg. 33,637, 33,637 (June 30, 1981) ("Final Notice") ("This notice sets forth a schedule of limits on hospital per diem inpatient general routine operating costs that may be reimbursed under Medicare for cost reporting periods beginning on or after July 1, 1981."); 47 Fed. Reg. 43,296, 43,296 (Sept. 30, 1982) ("Interim final notice with comment period") ("This notice sets forth a schedule of limits on the hospital inpatient operating costs that may be reimbursed under Medicare for cost reporting periods beginning on or after October 1, 1982."). Here, in contrast, the *Federal Register* publication was a final rule, not a notice, and thus unmistakably intended to establish the .2 percent reduction as a binding regulation. *See* A.R. 904 ("Final rules") ("We are revising the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems.").

Natural Resources Defense Council's language that "[a]gency statements 'having general applicability and legal effect' are to be published in the [CFR]" to support claim that the "0.2 percent cut[, which] was not published in the [CFR] . . . cannot have 'general applicability and legal effect'"). Later in the same opinion, the D.C. Circuit stated that, as the Secretary did here, "[a]gencies must publish substantive rules in the Federal Register to give them effect."¹⁰ *Natural Resources Defense Council*, 559 F.3d at 565. Thus, Plaintiff's challenge to the means by which the .2 percent reduction was established is baseless. The Secretary's issuance of that statutory adjustment clearly was "by regulation."

CONCLUSION

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

Dated: November 21, 2014

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¹⁰ The Secretary does not contend that publication in the *Federal Register* alone is sufficient to create a substantive regulation.

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