SHANDS JACKSONVILLE MEDICAL CENTER, INC. et al v. SEBELIUS Doc. 50

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

SHANDS JACKSONVILLE MEDICAL CENTER, et al., **Plaintiffs,** **v.** **SYLVIA M. BURWELL, Secretary, United States Department of Health and Human Services,** **Defendant.**	**Consolidated Civil Case Nos. 14-263, 14-503, 14-536, 14-607, 14-976, 14-1477**

MEMORANDUM OPINION

Under the Medicare system, participating hospitals are paid for services provided to Medicare-eligible patients. Medicare Part A provides compensation for services provided on an inpatient basis, while Medicare Part B provides compensation for outpatient services. In general, hospitals are paid more for inpatient stays.

Prior to 2013, Medicare guidance stated that it was generally appropriate for hospitals to admit a Medicare beneficiary as an inpatient if the patient was expected to stay for 24 hours or more. But the guidance also stressed that length of stay was not the only relevant factor in the "complex medical judgment" whether to admit a Medicare beneficiary for inpatient care. Because this open-ended approach generated uncertainty among providers and, at times, discouraged hospitals from treating Medicare beneficiaries as inpatients, in May 2013, the Department of Health and Human Services ("HHS" or "Department") proposed a new standard for inpatient admissions. This new standard—the "2-midnight benchmark"—authorized

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inpatient admission if the patient's stay was expected to span at least two midnights. *See* Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates, 78 Fed. Reg. 27486, 27645, 27648 (May 10, 2013) (proposed rules). To reduce uncertainty, the proposed rule then provided that "Medicare's external review contractors would presume that hospital inpatient admissions are reasonable and necessary for beneficiaries who" satisfy the 2-midnight benchmark. *Id*. at 27645.

The Secretary of HHS predicted that in fiscal year 2014 the new 2-midnight benchmark and the related presumption would result in "a net shift of 40,000 encounters" from outpatient status to inpatient status, *id.* at 27649, at an estimated cost of $220 million to the Medicare program, *id*. She proposed to offset this cost by making adjustments that would effect an across-the-board reduction in compensation for inpatient services. *Id.* at 27650, 27651. The final rule—including the 2-midnight benchmark, related policies, and the reduction in compensation for inpatient services—was published in August 2013. *See* Medicare Program; Hospital Inpatient Prospective Payment Systems For Acute Care Hospitals . . . Payment Policies Related to Patient Status, 78 Fed. Reg. 50496, 50965 (Aug. 19, 2013) (final rule), *codified as amended at* 42 C.F.R. § 412.3(d)(1).

Plaintiffs in these consolidated actions challenge only one aspect of the final rule: the reduction in compensation for inpatient services. They argue, among other things, that this reduction is invalid for three independent reasons: (1) it exceeds the Secretary's general "exceptions and adjustments" authority under the Medicare Act, *see* 42 U.S.C. § 1395ww(d)(5)(I)(i); (2) it was promulgated without adequate notice or a meaningful

opportunity to comment, in violation of the Administrative Procedure Act; and (3) it is arbitrary and capricious.

This matter is presently before the Court on Plaintiffs' motions for summary judgment, Dkts. 15, 16, 17, 18, 19, and the Secretary's motion to dismiss and for summary judgment, Dkt. 23. For the reasons given below, the Secretary's motion is **DENIED**. The Plaintiffs' motions for partial summary judgment are **GRANTED** in part and **DENIED** in part, and this matter is **REMANDED** to the Secretary for further proceedings.

I. BACKGROUND

The Medicare Act, 42 U.S.C. §§ 1395 *et seq.*, provides medical care for the elderly and disabled. As relevant here, Medicare Part A reimburses hospitals for inpatient services on a prospective basis, *see* 42 U.S.C. §§ 1395c *et seq.*, while Medicare Part B pays for services not covered by Part A, including hospital outpatient services and visits to the doctor, *see* 42 U.S.C. §§ 1395j, 1395*l*(t); *see generally Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 205-07 (D.C. Cir. 2011). The amount of compensation that a hospital receives from the Medicare program, as well as the cost to the Medicare beneficiary, varies in part depending on whether the beneficiary was admitted to the hospital as an outpatient or an inpatient.

Under the Medicare Inpatient Prospective Payment System ("IPPS"), hospitals are prospectively compensated for inpatient services at a fixed rate that is not based on the actual cost of the services provided. *See Methodist Hosp. of. Sacramento v. Shalala*, 38 F.3d 1225, 1226-27 (D.C. Cir. 1994) (explaining that Congress enacted the prospective payment system to promote efficiency and discourage the provision of unnecessary services); *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 405-06, 406 n.3 (1993). The rates used to calculate these payments are set annually by the Secretary according to the Medicare Act's "'complex statutory

and regulatory regime.'" *Methodist Hosp.*, 38 F.3d at 1226 (quoting *Good Samaritan*, 508 U.S. at 404).

One important element in the statutory scheme is the "standardized amount," which is set each year by the Center for Medicare and Medicaid Services ("CMS"), acting on behalf of the Secretary. *See* 42 U.S.C. § 1395ww(d)(3). Roughly speaking, the standardized amount represents the average per-patient operating costs across all hospitals, *see* 42 C.F.R. § 412.64, modified to account for various economic and other factors. Most hospitals are compensated for Medicare inpatient services according to the "federal rate," which is "a formula that takes [the] standardized base amount . . . and multiplies it by a weight associated with a diagnosis-related group." *Adirondack Med. Ctr. v. Sebelius* ("*Adirondack*"), 740 F.3d 692, 694 (D.C. Cir. 2014); *see also Methodist Hosp.*, 38 F.3d at 1227, 42 U.S.C. § 1395ww(d)(3)(D). A "diagnosis-related group" ("DRG") is "a category of inpatient treatment." *Adirondack*, 740 F.3d at 694 n.1; *see* 42 U.S.C. § 1395ww(d)(4)(A). Each group is assigned a weight reflecting the relative amount of resources expended with respect to discharges in that group. *See id.* § 1395ww(d)(4)(B). "The upshot of applying a DRG weighting factor is that a hospital will be paid more for patients diagnosed with a heart condition requiring surgery than for those diagnosed with a sprained ankle." *Adirondack Med. Ctr. v. Sebelius*, 29 F. Supp. 3d 25, 30 (D.D.C. 2014) (quotation marks and citation omitted). A 2007 rule refined the DRG system by implementing "Medicare severity diagnosis related groups" ("MS-DRGs"), which are intended to better account for severity of illness in Medicare payments. *See generally* Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2008 Rates, 72 Fed. Reg. 47130 (Aug. 22, 2007) (final rule).

A minority of hospitals, including those providing treatment to underserved communities, are compensated based in part on "hospital-specific rates." *See Adirondack*, 740 F.3d at 694-95; 42 U.S.C. §§ 1395ww(d)(5)(D) & (G). These "hospital-specific rates" are calculated using a hospital-specific base amount that reflects historical per-patient operating costs at that particular hospital. *See Adirondack*, 740 F.3d at 695. The Secretary also sets a "Puerto Rico-specific rate" which is calculated using a Puerto Rico-specific base amount. *See* 42 C.F.R. § 412.212; 42 U.S.C. § 1395ww(d)(9)(A).

The Medicare Act does not define the term "inpatient" or specify when inpatient admission is appropriate. The Secretary, however, has issued both formal and informal guidance on the subject. Her regulations specify that certain procedures should be provided on an inpatient basis. *See* 42 C.F.R. § 419.22(n). She has also issued guidance explaining that patients should be admitted on an inpatient basis only where the admitting physician determines that certain criteria are satisfied. Prior to 2013, the Secretary advised physicians to "use a 24-hour period as a benchmark" and to "order [inpatient] admission for patients who are expected to need hospital care for 24 hours or more." *See* AR 1451 (Medicare Benefit Policy Manual, CMS Pub. 100-02, Ch. 1, § 10 (2003)). The guidance acknowledged that the admitting physician's decision involves "complex medical judgment" and should not be made solely on the expected length of hospitalization, *see id.*, but cautioned that a hospital stay expected to last "only a few hours (less than 24)" did not justify inpatient admission, even if it was expected to be an overnight stay. *See id.* (explaining that patients with known diagnoses admitted for less than 24 hours should be admitted as "**outpatients** for coverage purposes regardless of: . . . whether they remained in the hospital past midnight") (emphasis in original); *see also* 78 Fed. Reg. at 27645, 27648 (describing the Secretary's prior policy on inpatient admissions).

The Secretary became concerned, however, that there were systemic problems with inpatient admissions under the 24-hour benchmark. In 2012 she observed an increase in the number of Medicare beneficiaries who were kept as outpatients for long periods of observation. *See* Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 77 Fed. Reg. 45061, 45155 (July 30, 2012) (proposed rule). Admissions for long periods of outpatient observation may have "significant financial implications for Medicare beneficiaries," because the patient's copayments, deductibles, and eligibility for certain post-hospitalization services will depend in part on whether the patient was admitted as an inpatient or an outpatient. *Id.* at 45156.[1] The Secretary had "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." *Id.*; *see also* AR 3509-3510 (public comment in a subsequent rulemaking describing ongoing concerns that inpatient claims would be denied).[2] A 2012 review of Medicare claims found a high rate of payment denials associated with short inpatient stays. *See* 78 Fed. Reg. at 27647-27649 (describing findings of the Secretary's Comprehensive Error Rate Testing contractor). In 2013, the Secretary observed that Medicare contractors had "recovered more than $1.6 billion in improper payments because of inappropriate beneficiary patient status." *Id.* at 27649.

[1] *See also* "Find out if you're an inpatient or an outpatient—it affects what you pay," *available at* https://www.medicare.gov/what-medicare-covers/part-a/inpatient-or-outpatient.html (last visited Sept. 17, 2015).

[2] Citations are to the administrative record ("AR").

Against this backdrop, the Secretary solicited public comments on "[p]otential policy changes . . . 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." 77 Fed. Reg. at 45155. She asked whether "alternative approaches to defining inpatient status" could provide clarity, "consider[ing] opportunities for inappropriately taking advantage of the Medicare system that time-based . . . criteria for patient status may create." *Id.* at 45157. The Secretary received over three hundred public comments on this issue. 78 Fed. Reg. at 27649; *see also* Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 77 Fed. Reg. 68210, 68430-68431 (Nov. 15, 2012) (summarizing comments).

In May 2013, the Secretary proposed a new rule "to clarify our longstanding policy on how Medicare review contractors review inpatient hospital admissions for payment under Medicare Part A [and] issue revised guidance to physicians and hospitals regarding when a hospital inpatient admission should be ordered." 78 Fed. Reg. at 27647. She observed that "there [had] been considerable variation in the interpretation" of her prior inpatient admissions guidance and the 24-hour benchmark, *see* 78 Fed. Reg. at 27648, and that "[t]he majority of improper payments under Medicare Part A for short-stay inpatient hospital claims have been due to inappropriate patient status (that is, the services furnished were reasonable and necessary, but should have been furnished on a hospital outpatient, rather than hospital inpatient, basis)," *id.* at 27647. "Inpatient 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." *Id.* at 27647.

To address these issues, the Secretary proposed a new inpatient admissions policy based on a "2-midnight benchmark." *See id.* at 27645-27649. Under the 2-midnight benchmark, "in addition to services designated . . . as inpatient only, surgical procedures, diagnostic tests, and other treatment 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 on that expectation." *Id.* at 27648. "Conversely, when a patient enters a hospital" for care not specified as inpatient only and the stay is expected to last "a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A." *Id.*

To provide increased predictability, the Secretary also proposed a "2-midnight presumption" to be applied by Medicare reviewers. *See id.* at 27645-27649. It provided that reviewers "would presume that inpatient hospital admissions are reasonable and necessary for beneficiaries" whose hospital stay "cross[ed] 2 'midnights,'" unless the hospital was found to be "abusing this 2-midnight presumption." *Id.* at 27645; 27648-27649. For shorter stays, reviewers would consider whether the attending physician who authorized the inpatient admission reasonably expected the patient's stay to last at least two midnights. *See id.* The 2-midnight

benchmark and the 2-midnight presumption were included in the final rule published in August 2013. *See* 78 Fed. Reg. at 50965, *codified as amended at* 42 C.F.R. § 412.3(d)(1).[3]

This action does not challenge the 2-midnight benchmark, the 2-midnight presumption, or the other aspects of the final rule that relate to the Secretary's inpatient admissions guidance. Rather, Plaintiffs challenge a different aspect of the final rule: an across-the-board reduction in payments to hospitals for inpatient services. This reduction was premised on the Secretary's expectation that, in fiscal year 2014, the new rule would result in "a net shift of 40,000 encounters" from outpatient to inpatient status. 78 Fed. Reg. at 27649.

As explained in the notice of proposed rulemaking,

> Our actuaries have estimated that our proposed policy . . . would increase IPPS expenditures by approximately $220 million. These additional expenditures result from an expected net increase in hospital inpatient encounters due to some encounters spanning more than 2 midnights moving to the IPPS from the [Outpatient Prospective Payment System ("OPPS")], and some encounters of less than 2 midnights moving from the IPPS to the OPPS. Specifically, our 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 360,000 encounters would shift from inpatient to outpatient, causing a net shift of 40,000 encounters.

78 Fed. Reg. at 27649. The predicted "net shift of 40,000 encounters" "represent[ed] an increase of approximately 1.2 percent in the number of shorter stay hospital inpatient encounters." *Id.* Because hospitals are typically paid more for inpatient stays, the Secretary estimated that this "net shift of 40,000 encounters" would cost the Medicare program an additional $220 million over the course of the fiscal year. *Id.* at 27649-27650.

[3] The 2-midnight policy was originally codified at 42 C.F.R. § 412.3(e)(1). The regulation was subsequently amended in other respects, *see* Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems, 79 Fed. Reg. 66770, 67030 (Nov. 10, 2014) (effective Jan. 1, 2015), and as a result, the provision now appears at 42 C.F.R. § 412.3(d)(1).

The Secretary reasoned that the additional cost of the new rule should be offset by an across-the-board reduction to payments for inpatient services. Thus, she proposed to use her "exceptions and adjustments authority" under the Medicare Act, *see* 42 U.S.C. § 1395ww(d)(5)(I)(i), "to offset the estimated $220 million in additional . . . expenditures" by adopting 0.2 percent reductions to "the operating IPPS standardized amount, the hospital-specific rates, and the Puerto Rico-specific standardized amount." *Id.* at 27651. Likewise, she proposed to invoke her "broad authority" under § 1395ww(g) to reduce "the national capital Federal rate and Puerto-Rico specific capital rate" by 0.2 percent. 78 Fed. Reg. at 27651.

"Commenters generally did not support the proposed -0.2% payment adjustment." 78 Fed. Reg. at 50953. The comments raised two principal concerns of relevance here. First, they questioned whether the Secretary possessed the statutory authority to make the proposed across-the-board reductions. *Id.*; *see* AR 4411 ("it is questionable whether CMS has the authority to reduce the standardized amount by 0.2 percent"); AR 4998 ("these reductions are an inappropriate use of CMS's special exceptions and adjustments authority"); AR 4265 (same); AR 5672 (noting that this authority "has been used exceedingly sparingly" and its use "in this context, . . . seems unprecedented"); *see also* AR 4528, 4497, 4713, 5473. Second, they questioned the underlying basis for the reductions, specifically, the Secretary's prediction that the new policy would cause a net increase in inpatient cases at a cost of $220 million in 2014.

With respect to the latter concern, the commenters raised a number of different objections. As noted in the final rule, they argued that the Secretary's analysis was "unsupported and insufficiently explained to allow for meaningful comment." 78 Fed. Reg. at 50953; *see* AR 5010 ("CMS has not been transparent in identifying the criteria used by the actuaries to identify the patient status shifts that would occur."); AR 5312 ("we are very concerned that CMS has not

released any data or even its methodology for determining that a -0.2% payment adjustment is warranted"); AR 4654-4655; 4411. Some commenters asked for additional information, *see* AR 4883-4884, 5672, while others attempted to replicate the Secretary's analysis without success, *see* AR 4653-4655; *see also* AR 4411 (observing that "it has not been possible to replicate the [Secretary's] finding[s]"), AR 5235 (similar). The commenters also criticized the prediction resulting from that analysis. They argued that "CMS has profoundly underestimated the volume of [outpatient] encounters" that would result from the two-midnight rule, *see* AR 4654; predicted that there would instead be a net increase in outpatient encounters, *see id.*, *see also* AR 5010; and argued that Medicare reimbursement to hospitals would decrease significantly if inpatient rates were cut, *see* AR 4306.

The notice of final rulemaking did not engage with these comments in detail. The Secretary expressed her view that in light of the "widespread impact" of the new 2-midnight policy, the proposed adjustments were an appropriate use of her statutory exceptions and adjustments authority. *See* 78 Fed. Reg. at 50953. She explained that "while we generally agree with commenters that it is not necessary to routinely estimate utilization shifts to ensure appropriate IPPS payments, this is a unique situation. Policy clarifications such as this do not usually result in utilization shifts of sufficient magnitude and breadth to significantly impact the IPPS." *Id.* at 50953-50954. The Secretary did not receive any comments "that specifically addressed [her] proposal to make the -0.2 percent adjustment to the national capital Federal rate and Puerto Rico-specific capital rate." *Id.* at 50746.

With respect to the methodology used to predict the net shift and its cost, the Secretary acknowledged that "there is a certain degree of uncertainty surrounding any cost estimate," but maintained that "our actuaries have determined that the methodology, data, and assumptions

used are reasonable for the purpose of estimating the overall impact of our proposed policy." *Id.* at 50953. She further stated that "we specifically discussed the methodology used and the components of the estimate" and "[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." *Id.*

In addition, the Secretary revealed two aspects of her methodology that were not disclosed in the notice of proposed rulemaking. First, she explained that when estimating the number of cases expected to shift from outpatient to inpatient status under the new rule, her actuaries excluded "[c]laims not containing observation or a major procedure":

> 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. . . .*

Id. (emphasis added). Second, when calculating the number of cases expected to shift in the opposite direction, her actuaries excluded different claims. In particular, they examined claims involving *surgical* MS-DRGs, and excluded claims involving *medical* MS-DRGs:

> 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. . . .*

Id. (emphasis added).

On the same day that the final rule was published, the CMS Office of the Actuary issued a memorandum entitled "Estimated Financial Effects of Two Midnight Policy," which "summarizes [its] financial estimate for clarifying inpatient vs. outpatient hospital services when all stays which span two midnights will be presumed to be inpatient." AR 2046-2048. The memorandum explains that "[s]everal assumptions were made to estimate the financial impact of this policy change." AR 2047 (describing these "key assumptions"). Notably, when calculating

the number of cases expected to shift from outpatient to inpatient status, "stays . . . not for observation care or for a major procedure were excluded because it was assumed that these cases would be unaffected by the policy change," *id.*, and when calculating the cases expected to shift from inpatient to outpatient status, claims containing a medical MS-DRG were excluded "because it was assumed that those cases would be unaffected by the policy change," *see id*. The memorandum did not explain, however, why the actuaries assumed that the excluded cases "would be unaffected by the policy change." *Id.*

The notice of final rulemaking confirmed that "after consideration of the comments we received . . . we 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," 78 Fed. Reg. at 50954; *see also id.* at 50746, and similarly "finalizing the proposed 0.2 percent reduction . . . to the national capital Federal rate and Puerto Rico-specific capital rate," *id*. at 50756.

After the final rule was published, the Plaintiff hospitals timely challenged the 0.2 percent reduction "to the . . . standardized amount, the hospital-specific rates, and the Puerto Rico-specific standardized amount" (collectively, "the 0.2 percent reduction"). 78 Fed. Reg. at 50746. The Provider Reimbursement Review Board granted Plaintiffs' requests for expedited judicial review pursuant to 42 U.S.C. § 1395oo(f)(1). AR 1-7. Plaintiffs then filed these actions against the Secretary in her official capacity, pursuant to the Administrative Procedure Act ("APA") and the Medicare Act. *See* Case No. 14-cv-263, Dkt. 1; Case No. 14-cv-503, Dkt. 1;

Case No. 14-cv-536, Dkt. 1; Case No. 14-cv-607, Dkt. 1; Case No. 14-cv-976, Dkt. 1; Case No. 14-cv-1477, Dkt. 1.[4]

The Court consolidated the actions and set a schedule for dispositive briefing. *See* May 23, 2014, Minute Order; July 23, 2014, Minute Order; Aug. 13, 2014, Scheduling Order; Sept. 9, 2014, Minute Order. Plaintiffs moved for summary judgment, *see* Dkts. 15, 16, 17, 18, 19, and the Secretary cross-moved for summary judgment, and—with respect to the St. Helena Plaintiffs only—moved to dismiss for failure to state a claim, *see* Dkt. 23.

On August 3, 2015, the Court held oral argument on the parties' cross-motions. At the oral argument, the Court raised the issue of appropriate remedy should it conclude that the Secretary promulgated the 0.2 percent reduction in violation of the APA, and it invited the parties to submit supplemental briefs on that issue. The parties filed supplemental briefs, *see* Dkts. 42, 43, and replies, *see* Dkts. 44, 45, 47. The Secretary moved for leave to file a surreply, Dkt. 49, which the Court granted, *see* Sept. 21, 2015, Minute Order.

II. DISCUSSION

Plaintiffs' motions for summary judgment present three principal arguments. First, they argue that the Medicare Act does not authorize the Secretary to make an across-the-board 0.2 percent reduction to compensation for inpatient services. Second, they argue that the Secretary failed to comply with the procedural requirements of the APA, 5 U.S.C. § 706(2)(A), in promulgating the 0.2 percent reduction, because she failed to disclose critical information about her methodology, and thus deprived Plaintiffs of a meaningful opportunity for comment; she

[4] These actions were originally brought against Secretary Kathleen Sebelius. Pursuant to Federal Rule of Civil Procedure 25(d), however, Secretary Burwell is automatically substituted for Secretary Sebelius.

failed to offer meaningful responses to substantial comments; and she failed to offer a reasoned basis for her final rule. Third, they argue that the 0.2 percent reduction is arbitrary and capricious and that it is ineffective because it merely appeared in the preamble to the final regulation. The Court starts with Plaintiffs' challenge to the Secretary's statutory authority.

A. The Secretary's "Exceptions And Adjustments" Authority

The Medicare inpatient prospective payment system is governed by a complex statutory scheme. *See* 42 U.S.C. § 1395ww(d). Among other things, § 1395ww(d)(3) instructs the Secretary how to set the standardized amount that is used to calculate inpatient prospective payments for most hospitals. Section 1395ww(d)(5) authorizes her to make additional payments, exceptions, and adjustments, most of which relate to atypical circumstances or particular types of hospitals. For example, the Secretary is authorized to "provide for an additional payment" (an "outlier" payment) when the duration of a patient stay exceeds that typical for patients with that diagnosis group. *See* 42 U.S.C. § 1395ww(d)(5)(A). She is also authorized to make additional payments to hospitals serving "a significantly disproportionate number of low-income patients," *see id.* § 1395ww(d)(5)(F)(i)(I), and to teaching hospitals, *see id.* § 1395ww(d)(5)(B). And she is authorized to make "exceptions and adjustments" to payments to "rural referral" hospitals, *see id.* § 1395ww(d)(5)(C)(i); and to make "adjustments . . . to take into account the unique circumstances of hospitals located in Alaska and Hawaii," *see id.* § 1395ww(d)(5)(H).

The provision at issue in this case, § 1395ww(d)(5)(I)(i), is a catch-all provision that the Court of Appeals has described as a "broad-spectrum grant of authority." *Adirondack*, 740 F.3d at 694. The provision states:

> The 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). According to the Secretary, this "exceptions and adjustments" provision unambiguously authorizes her to effect an across-the-board 0.2 percent reduction to the standardized amount, the hospital-specific rates, and the Puerto Rico-specific rate. In the Secretary's view, if Congress did not intend to include such adjustments in § 1395ww(d)(5)(I)(ii)'s "broad-spectrum grant of authority," *see* 740 F.3d at 694, it would have included express language to that effect, *see* Dkt. 35 at 11 ("nothing in the statute precludes the Secretary from making an across-the-board adjustment").

Plaintiffs, for their part, argue that this provision does not authorize the Secretary to make an across-the-board reduction by adjusting the standardized amount. They concede that § 1395ww(d)(5)(I)(i) does not expressly exclude adjustments to the standardized amount, but argue that the Secretary errs by reading § 1395ww(d)(5)(I)(i) in isolation. *See* Dkt. 17-1 at 20-26; Dkt. 15 at 34-35; Dkt. 18-1 at 22-27. They point out that other provisions in § 1395ww(d)(5) only authorize the Secretary to adjust reimbursement rates in unique circumstances or to avoid disproportionately affecting certain kinds of hospitals. Thus, they argue, basic tenets of statutory interpretation compel the conclusion that the general exceptions and adjustments provision does not confer the sweeping authority that the Secretary invoked here. Plaintiffs further argue that to the extent the statutory language is ambiguous, the Secretary's broad interpretation is irreconcilable with the rest of the Medicare Act's inpatient payment scheme, because it enables her to override the mandatory payment-setting framework established in § 1395ww(d)(3). For these reasons, they argue that the Act, read as a whole, unambiguously does *not* authorize the challenged 0.2 percent reduction.

In reviewing the Secretary's interpretation of the Medicare Act, the Court follows the two-step framework set forth in *Chevron, U.S.A., Inc. v. Nat'l Res. Defense Council*, 467 U.S.

837, 842-45 (1984), *see, e.g.*, *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203 (D.C. Cir. 2011), and first asks "whether Congress has directly spoken to the precise question at issue," *Chevron*, 467 U.S. at 842. If so, the Court must "give effect to the unambiguously expressed intent of Congress." *Id.* at 843. If the statute is "silent or ambiguous with respect to the specific issue," the Court next asks "whether the agency's answer is based on a permissible construction of the statute." *Id.*

1. *Whether The "Exceptions And Adjustments" Provision Is Ambiguous*

"In evaluating the first *Chevron* inquiry, [courts] use 'traditional tools of statutory construction' to determine whether Congress has unambiguously expressed its intent." *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1319 (D.C. Cir. 1998) (quoting *Chevron*, 467 U.S. at 843 n.9). To this end, the Court looks to the statute as a whole, recognizing that "[t]he meaning—or ambiguity—of certain words or phrases may only become evident when placed in context." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 132 (2000)*; see also Cnty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1014 (D.C. Cir. 1999) ("Under *Chevron* step one, [courts] consider not only the language of the particular provision under scrutiny, but also the structure and context of the statutory scheme of which it is a part.") (quotation marks omitted).

The plain language of the general exceptions and adjustments provision is sweeping. As long as she acts by regulation, the Secretary is authorized to make "such other exceptions and adjustments to [the] payment amounts under this subsection as [she] deems appropriate." 42 U.S.C. § 1395ww(d)(5)(I)(i). Given its plain meaning, this language includes adjustments to the standardized amount: the standardized amount is a "payment amount[ ] under this subsection," *id.*, and it is evident that the word "adjustments" can describe modifications to the standardized amount, because Congress uses it that way elsewhere, *see* 42 U.S.C. §§ 1395ww(d)(5)(I)(ii),

1395ww(d)(3)(A)(vi). Although Congress spoke with particularity in defining the scope of other adjustments authorized by § 1395ww(d), including other adjustments to the standardized amount, *see id.* §§ 1395ww(d)(5)(I)(ii), 1395ww(d)(3)(A)(vi), the only limit contained in the general exceptions and adjustments provision is that the exception or adjustment must be "appropriate." The plain language of this provision thus supports the Secretary's contention that she has the authority to make the adjustments at issue here.

Notwithstanding this broad language, Plaintiffs contend that the Secretary's authority is more limited. In particular, they seek to turn the contrast between the broad language of § 1395ww(d)(5)(I)(i) and the more specific provisions elsewhere in the statute to their favor, arguing that limits on the Secretary's general exceptions and adjustments authority can—and should—be inferred from the very detail contained in these other provisions. In support of this contention, they first rely on the *ejusdem generis* canon, which posits 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." *Cement Kiln Recycling Coalition v. EPA*, 493 F.3d 207, 221 (D.C. Cir. 2007) (quotation marks and alterations omitted). They contend that *ejusdem generis* is applicable here because "[t]he provision for 'other exceptions and adjustments' in (d)(5)(I) follows a list of specific exceptions and adjustments that are enumerated in (d)(5)," and "[a]ll of these exceptions or adjustments relate to particular categories of hospitals or unique cases." Dkt. 17-1 at 22. For this reason, they argue, the "adjustments" authorized by § 1395ww(d)(5)(I)(i) must be similarly limited.

It is difficult to reconcile Plaintiffs' characterization of the general exceptions and adjustments authority as the final item on a list of specific terms with the actual hodgepodge of provisions gathered under the umbrella of § 1395ww(d)(5). Section 1395ww(d)(5) occupies

almost seven pages of the U.S. Code. It contains dozens of subparagraphs. It deals with subjects big and small. Not all the provisions in § 1395ww(d)(5) relate to unique circumstances or special types of hospitals; § 1395ww(d)(5)(E)(ii), for example, authorizes an "adjustment" of general applicability.[5] Other provisions do not speak to "adjustments" but, rather, authorize "additional payment[s]." *See* 42 U.S.C. § 1395ww(d)(5)(A)(i). The "[c]anons of construction," moreover, are merely "aids in the process of statutory construction, nothing more, nothing less." *Eagle-Picher Indus. v. United States EPA*, 759 F.2d 922, 927 n.6 (D.C. Cir. 1985). Here, the *ejusdem generis* canon reveals little, if anything, about congressional intent, and it certainly does not provide sufficient clarity to foreclose the Secretary's interpretation at *Chevron* step one. *See Chevron*, 467 U.S. at 842-43.

Second, and more persuasively, Plaintiffs rely on the canon against surplusage. But they still fail to show that Congress unambiguously foreclosed the Secretary's interpretation. *See id*. In particular, they argue that the Secretary's construction of the first clause of § 1395ww(d)(5)(I) renders the second clause meaningless. Added by Congress in 1994, *see* Pub. L. No. 103-432, tit. I, § 109, the second clause expressly confers on the Secretary the authority, when making adjustments for "transfer cases," to adjust the standardized amounts to achieve budget neutrality:

> (ii) In making adjustments under clause (i) for transfer cases (as defined by the Secretary) in a fiscal year, not taking in account the effect of subparagraph (J), the Secretary may make adjustments to each of the average standardized amounts determined under paragraph (3) 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.

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[5] Section 1395ww(d)(5)(E) provides that "(i) The Secretary shall estimate the amount of reimbursement made for services described in [§ 1395y(a)(14)] with respect to which payment was made . . . and . . . is no longer being made. (ii) The Secretary shall provide for an adjustment to the payment for subsection (d) hospitals in each fiscal year so as appropriately to reflect the net amount described in clause (i)." Section 1395y(a)(14) bars Medicare repayment for certain nonphysician services "which are furnished to an individual who is a patient of a hospital or critical access hospital by [another] entity."

42 U.S.C. § 1395ww(d)(5)(I)(ii). Plaintiffs argue that this clause would be superfluous, and the amendment adding it unnecessary, if the first clause already authorized adjustments to the standardized amounts to achieve budget neutrality. They urge a narrow construction of the first clause to avoid this anomalous result.

Although the parties do not cite to any legislative history that sheds light on Congress's intent in enacting the second clause of § 1395ww(d)(5)(I), the circumstances surrounding the amendment are consistent with—but do not compel—Plaintiffs' reading. Because a hospital discharge triggers eligibility for payments under the prospective payment system, the Medicare program was required to decide how to handle cases where a patient is transferred from one facility to another before the patient's final discharge. *See* Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1994 Rates, 58 Fed. Reg. 30222, 30244 (May 26, 1993) (proposed rule). In 1992 and 1993, the Prospective Payment Assessment Commission ("ProPAC") issued two reports to Congress that included recommendations regarding transfer cases. *See id.* at 30223, 30245. As relevant here, ProPAC recommended that the Secretary change the "flat per diem methodology" then in use, *id.* at 30245, and further "recommended that Congress provide authority to the Secretary to implement a graduated per diem in a budget neutral manner," *id.* In September 1993, the Secretary "noted" the ProPAC recommendation and stated that "we intend to seek that authority" from Congress. Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1994 Rates, 58 Fed. Reg. 46270, 46308 (Sept. 1, 1993) (final rule). Then, in 1994, the Secretary declined "to change the transfer payment methodology absent an offsetting savings provision," and noted that Congress had yet to act on the ProPAC recommendation. *See* Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal

Year 1995 Rates, 59 Fed. Reg. 45330, 45366 (Sept. 1, 1994). Subsequently, Congress enacted § 1395ww(d)(5)(I)(ii). *See* Pub. L. No. 103-432, tit. I, § 109 (Oct. 31, 1994). "In light of this authority," the Secretary then acted, explaining that the amendment "authorized [her] to make adjustments to the prospective payment system standardized amounts so that adjustments to the payment policy for transfer cases do not affect aggregate payments." *See* Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1996 Rates, 60 Fed. Reg. 45778, 45805 (Sept. 1, 1995) (final rule).

This history shows that the Secretary was not prepared to adopt a change in the methodology for calculating transfer payments, along with adjustments in the standardized amount to achieve budget neutrality, without specific congressional authorization. But nowhere along the way did the Secretary expressly disavow the authority that she now asserts under the first clause of § 1395ww(d)(5)(I), nor did Congress declare that the specific authority was required. In dealing with a massive program, where modest changes can affect hundreds of millions of dollars of federal expenditures, and where the success of the program turns on annual appropriations, it is not surprising that the Secretary would conclude that it was prudent—even if not legally required—to obtain the express approval of Congress before acting. The fact that she did so with respect to transfer payments, and the fact that Congress provided express authority, could mean that the general authority already provided in the first clause of § 1395ww(d)(5)(I) was insufficient—or it might not. As the Court of Appeals has recognized, "Congress . . . sometimes drafts provisions that appear duplicative of others simply, in Macbeth's words, 'to make assurance double sure.'" *Shook v. Dist. of Columbia Fin. Responsibility & Mgmt. Assistance Auth.*, 132 F.3d 775, 782 (D.C. Cir. 1998). And just as Congress might seek "to

clarify what might be doubtful," *id.* at 782, the Secretary might seek comfort that a consequential administrative decision will not prompt a congressional backlash or criticism.

The Court of Appeals' analysis of § 1395ww(d)(5)(I)(i) in *Adirondack Med. Ctr. v. Sebelius*, 740 F.3d 692 (D.C. Cir. 2014), is instructive. *Adirondack* also involved a challenge to the Secretary's use of her exceptions and adjustments authority. In that case, the Secretary made revisions to the DRG classification system and sought ways to offset the corresponding increases in aggregate payments. *See* 740 F.3d at 694-96; *see also, e.g.*, Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2001 Rates, 65 Fed. Reg. 47054, 47103 (Aug. 1, 2000). Congress expressly granted her the authority to make the needed offset by "adjust[ing] the average standardized amounts." *See* Pub. L. No. 106–554, § 301(e)(1) (Dec. 21, 2000); *codified at* 42 U.S.C. § 1395ww(d)(3)(A)(vi). But reducing only the standardized amounts would not have reduced payments to hospitals reimbursed based on hospital-specific rates. *See Adirondack*, 740 F.3d at 695-96. Resolving that "the fiscal pain" resulting from the changes to the DRG classification system "should be shared," *id.* at 694, the Secretary used her general adjustment authority under § 1395ww(d)(5)(I)(i) also to reduce the hospital-specific rates, thereby achieving an across-the-board reduction. *Id.* at 694-96.

Hospitals reimbursed pursuant to the hospital-specific rate sued, arguing that the Secretary exceeded her authority under § 1395ww(d)(5)(I)(i). They first argued that, under the *expressio unius* canon, the express grant of statutory authority to offset "the effect of . . . coding or classification changes" through adjustments to the *standardized amounts*, *id.* at 695 (quoting 42 U.S.C. § 1395ww(d)(3)(A)(vi)), impliedly precluded the use of the Secretary's general (d)(5)(I)(i) authority to adjust the *hospital-specific rate* for the same purpose, *see id.* at 697. The Court of Appeals disagreed. The Court held that "the once-obscure grant of authority in

§ 1395ww(d)(5)(I)(i)" is ambiguous, and it thus deferred to the Secretary's interpretation. *Id.* at 696-99, 701. In reaching this conclusion, the Court of Appeals recognized that, as here, the plaintiffs' constrained interpretation of § 1395ww(d)(5)(I)(i) "may be a reasonable reading of the statute." *Id.* at 697. But the Court also recognized that a "reasonable" construction of a statute, standing alone, is not enough to thwart an agency at *Chevron* step one. *Id*. Even more importantly for present purposes, the Court also held that the application of the *expressio unius* canon "offers too thin a reed to support the conclusion that Congress has clearly resolved an issue." *Id.* (quotation marks omitted). It is, in the words of an earlier opinion from the Court of Appeals, a "feeble helper in an administrative setting, where Congress is presumed to have left to reasonable agency discretion questions that it has not directly resolved." *Id.* (quoting *Cheney R.R. Co. v. ICC*, 902 F.2d 66, 68-69 (D.C. Cir. 1990)). "And when countervailed," as here, "by a broad grant of authority contained within the same statutory scheme, the canon is a poor indicator of Congress' intent." *Id.*

Adirondack goes on, moreover, to offer guidance directly responsive to the Plaintiffs' surplusage argument. As Plaintiffs do here, the *Adirondack* plaintiffs argued that the Secretary's broad construction of § 1395ww(d)(5)(I)(i) rendered other "parts of the statutory scheme . . . meaningless excess." *Id.* at 699. Again, the Court of Appeals rejected the plaintiffs' contention, concluding that "[t]he surplusage canon is neither inviolable nor insurmountable," especially "when agency authority is at stake." *Id.* at 699. This conclusion, moreover, is particularly true when some surplusage will remain under either of the competing interpretations. *Id.* at 699. Because Congress may simply have intended "to clarify—not once, but twice—what the Secretary was permitted to do," the Court of Appeals, "[a]t the very least, . . . remain[ed] unconvinced the statutory scheme [was] unambiguous in evincing Congress' intent." *Id.* at 700.

A similar conclusion follows here. The Court of Appeals has not only held that § 1395ww(d)(5)(I)(i) is ambiguous, it has approved the same kind of broad construction that the Secretary defends here, and it has rejected arguments that—if not identical—are indistinguishable from those Plaintiffs now make. In short, the plain language of § 1395ww(d)(5)(I)(i) grants the Secretary broad discretion to make exceptions and adjustments as she "deems appropriate." Although various canons of interpretation may support a constrained reading of this authority, Plaintiffs offer no construction of the provision that would avoid all redundancy in the statute, and the Court of Appeals has held that, in this context, the canons offer little basis for rejecting the presumption that Congress has left the administrative agency with discretion to read the provision more broadly. *Id.* at 697-99. As in *Adirondack*, the Court, accordingly, concludes that the language is "[a]t the very least" ambiguous for purposes of *Chevron* step one. *Id.* at 700.

The Court also concludes that the scant legislative history cited by the parties is equivocal. As originally enacted in 1983, the general exceptions and adjustments provision stated:

> The Secretary shall provide by regulation for such other exceptions and adjustments to such payment amounts under this subsection 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).

Pub. L. No. 98-21, tit. VI, § 601, 97 Stat. 158 (originally codified as 42 U.S.C. § 1395ww(d)(5)(C)(iii)). The accompanying conference report explains that the conference agreement followed the House bill, which authorized "such exceptions and adjustments as [the Secretary] deems appropriate (including those that may be appropriate with respect to public and teaching hospitals and hospitals involved extensively in treatment for, and research on, cancer),"

but omitted "the requirement with respect to public and teaching hospitals," H.R. Rep. No. 98-47, 195 (Conf. Rep.). The conference report states that "[t]he conferees wish to make it clear that this authority permits the Secretary to provide for such exceptions and adjustments as may be appropriate with respect to hospitals experiencing special problems because of their location in a particular census division." *Id.* The report thus indicates that the conferees expected the Secretary to use her authority to address payment disparities affecting certain kinds of hospitals, e.g., cancer hospitals, *see id.*; but it does not indicate that the conferees intended to restrict her authority to that circumstance.

The parenthetical relating to cancer hospitals was deleted in 1989, when cancer hospitals were removed from the prospective payment system. *See* Pub. L. No. 101-239, tit. VI, § 6004, 103 Stat. 2159. The Secretary argues that this amendment had, if anything, a broadening effect, but because the amendment did not reflect legislative attention to the scope of the Secretary's adjustments authority, it does not cut either way.

Congress has also added provisions expressly authorizing adjustments to the standardized amounts. For example, as discussed above, in 1984 Congress provided the Secretary with authority to adjust the standardized amounts to offset transfer-related costs, *see* § 1395ww(d)(5)(I)(ii), and in 2000, Congress provided the Secretary with authority to adjust the standardized amounts to offset changes to the DRG classification system, *see* § 1395ww(d)(3)(A)(vi). But the legislative and administrative materials cited by the parties do not explain why the Secretary concluded that she needed express legislative authority to make these offsets, nor is it clear that Congress enacted these provisions on the understanding that the Secretary's general adjustment authority did not authorize her to adjust the standardized amounts. Plaintiffs are correct that the Secretary has previously used her authority under

§ 1395ww(d)(5)(I)(i) only for targeted adjustments. *See, e.g.*, Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2005 Rates, 69 Fed. Reg. 48916, 49106-49108 (Aug. 11, 2004) (adjusting wage index assignments in light of "unique and temporary" circumstances adversely affecting small community hospitals). They cite no case, however, holding that a "broad-spectrum grant of authority" atrophies merely because it goes unused. *See Adirondack,* 740 F.3d at 694, 695-96.

Accordingly, as the Court of Appeals held in *Adirondack*, *see* 740 F.3d at 700-01, the Court concludes that the general exceptions and adjustments provision is ambiguous with respect to whether it provides a broad grant of authority untethered from the more specific provisions of § 1395ww(d)(5), and thus proceeds to *Chevron*'s second step. *See id.*; *see, e.g.*, *Regions Hosp. v. Shalala*, 522 U.S. 448, 460 (1998) ("Because the Hospital's construction is not an inevitable one, we turn to the Secretary's position, examining its reasonableness as an interpretation of the governing legislation.").

Finally, the St. Helena and Bakersfield Plaintiffs separately contend that the Secretary exceeded her statutory authority under 42 U.S.C. § 1395ww(g) when she reduced the national capital Federal rate and Puerto Rico-specific capital rate by 0.2 percent. *See* Dkt. 18-1 at 29-30; Dkt. 15 at 34-35; *see also* 78 Fed. Reg. at 27651, 50746. Section 1395ww(g), like § 1395ww(d)(5)(I)(i), authorizes certain "exceptions" and "adjustment[s]," but the two provisions are not identical. The St. Helena Plaintiffs' opening brief does not explain why the text of § 1395ww(g) compels their reading, *see* Dkt. 18-1 at 29-30, and the Bakersfield Plaintiffs' opening brief does not analyze the text of § 1395ww(g) at all, *see* Dkt. 15 at 34-35. The Secretary's briefing also fails to grapple with this question. *See* Dkt. 23-1 at n.5, Dkt. 35 at 18-19. The Court thus concludes that this issue is not sufficiently briefed to permit resolution at

this time. Accordingly, to the extent Plaintiffs raise an independent challenge to the Secretary's reduction of the capital rates, the parties' motions are denied without prejudice.[6]

2. *Whether The Secretary's Interpretation Is Reasonable*

At *Chevron*'s second step the question for the reviewing court is whether the agency's interpretation is a reasonable one. The court, accordingly, will "uphold the Secretary's judgment as long as it is a permissible construction of the statute, even if it differs from how the court would have interpreted the statute in the absence of an agency regulation." *Sebelius v. Auburn Reg'l Med. Ctr.*, 133 S. Ct. 817, 826-27 (2013). "[G]iven the tremendous complexity of the Medicare statute," moreover, courts "accord particular deference to the Secretary's interpretation" of the statute's detailed provisions. *Cnty. of Los Angeles*, 192 F.3d at 1014. According to Plaintiffs, however, that usual deference is unwarranted here, because the Secretary has purportedly abandoned the "more limited interpretation of . . . § 1395ww(d)(5)(I)" that she espoused in prior rulemakings. Dkt. 17-1 at 27, *see also* Dkt. 27 at 10-13. The Court disagrees.

An agency is "not estopped from changing" its interpretation of a statute. *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417 (1993); *see also Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1207-09 (2015). When it does so, however, the reviewing court should consider that change in position as "a factor in assessing the weight that" the agency's new position is due. *Good Samaritan Hosp.*, 508 U.S. at 417. At times, the change may require that the court accord the new interpretation "considerably less deference than a consistently held agency view." *Thomas Jefferson Univ.*, 512 U.S. 504, 515 (1994) (quotation marks and citation

[6] Should the parties seek to revisit this issue, they should address whether such a challenge is properly before the Court. *See* 78 Fed. Reg. at 50746 (final rule, stating that the Secretary "did not receive any comments that specifically addressed [her] proposal to make the -0.2 percent adjustment to the national capital Federal rate and Puerto Rico specific capital rate" during the rulemaking).

omitted). But, this proviso is not absolute, and its application turns on "the facts of individual cases." *Good Samaritan Hosp.*, 508 U.S. at 417.

Here, the Court concludes that the prior occasions when the Secretary declined to rely on her general adjustment and exception authority, and where she, instead, waited for specific congressional authorization to act, do not undercut her current claim to deference. First, unlike the cases on which they rely, Plaintiffs have not identified any prior actions in which the Secretary expressly interpreted or applied § 1395ww(d)(5)(I) in a manner that conflicts with her current reading. It is true, as discussed above, that she has previously declined to rely on that provision where, under her current reading, she might have invoked it. But the fact that the Secretary, at one time, "expressed doubts about [her] ability to" make adjustments without specific legislative authority to do so does not mean that a later, expansive construction of her general adjustment authority is not entitled to deference. *Adirondack*, 740 F.3d at 698. That is particularly true in this context, since the Secretary never expressly construed § 1395ww(d)(5)(I)(i) in a manner inconsistent with her current reading.

Plaintiffs invoke *Dillmon v. Nat'l Transp. Safety Bd.*, 588 F.3d 1085, 1089-90 (D.C. Cir. 2009), where the Court of Appeals held that an agency must explain its changed interpretation in order "to ensure [that] the agency's 'prior policies and standards are being deliberately changed, not casually ignored.'" *see* Dkt. 17-1 at 27. And they assert, correctly, that an agency may not "'depart from a prior policy *sub silentio*, or simply disregard rules that are still on the books.'" *Dillmon*, 588 F.3d at 1089 (quoting *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515 (2009)). Here, however, it is far from clear that the Secretary previously articulated a policy or interpretation from which she now departs. There certainly was no reasoned explanation of how the Secretary construed § 1395ww(d)(5)(I)(i) or why she read the statute in that manner. Indeed,

the Secretary made no mention whatsoever of § 1395ww(d)(5)(I)(i) in the administrative actions on which Plaintiffs rely. Those actions, accordingly, hardly represent the type of established administrative policy that requires some justification to discard. *See, e.g.*, *Dillmon*, 588 at 1089-90; *King Broad. Co. v. FCC*, 860 F.2d 465, 470 (D.C. Cir. 1988) (refusing to defer to an interpretation that could not be reconciled with the agency's prior interpretation of the same provision); *Northpoint Tech., Ltd. v. FCC*, 412 F.3d 145, 152-56 (D.C. Cir. 2005) (refusing to defer to an interpretation that could not be reconciled with "prior [agency] policy and practice").

Plaintiffs further argue that, even if entitled to deference, the Secretary's use of her adjustment authority to adopt "an across-the-board reduction" cannot be reconciled with the overall statutory scheme. *See, e.g.*, Dkt. 17-1 at 30. They argue that "the Secretary has made no attempt to explain how this system wide payment reduction serves *any* statutory purposes, rendering her interpretation unreasonable." *Id.* (emphasis added). This contention, however, merely repeats the arguments already rejected at *Chevron* step one—and, for that matter, already rejected in *Adirondack*, 740 F.3d at 700. It is true that the Secretary's reading of § 1395ww(d)(5)(I)(i) invites overlap with other portions of § 1395ww(d)(5). But a general exception or waiver authority, by its nature, will always—or will frequently—overlap with more specific authorities. At least in the context of § 1395ww(d)(5), the Court of Appeals has already opined that such "superfluity" is not unreasonable. 740 F.3d at 699-700; *cf. Adirondack Med. Ctr. v. Burwell*, 782 F.3d 707, 710 (D.C. Cir. 2015) (per curiam) (concluding that an "adjust[ment to] the hospital-specific rates" was not arbitrary and capricious because "the Secretary reasonably chose to achieve budget neutrality pursuant to a method that spreads the cost of budget neutrality fairly between . . . hospitals"). And, even if the overall structure of the Medicare Act and § 1395ww(d)(5) might be read implicitly to limit this broad grant of authority,

the Secretary's decision to give the expansive language of § 1395ww(d)(5)(I)(i) its plain meaning cannot be described as "unreasonable."

Plaintiffs also argue that the 0.2 percent reduction effectively negates payment for the additional inpatients that hospitals are expected to treat and that this violates the Medicare Act. *See, e.g.*, Dkt. 17-1 at 23-24. In this respect, Plaintiffs argue that this case is unlike *Adirondack*, which involved the Secretary's effort to address an "artificial" increase in payments to hospitals. 740 F.3d at 700. The Secretary correctly responds that nothing in the final rule departs from the per-discharge structure of the payment scheme—providers are paid for each patient treated and discharged, and providers who treat additional inpatients are reimbursed pursuant to the inpatient prospective payment system. *See* Dkt. 23-1 at 25-27. It is, of course, possible that the 0.2 percent reduction does deny providers reimbursement in the aggregate for the additional inpatient stays. But, Plaintiffs point to no evidence in the record supporting actual increased provider costs, and, in any event, to the extent those additional costs exist, they are shared across the inpatient prospective payment system. As a result, the 0.2 percent reduction does not differ in application from the numerous other adjustments made to the standardized rate. The Secretary's use of her general exceptions and adjustments authority in this manner may be unusual, but it is not unreasonable.

Finally, Plaintiffs argue with some force that any interpretation of the Act that grants the Secretary unfettered adjustment authority would conflict with the overall statutory scheme. The Court agrees that the "exceptions and adjustments" provision does not give the Secretary *carte blanche* to override the rest of the Act. The Court is not persuaded, however, that the reduction at issue in this case raises that concern. *Cf. Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1224 (D.C. Cir. 1993) (holding that "[t]he Secretary may" invoke her exceptions and

adjustments authority to "vary the definition" of "urban areas" under the prospective payment system, even though it was possible to "hypothesize forms of regulatory amendments that could be thought unreasonable in light of the statute"). In *Amgen Inc. v. Smith*, for example, the Court of Appeals held that an "adjustment . . . involving only the payment amount for a single drug[ ] does not work 'basic and fundamental changes in the scheme' Congress created in the Medicare Act." 357 F.3d 103, 118 (D.C. Cir. 2004) (quoting *MCI Telecomm. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994)). The Court of Appeals reasoned that "the statutory requirement that the Secretary 'shall' develop certain aspects of the payment system is qualified by the Secretary's authority to 'adjust[ ]' those payment amounts." *Id.* (modifications in original) (quoting 42 U.S.C. §§ 1395*l*(t)(2)(E), 1395*l*(t)(12)(A)). It cautioned that "a more substantial departure from the default amounts would, at some point, violate the Secretary's obligation to make such payments *and cease to be an adjustment*[ ]," but concluded that it had "no occasion" to draw that line. *Id.* (emphasis added).

The same is true here. Nothing in this case requires the Court "to engage in line drawing to determine when 'adjustments' cease being 'adjustments.'" *Amgen*, 357 F.3d at 117. The challenged 0.2 percent reduction, which is smaller than the 2.9 percent reduction upheld in *Adirondack*, *see* 740 F.3d at 700, does not present a fundamental conflict with the Act's inpatient prospective payment scheme. For present purposes, it therefore suffices to conclude that the Secretary's interpretation of the exceptions and adjustments provision is a reasonable one.

B. APA Challenges To The 0.2 Percent Reduction

Plaintiffs further argue that, even if the Secretary had the statutory authority to make the across-the-board 0.2 percent reduction, the process she employed was riddled with procedural and other errors. As already discussed, the Secretary estimated that the new 2-midnight rule

would result in a net shift of 40,000 cases to inpatient status in fiscal year 2014, at a cost of $220 million. On this basis, she adjusted the standardized amount, the hospital-specific rates, and the Puerto Rico-specific standardized amount downward by 0.2 percent, effecting an across-the-board 0.2 percent reduction to compensation for inpatient services. *See* 78 Fed. Reg. at 50746. Plaintiffs contend that the notice of proposed rulemaking omitted important information about the Secretary's methodology, thereby depriving them of a meaningful opportunity to comment. They further argue that the Secretary failed to provide a reasoned response to the relevant comments that they were able to make and that the final rule fails to provide a sufficient explanation for the agency's action.[7] Plaintiffs also argue that the 0.2 percent reduction is arbitrary and capricious and, that it violates the Medicare Act's requirement that an adjustment be promulgated as a "regulation."

Pursuant to the Medicare Act, 42 U.S.C. § 1395oo(f)(1), this Court reviews the Secretary's action under the familiar provisions of the APA, 5 U.S.C. § 706(2)(A). The APA, in turn, requires an agency to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made."

[7] The Medicare Act includes several budget neutrality provisions, *see, e.g.*, 42 U.S.C. §§ 1395ww(d)(8)(D), 1395ww(d)(4)(C)(iii), 1395*l*(t)(2)(E), and the Court of Appeals has held that the Secretary has "wide discretion" to invoke her exceptions and adjustments authority, *see Adirondack Med. Ctr.*, 782 F.3d at 709-11. The Secretary concedes that none of the Act's budget neutrality provisions required her to offset the added costs of the 2-midnight rule, *see* Dkt. 43 at 18-19, but argues that the offset was appropriate in light of Congress' general preference for budget-neutral Medicare rule changes and in the interests of sound management of the public fisc. In their supplemental briefs, Plaintiffs argue that the rate reduction is arbitrary because "no statutory authority exists here for true budget neutrality." *See* Dkt. 44 at 3-4. But to the extent Plaintiffs raised a similar argument in their opening briefs, it was in relation to the interpretation of the Secretary's adjustment authority under § 1395ww(d)(5)(I)(i), not Plaintiffs' substantive APA challenge, *see, e.g.*, Dkt. 17-1 at 23-24, 27-29. Accordingly, this argument is not properly presented. *See, e.g.*, *New York v. EPA*, 413 F.3d 3, 20 (D.C. Cir. 2005) (argument not raised in opening brief is waived).

Dist. Hosp. Partners, L.P. v. Burwell, 786 F.3d 46, 56-57 (D.C. Cir. 2015) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)) (emphasis omitted). The agency must also provide the public with a meaningful opportunity to comment on a proposed rule and must offer reasoned responses to significant comments. *Id.*; *Connecticut Light & Power Co. v. Nuclear Reg. Comm.*, 673 F.2d 525, 528, 530 (D.C. Cir. 1982). Here, all agree that the basis for the challenged 0.2 percent reduction was the predicted shift of 40,000 stays to inpatient status in fiscal year 2014, at an estimated cost of $220 million. The actuarial basis for this prediction, and the extent to which the Secretary was required to disclose and explain the underlying assumptions, however, are subject to substantial dispute.

As explained below, the Court agrees with Plaintiffs that the Secretary did not provide sufficient notice of the actuarial assumptions and methodology she employed and that disclosure of this information was essential to communicate the basis for the proposed adjustments and to permit meaningful public comment. The Court further concludes that this error was not harmless. Finally, in light of these conclusions, the Court determines that it need not reach Plaintiffs' remaining challenges.

1. *Opportunity For Meaningful Notice And Comment*

"The APA sets forth several steps an agency must take when engaged in rulemaking: it must publish a general notice of proposed rulemaking in the Federal Register; give an opportunity for interested persons to participate in the rulemaking through submission of written data, views, or arguments; and issue publication of a concise general statement of the rule's basis and purpose." *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 95 (D.C. Cir. 2002). "[T]he opportunity for interested parties to participate in a meaningful way in the discussion and final formulation of rules" is a "particularly important component" of this process. *Connecticut*

Light & Power, 673 F.2d at 528. "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. 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. As a result, the agency may operate with a one-sided or mistaken picture of the issues at stake in a rule-making." *Id.* at 530.

Given the APA's requirement that an agency "examine the relevant data and articulate a satisfactory explanation for its action," *see Dist. Hosp. Partners*, 786 F.3d at 56-57 (quotation marks, citation, and emphasis omitted), "it is especially important for the agency to identify and make available technical studies and data that it has employed" prior to the comment period, *see Connecticut Light & Power*, 673 F.2d at 530. "[A]n agency cannot rest a rule on data that, in critical degree, is known only to the agency." *Time Warner Entm't Co., L.P. v. FCC*, 240 F.3d 1126, 1140 (D.C. Cir. 2001) (quotation marks, citation, and alterations omitted). Rather, "'[t]he most critical factual material that is used to support the agency's position on review must have been made public in the proceeding and exposed to refutation.'" *Owner-Operator Indep. Drivers v. FMCSA*, 494 F.3d 188, 199 (D.C. Cir. 2007) (quoting *Ass'n of Data Processing Serv. Orgs. v. Bd. of Governors of the Fed. Reserve Sys.*, 745 F.2d 677, 684 (D.C. Cir. 1984)) (emphasis omitted); *see also Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 237 (D.C. Cir. 2008); *Wisconsin Power & Light Co. v. FERC*, 363 F.3d 453, 463 (D.C. Cir. 2004).

The "critical factual material" that the agency must disclose and "expose[ ] to refutation" includes the models and methodology used by an agency to support its action. *See Owner-Operator Indep. Drivers*, 494 F.3d at 199, 201. In *Owner-Operator Independent Drivers*, the

Court of Appeals invalidated a final rule because the agency had failed to disclose "the model and methodology" it used "to determine the benefits and costs of [the] regulatory options." 494 F.3d at 201. As the Court of Appeals explained, "because the output of that model was central to [the agency's] decision to adopt the [final] [r]ule . . . [,] the model and its methodology were unquestionably among the most critical factual material that was used to support the agency's position." 494 F.3d at 201 (quotation marks, citation and alterations omitted); *see also Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 535 (D.C. Cir. 1983) (where an agency chooses to use a predictive model, it "must explain the assumptions and methodology used in preparing the model and, if the methodology is challenged, must provide a complete analytic defense.") (quotation marks and citation omitted).

Borrowing a metaphor from the Court of Appeals, Plaintiffs contend that the Secretary engaged in a game of "hunt the peanut" by failing to disclose critical aspects of her methodology until after the comment period. *See* Dkt. 16 at 24 (quoting *Connecticut Light & Power*, 673 F.2d at 530); *see also* Dkt. 19-1 at 26, Dkt. 18-1 at 33. In particular, they contend that she failed to reveal key assumptions applied by the HHS actuaries in concluding that the change from the 24-hour rule to the 2-midnight rule would actually increase the number of inpatient stays, and that it would do so by 40,000 stays in fiscal year 2014. Most significantly, according to Plaintiffs, *see* Dkt. 16 at 24; Dkt. 19-1 at 19; Dkt. 18-1 at 31-33, it was not until the final rule was announced that the Secretary disclosed that (1) in estimating the number of "encounters" that would likely shift from outpatient to inpatient status, the actuaries examined only "outpatient claims for observation or a major procedure," and (2) in estimating the number of "encounters" likely to shift from inpatient to outpatient status, the actuaries examined only "claims containing a surgical MS-DRG." 78 Fed. Reg. at 50,953. Plaintiffs contend that these methodological steps

were both unjustifiable and consequential. The decision to consider only *surgical* MS-DRGs when estimating the number of cases predicted to move to outpatient status, and thus the exclusion of *medical* MS-DRGs, eliminated "hundreds of thousands of cases that could potentially shift from inpatient to outpatient" from the Secretary's analysis. Dkt. 16 at 31. According to Plaintiffs, approximately "half of the roughly 1.5 million short stays involve medical MS-DRGs," and "five medical MS-DRGs alone . . . represent nearly 160,000 short stay cases." *Id.* at 30. Many of the excluded stays, moreover, were short and thus likely to be classified as outpatient stays under the new rule. "The medical MS-DRG for chest pain, for example, has an average length of stay of 1.8 days." Dkt. 19-1 at 17. Plaintiffs argue that because these assumptions were not revealed prior to the close of the notice and comment period, "hospitals and other stakeholders—including Plaintiffs—could not meaningfully critique the actuaries' estimates or attempt to reproduce or assess the reliability of CMS's results." Dkt. 16 at 23; *see also* Dkt. 19-1 at 19.

The Court agrees that the Secretary's failure to disclose the critical assumptions relied upon by the HHS actuaries deprived Plaintiffs and other members of the public of a meaningful opportunity to comment on the proposed 0.2 percent reduction. The undisclosed information was central to the analysis that led to the Secretary's conclusion that 40,000 discharges would shift to inpatient status in 2014, and, without that information, commenters had no basis to understand or to critique the Secretary's conclusion.

In the final rule, the Secretary asserted that the proposed rule "specifically discussed the methodology used and the components of the estimate." 78 Fed. Reg. at 50953. That is incorrect. The proposed rule stated only that the Secretary analyzed "FY 2009 through FY 2011 Medicare claims data for extended hospital outpatient encounters and shorter stay hospital

inpatient encounters." 78 Fed. Reg. at 27649. That was far from sufficient to permit meaningful comment on the actuarial predictions or to put the public on notice of the basis for the proposed adjustments. Where an agency disregards a significant portion of the information on which it claims to have based its analysis, the APA requires *some* disclosure and explanation. *Cf. Dist. Hosp. Partners*, 786 F.3d at 56-57 ("If an agency fails to examine the relevant data . . . it has failed to comply with the APA.").

Even accepting the fact that she did not disclose the key assumptions applied by the actuaries, the Secretary contends that the proposed rule satisfied APA standards because interested parties had access to all of the information that, in her view, they needed. In particular, the notice of proposed rulemaking identified the data set the Secretary used in her analysis—"FY 2009 through FY 2011 Medicare claims data for extended hospital outpatient encounters and shorter stay hospital inpatient encounters," 78 Fed. Reg. at 27649—and this data set was publicly available, *see* Dkt. 23-1 at 38-39. Thus, she argues, interested parties could perform their own analyses of the same data and, to the extent they obtained different results, submit comments to that effect. *See, e.g.*, AR 4653-4655.

The Secretary is correct that an agency is not invariably required to disclose information on which it relies, at least as long as the public already has that information. In *Connecticut Light & Power*, 673 F.2d at 532, for example, the Court of Appeals concluded that a notice of proposed rulemaking passed muster—although only barely so—even though it failed to disclose information upon which the agency relied. This was because the undisclosed information included studies that "had already been subject to widespread public comment" and because the commenters were aware "of problems that had recurred in plant after plant and of reports that had been publicly filed." *Id.* at 531-32. Given that the "rule-making process took place against a

background of five years during which the Commission explored safety proposals in a public forum and exposed the important technical studies to adversarial comment," the Court of Appeals held that, although "it would have been better practice for the [agency] to have identified these technical materials specifically in the notice of proposed rule-making," "the technical background of the rules was sufficiently identified to allow for meaningful comment during the rule-making process." *Id.*

The circumstances here, however, are very different. Plaintiffs are not arguing that the Secretary needed to disclose the publicly available Medicare claims data the actuaries used in their analysis. They are arguing that she was required to disclose what the actuaries did with that data. It is that deficiency that precluded meaningful public comment, and, unlike in *Connecticut Light & Power*, the Secretary offers no reason to believe that commenters had any idea what the actuaries did. Indeed, at least one commenter endeavored—without success—to recreate the Secretary's conclusions. *See* AR 4653-4655; *see also* AR 4411 (observing that "it has not been possible to replicate the [Secretary's] finding[s]"), AR 5235 (similar). Under these circumstances, public access to the underlying data does not save the rule.

Nor does public awareness regarding the longstanding agency concern about inpatient admissions alter this result. The Secretary, for example, points to discussion contained in the proposed rule itself, the Secretary's 2012 request for comment on inpatient admissions, and a 2013 report by the HHS Office of Inspector General addressing "Hospitals' Use of Observation Stays and Short Inpatient Stays."[8] Although the public may have been aware of the various

[8] The Secretary concedes that the Inspector General report was not published until after the comment period had already closed, *see* Dkt. 35 at 23 n.6, but argues that it represents "further evidence of her very public study of the systemic nature of the issue of hospital inpatient determinations," *id.* (quotation marks omitted).

considerations that prompted the Secretary to propose the 2-midnight rule, the basis for that rule is not the question. The question is whether the public was aware of the methodology the HHS actuaries used to predict the effects of that policy. And that is where the Secretary's argument falls short.

At oral argument, counsel for the Secretary argued for the first time that it should have been "self-evident" that the medical MS-DRG cases would be unaffected by the new rule and, accordingly, could be excluded. *See* Dkt. 40 at 38-41. Given the ample evidence that interested parties did not find that assumption self-evident, *see* AR 4653-4655; 4883-4884; 4411; 5010; 5235; 5672, the Court is not persuaded. This is not a case where a "decision of less than ideal clarity" may be upheld because "the agency's path may reasonably be discerned." *State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43. To the contrary, there is no hint of this "self-evident" rationale in the administrative record—or elsewhere.

The Secretary also argues that "the APA does not impose . . . the obligation to explain every element of her actuaries' analysis," down to "every last detail and all granular considerations of the actuaries' calculations." Dkt. 35 at 22-23 (citing *Combs v. Classic Coal Corp.*, 931 F.2d 96, 99-100 (D.C. Cir. 1991)). Maybe so, but the APA does require the disclosure of assumptions critical to the agency's decision, in order to facilitate meaningful comment and allow a "genuine interchange" of views. *See Connecticut Light & Power*, 673 F.2d at 530. Here, neither Plaintiffs nor other members of the public ever had an opportunity to offer meaningful comments on the Secretary's proposal, and thus the 0.2 percent reduction that the Secretary proposed, and ultimately adopted, fails to pass muster under the APA.

2. *Harmless Error*

The Secretary further argues that any flaw in the notice and comment process was "harmless" and that, accordingly, the rule should be sustained under the prejudicial-error doctrine. The Secretary is correct that the APA "instructs reviewing courts to take 'due account . . . of the rule of prejudicial error.'" *PDK Labs. Inc. v. DEA*, 362 F.3d 786, 799 (D.C. Cir. 2004) (quoting 5 U.S.C. § 706). As a general matter, however, the Court of Appeals has "not been hospitable to government claims of harmless error in cases" involving a failure of notice and comment. *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1109 (D.C. Cir. 2014). Merely "technical" failures with respect to notice and comment may be harmless, *see Sugar Cane Growers*, 289 F.3d at 96; *United States Telecom Ass'n v. FCC*, 400 F.3d 29, 40-41 (D.C. Cir. 2005) (holding that even if the mislabeling of a published notice violated the APA, that violation was harmless), while "an utter failure to comply with notice and comment cannot be considered harmless if there is any uncertainty at all as to the effect of that failure," *Sugar Cane Growers*, 289 F.3d at 96. Here, the question is whether Plaintiffs have "show[n] that an opportunity to comment regarding an agency's important information created 'enough uncertainty' as to its possible effect on the agency's disposition." *Allina Health Servs.*, 746 F.3d at 1110 (quoting *Chamber of Commerce v. SEC*, 443 F.3d 890, 904-06 (D.C. Cir. 2006)). There is no doubt that they have made this showing.

Although this case does not involve an "utter failure" to provide notice and an opportunity for comment, *see Sugar Cane Growers*, 289 F.3d at 96, it does involve a significant defect. The 0.2 percent reduction was the product of the Secretary's conclusion that the 2-midnight rule would result in an increase of 40,000 inpatient stays. Until the actuarial assumptions were disclosed, however, the Secretary's thought process was a black box—and

even then, her analysis was not fully explained. The Secretary, once again, insists that her "alleged failure to disclose additional details about her actuaries' estimates" "did not preclude the submission of comments" on those estimates. Dkt. 23-1 at 46. But there is a vast difference between announcing a conclusion and articulating the reasons for that conclusion. One can disagree with a conclusion, but, absent some insight into how the conclusion was reached, it is not possible to explain where and why the agency went wrong.

To the extent the Secretary argues that her undisclosed assumptions made no difference to the outcome, the Court also disagrees. The assumptions the HHS actuaries applied substantially curtailed the universe of hospital stays the Secretary considered and likely affected the outcome of the Secretary's analysis. The validity of those assumptions, moreover, is far from self-evident. Against this background, the Court cannot conclude that the Secretary's failure to provide the public with the opportunity to offer meaningful comment on the assumptions and methodology used to derive the 0.2 percent reduction was harmless.

To be clear, this is not to say that the Court has concluded that the Secretary's assumptions and methodology were unreasonable. Plaintiffs contend that the predicted increase in inpatient cases "defies reason" and "common sense" because it will be harder to satisfy the new 2-midnight benchmark than the old 24-hour benchmark. *See* Dkt. 29 at 18; Dkt. 15 at 32; Dkt. 17-1 at 35-36. That likely overstates their case. They ignore the fact, for example, that the increased predictability supplied by the 2-midnight presumption might lead to an increase in inpatient stays. The reasonableness of the Secretary's assumptions and methodology, however, is a question that should be considered first, if at all, on remand. For present purposes, it is sufficient to conclude that the Secretary's failure to provide an opportunity for meaningful comment "created enough uncertainty as to its possible effect on the agency's disposition,"

Allina Health Servs., 746 F.3d at 1110 (quotation marks omitted), to preclude reliance on the prejudicial-error doctrine. As in *Owner-Operator Independent Drivers*, 494 F.3d at 202, the Court has "no difficulty in concluding that the agency's failure to disclose the methodology of [its] model in time for comment was prejudicial."

3. *Remaining APA Challenges*

A number of Plaintiffs' other APA-style challenges are closely related to the Secretary's failure to provide an opportunity for meaningful comment on her actuarial assumptions. Plaintiffs argue, among other things, that after the Secretary unjustifiably excluded certain claims in estimating the outpatient-to-inpatient and inpatient-to-outpatient shift, she also made inappropriate comparisons of estimates based on different types of claims, failed to grapple with the uncertainties in her analysis, and improperly calculated the cost of the net increase in inpatient cases. Because commenters were not able to raise all these concerns in response to the deficient notice of proposed rulemaking, however, no administrative record was ever developed for the Court to review. Thus, the Court concludes that these arguments should be addressed, if at all, after further proceedings at the administrative level and an opportunity for additional comment.

Plaintiffs also contend that the Secretary failed to provide meaningful responses to the substantial comments they did make and that her final conclusions are not accompanied by a reasoned explanation of her methodology. In addition, they argue that the 0.2 percent reduction is invalid because it was announced in the preamble to the rule, and not in a separate "regulation." In light of the Court's conclusion that the Secretary failed to provide adequate notice of the underlying basis for the proposed reduction, and thereby deprived the public of a meaningful opportunity to comment on that proposal, it is unnecessary to reach these additional

grounds. The Secretary's decision and accompanying explanation may change on remand, and she will have an opportunity to address whatever comments are made, to explain whatever decision she reaches, and to decide whether to include any adjustment in the body of a regulation.

C. The Appropriate Remedy

There remains the question of appropriate remedy. Where a rule is adopted "without observance of procedure required by law," the APA directs that the court shall "hold unlawful and set aside [the] agency action." 5 U.S.C. § 706(2). Courts in this Circuit, however, have long recognized that "when equity demands, an unlawfully promulgated regulation can be left in place while the agency provides the proper procedural remedy."[9] *Fertilizer Institute v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991); *see, e.g., EME Homer City Generation, L.P. v. EPA*, No. 11-1302, 2015 WL 4528137, at *9 (D.C. Cir. July 28, 2015).

Although acknowledging this general rule, Plaintiffs contend that it has no application here, since the Court of Appeals has repeatedly held that "[f]ailure to provide the required notice and to invite public comment . . . is a fundamental flaw that 'normally' requires vacatur of the rule." *Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009) (citing *Sugar Cane Growers*, 289 F.3d at 97). That proposition, however, is not absolute. The Court of Appeals has, at times, remanded without vacatur despite a failure to provide adequate notice or opportunity for comment. *See Am. Radio Relay League, Inc.*, 524 F.3d at 242 (remanding for the agency to "afford a reasonable opportunity for public comment on the unredacted studies on

[9] Exceptions to this equitable doctrine do exist. 42 U.S.C. § 1395hh(a)(4), for example, states that if "a final regulation . . . is not a logical outgrowth of . . . a . . . notice . . . [it] shall not take effect," and the Court of Appeals has suggested in *dicta* that this provision requires vacatur. *See Allina Health Servs.*, 746 F.3d at 1111 n.5. This provision, however, is not applicable here.

which it relied in promulgating the rule, make the studies part of the rulemaking record, and provide a reasoned explanation of its choice"); *Am. Med. Ass'n v. Reno*, 57 F.3d 1129, 1135 & n.4 (D.C. Cir. 1995) ("Because the inadequately explained rules are imposing an immediate monetary burden on fee-payers, we assume that the agency will act with due haste to provide the requisite opportunity for meaningful comment and explanation.").

In the absence of a *per se* rule, the Court must turn to the standard articulated by the Court of Appeals in *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Commission*, 988 F.2d 146 (D.C. Cir. 1993); *see, e.g.*, *Heartland Reg'l Med. Ctr.*, 566 F.3d at 197-99; *Sugar Cane Growers*, 289 F.3d at 97. Although Plaintiffs question whether the *Allied-Signal* test should apply to rulemaking cases, *see* Dkt. 42 at 9 & n.2, the Court of Appeals has repeatedly applied that test in such cases, *see, e.g.*, *Sugar Cane Growers*, 289 F.3d at 97-98; *Chamber of Commerce*, 443 F.3d at 908. The inquiry will, of course, vary with context, but the starting point is the same. The Court, accordingly, must weigh (1) "the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and" (2) "the disruptive consequences of an interim change that may itself be changed." *Allied-Signal*, 988 F.2d at 150-51 (quotation marks and citation omitted).

1. *The Final Rule's Deficiencies*

The first *Allied-Signal* factor is "the seriousness of the [rule's] deficiencies (and thus the extent of doubt whether the agency chose correctly)." 988 F.2d at 150-51. As the Court of Appeals has explained, "[t]here is a fine line between agency reasoning that is 'so crippled as to be unlawful' and action that is potentially lawful but insufficiently or inappropriately explained." *Radio-Television News Directors Ass'n*, 184 F.3d 872, 888 (D.C. Cir. 1999) (quoting *Checkosky v. SEC*, 23 F.3d 452, 464 (D.C. Cir. 1994) (separate opinion of Silberman, J.)). "In the former

circumstance, the court's practice is to vacate the agency's order, while in the later the court frequently remands for further explanation (including discussion of relevant factors and precedents) while withholding judgment on the lawfulness of the agency's proposed action." *Id.* As Plaintiffs stress, "the court typically vacates when an agency 'entirely fails' to provide notice and comment." *Daimler Trucks North America LLC v. EPA*, 737 F.3d 95, 103 (D.C. Cir. 2013) (quoting *Shell Oil Co. v. EPA*, 950 F.2d 741, 752 (D.C. Cir. 1991)) (alteration omitted). That is presumably because, where an agency has completely bypassed the notice and comment procedure, there is substantial basis to "doubt whether the agency chose correctly," *Allied-Signal*, 988 F.2d at 150-51, and the agency's decision lacks the legitimacy that comes with following the APA-mandated procedures for creating binding legal obligations.

The flaws present here do not rise to that level, but they are nonetheless substantial. This is not a case where the agency simply failed to provide sufficient detail in its explanation for its action or failed to address a discrete comment. *See, e.g., La. Fed. Land Bank Ass'n v. Farm Credit Admin.*, 336 F.3d 1075, 1085 (D.C. Cir. 2003). Rather, the Secretary omitted "critical material on which it relie[d]," and thus "deprive[d] commenters of a right under [the APA] 'to participate in rulemaking.'" *Allina Health Servs.*, 746 F.3d at 1110. In this respect, the case is similar to *Owner-Operator Independent Drivers*, where the Court of Appeals vacated a rule on the ground that the agency failed "to disclose the methodology of the . . . model" on which it relied "in time for comment," 494 F.3d at 202. At the same time, the Court is not convinced that the Secretary would be unable to "justify" her decision on remand, *see Heartland*, 566 F.3d at 197—nor is the Court convinced that she would be able to do so. But the Court's uncertainty on that point merely highlights the magnitude of the procedural violation. The Court is unable to evaluate whether the Secretary's decision was reasonable because her omission prevented the

public from offering meaningful comments.[10] The Plaintiffs never had the opportunity to explain where, in their view, she went wrong, and, thus, the Secretary never had to provide a reasoned justification of her position.

With respect to the first *Allied-Signal* factor, all that the Court can conclude is that the flaw in the notice and comment process was substantial and that it is possible that the procedural error affected the Secretary's final decision to adopt the 0.2 percent reduction. To the extent the Secretary bears the burden of demonstrating that the "normal remedy" of vacatur does not apply, *Allina Health Servs.*, 746 F.3d at 1110, she has failed to show that the flaw in the rule was not serious.

Plaintiffs further argue that the deficiencies in the rule are exacerbated by the addition of other errors that they have alleged, including the failure of the Secretary to respond to significant comments or to offer an adequate explanation for the final rule containing the 0.2 percent reduction. Given the Court's conclusion that the failure to provide a meaningful opportunity for public comment was "serious" for purposes of the *Allied-Signal* test, it is not clear that these additional alleged errors add significantly to the Court's conclusions. Indeed, assuming for present purposes that Plaintiffs are correct about these additional flaws, their presence does not fundamentally change the seriousness of the deficiencies in the rule. They are, if anything, an unsurprising outgrowth of the Secretary's failure to treat the actuarial methodology as a critical

[10] The Secretary concedes that on remand, she will have to provide a fuller explanation of her analysis and respond to the challenges that are raised, *see* Dkt. 43 at 10, and argues that she will be able to provide an explanation justifying both her methodology and her conclusions. As support, she cites her notice of proposed rulemaking for FY 2016. *Id.* (citing 80 Fed. Reg. 39200, 39369 (July 8, 2015)). The rationale stated in the FY 2016 notice is no basis for affirmance in the present case and plays no role in the Court's decision.

component of her decision. It is that failure that was at the core of the problem here, and the Court concludes that that failure is—however manifest—a serious one.

2. *Disruptive Consequences*

That does not end the inquiry. The Court must also consider "the disruptive consequences" of vacating the 0.2 percent reduction. *Sugar Cane Growers*, 289 F.3d at 97 (quoting *Allied-Signal*, 988 F.2d at 151). The Court of Appeals' decision in *Heartland Regional Medical Center* is particularly instructive. And, for the reasons given in that decision, the Secretary fares better on this factor.

In *Heartland*, a district court had concluded in a prior action that the Secretary's "rural local rule" was invalid, but did not expressly address whether the ensuing remand was with or without vacatur. 566 F.3d at 196-97. In light of intervening events, the Court of Appeals was called upon to characterize the remand in retrospect. 566 F.3d at 197. Applying *Allied-Signal*, the Court first concluded that the administrative error identified in the earlier case—failure to respond to reasonable alternatives—could be cured on remand. *See id.* at 197-98. Turning to the second factor, the Court of Appeals noted that vacatur "likely would have required HHS to make payments to [certain] hospitals for [the relevant] years . . . until the agency repromulgated the same rule and gave an adequate reason for rejecting the alternatives." *Id.* at 198. This posed a significant consequence: in light of the presumption against retroactive rulemaking, *see Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 207, 215 (1988) (rejecting the Secretary's attempt to promulgate a retroactive rule that would allow her to recoup payments made in response to vacatur of a rule), "vacatur . . . would have raised substantial doubt about HHS's ability to recoup payments it made for years prior to reinstatement of that requirement," 566 F.3d at 198.

That "substantial doubt" was sufficient, in the view of the Court of Appeals, to conclude that vacatur would have had "disruptive consequences" under *Allied-Signal*. *Id*.

The consequences of remand in the present action do not rise to the level of the "scrambled egg" at issue in *Sugar-Cane Growers*, 289 F.3d at 97, where "crops were plowed under" and there was no "way to restore the status quo ante," *id*. The consequences are, however, very similar to the disruptive consequences relied upon in *Heartland*, 566 F.3d at 198. As in *Heartland*, it is unclear whether the presumption against retroactive rulemaking would apply. Plaintiffs say it would, *see* Dkt. 42 at 9, 14, while the Secretary disputes that, *see* Dkt. 43 at 20-22. But even the Secretary expresses substantial doubt that, if the rule were vacated, she would attempt to reinstate the reduction for fiscal year 2014—particularly in light of the same "reliance" interests that animate the presumption against retroactive rulemaking in circumstances where it applies, *see* Dkt. 43 at 21.

Plaintiffs attempt to turn the presumption against retroactive rulemaking to their favor, arguing that the inability of the Secretary to reissue the rule means that there will be little "disruption" on remand—there is no risk, in Plaintiffs' view, that hospitals will receive additional payments that they might someday be required to return. *See* Dkt. 42 at 9. In the abstract, that contention might have some appeal. But it is directly at odds with the Court of Appeals' decision in *Heartland*, which concluded that a "substantial doubt about HHS's ability to recoup payments" favored remand without vacatur. 566 F.3d at 198; *see also Allied-Signal*, 988 F.2d at 151 (observing that "the consequences [of vacatur] may be quite disruptive" because "the Commission would need to refund . . . fees collected . . . [and] it evidently would be unable to recover those fees under a later-enacted rule").

Plaintiffs also argue that the potential costs to the Medicare program of providing further reimbursement to providers do not counsel against vacatur. *See* Dkt. 42 at 15. They cite *In re Medicare Reimbursement Litigation*, 414 F.3d 7 (D.C. Cir. 2005), in which the Court of Appeals observed that "[h]aving to pay a sum one owes can hardly amount to an equitable reason for not requiring payment," *id.* at 13. That language, however, was addressed to a very different situation; it involved the Secretary's refusal to reopen past proceedings that would have allowed the plaintiff hospitals to recover certain funds. *See id.* Counsel for the Secretary had "rightly conceded at oral argument" that the Secretary had "a clear statutory duty to pay [plaintiff] hospitals [those] funds." *Id.* But the Secretary nonetheless opposed reopening the proceedings, citing "the extraordinary sums at stake." *Id.* Here, in contrast, the Secretary has not conceded that the hospitals have a right to additional inpatient compensation for fiscal year 2014, but rather maintains that the 0.2 percent reduction is justified and that it would be contrary to the public interest to pay hospitals at the pre-reduction level.

The Court, accordingly, concludes that the second *Allied-Signal* factor supports remand without vacatur.

* * *

Having concluded that the first *Allied-Signal* factor favors Plaintiffs, while the second favors the Secretary, the Court must weigh these competing considerations. There is no rule requiring either the proponent or opponent of vacatur to prevail on both factors. *See, e.g.*, *North Carolina v. EPA*, 550 F.3d 1176, 1178 (D.C. Cir. 2008) (remanding without vacatur, despite serious flaws in rule, where vacatur would be disruptive); *Fox Television Stations, Inc. v. FCC*, 280 F.3d 1027, 1048-49 (D.C. Cir. 2002) (remanding without vacatur even though "the disruptive consequences of vacatur might not be great"), *amended in other respects by Fox*

Television Stations, Inc. v. FCC, 293 F.3d 537, 540 (D.C. Cir. 2002); *U.S. Telecom Ass'n v. FBI*, 276 F.3d 620, 626-27 (D.C. Cir. 2002) (remanding several rules but vacating only one in light of the first *Allied-Signal* factor). Rather, resolution of the question turns on the Court's assessment of the overall equities and practicality of the alternatives. Taking the parties at their word, the Court assumes that a remand with vacatur would, in effect, dictate a substantive outcome based on a procedural error, and thus concludes that the disruptive consequences would be considerable. Although the deficiencies in the rule are serious, the Court is not convinced that they are so grave that the Secretary should be precluded from taking corrective steps with respect to the 2014 inpatient prospective payment system. In addition, the Secretary has indicated her willingness to abide by a timetable and to expedite proceedings on remand. *See* Dkt. 43 at 10-11. If the Secretary fails to comply with that timetable, her failure may counsel in favor of vacatur of the rule at a future time. Similarly, to the extent the Secretary fails on remand to give meaningful consideration to significant comments, vacatur may be appropriate in a future proceeding. The Court concludes for now, however, that the Secretary should be given this opportunity.

Accordingly, the Court concludes that the remand should be without vacatur. The parties are directed to confer and to propose to the Court no later than October 1, 2015, a timetable for repromulgation of the proposed rule and an opportunity for further comment.

IV. CONCLUSION

For the reasons given above, the Secretary's motion for summary judgment is **DENIED**. The Plaintiffs' motions for partial summary judgment are **GRANTED** in part and **DENIED** in part, and this matter is **REMANDED** to the Secretary for further proceedings. The parties are

ORDERED to confer and propose, no later than October 1, 2015, a timetable for administrative proceedings on remand.

An appropriate Order will issue after the parties have submitted a proposed timetable.

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: September 21, 2015