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

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| NEW LIFECARE HOSPITALS OF CHESTER COUNTY LLC, *et al.*,<br><br>*Plaintiffs,*<br><br>v.<br><br>ALEX M. AZAR II, U.S. Secretary of Health and Human Services,<br><br>*Defendant*. | Civil Action No. 19-00705 (EGS) |

**REPLY IN SUPPORT OF DEFENDANT'S**
**CROSS-MOTION FOR SUMMARY JUDGMENT**

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## GLOSSARY

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| **BNA** | Budget Neutrality Adjustment |
| **BIPA** | Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 |
| **CMS** | Centers for Medicare & Medicaid Services |
| **EJR** | Expedited Judicial Review |
| **IPPS** | Inpatient Prospective Payment System |
| **LTCH** | Long Term Care Hospital |
| **PPS** | Prospective Payment System |
| **PRRB** | Provider Reimbursement Review Board |
| **SSO** | Short Stay Outlier |

## ARGUMENT

### I. The Secretary's Decision to Apply a Budget Neutrality Adjustment ("BNA") to Site Neutral Payments Was Reasonable

Plaintiffs' reply brief strongly implies that the Secretary of Health and Human Services calculates the site neutral payment rate and then *twice* reduces it by 5.1% to adjust for outliers in site neutral cases. After all, Plaintiffs claim that "CMS applies *both* the Inpatient Prospective Payment System ("IPPS") outlier BNAs *and* the LTCH PPS site neutral outlier BNA to site neutral payments[.]" Pls' Reply in Supp. of Mot. for Summ. J. and Opp'n to Def's Cross-Mot. for Summ. J. ("Reply") at 1 (emphasis in original). But Plaintiffs' characterization is inaccurate. As the Secretary has explained, he calculates the site neutral payment rate according to the formula specified by Congress and then applies a single 5.1% reduction to adjust for outliers in site neutral payment rate cases. *See* Def's Cross-Mot. for Summ. J. & Opp'n to Pls' Mot. for Summ. J. ("Cross-Mot.") at 16-24. The calculation is depicted visually in the Secretary's Exhibit B, attached hereto.

To be sure, certain of the amounts the Secretary uses to calculate the site neutral payment rate were themselves computed using, among many other values, a BNA for the IPPS. But Plaintiffs are mistaken when they claim that "[t]he Secretary . . . admits that the IPPS BNA is an 'adjustment' to the LTCH site neutral payment rate." Reply at 1. The IPPS BNA is *not* an adjustment to the site neutral payment rate itself (and the Secretary has never said it was). Rather, the IPPS BNA is simply part of the background math that went into computing the IPPS standardized amount and the IPPS Federal rate – two amounts that Congress requires the Secretary to use when calculating site neutral payments. *See* Cross-Mot. at 17.

More specifically, Congress directed the Secretary to compute site neutral payments using several specific amounts. *See* 42 U.S.C. § 1395ww(m)(6)(B)(II)(ii) (directing Secretary to follow

calculation described at 42 C.F.R. § 412.529(d)(4)); *see also* Ex. B (listing all inputs to calculate the "IPPS comparable per diem amount"). The Secretary faithfully adheres to the calculation described at 42 C.F.R. § 412.529(d)(4) and uses each of the specified inputs. The result of that calculation is a payment rate – the IPPS comparable per diem amount before the site neutral BNA is applied. *See* Ex. B. In order to account for estimated outlier payments, the Secretary adjusts the payment rate downward by 5.1% to maintain budget neutrality. *See id*. The Secretary's methodology reflects an eminently reasonable approach to budget neutrality: first determine the payment rate according to the formula set by Congress and then adjust that rate downward to account for the outlier payments that are projected to be made.

Plaintiffs, however, insist that the Secretary is required by the Administrative Procedure Act to take a different approach to budget neutrality. Plaintiffs' position is effectively that the Secretary is required to consider, not just the inputs that Congress specified for the payment calculation, but also the amounts that were used to calculate those inputs and treat each of those amounts as adjustments that are made directly to the site neutral payment rate. For instance, the IPPS standardized amount is the product of a complicated calculation that starts with "per discharge averages of adjusted hospital costs from a base period" to which several adjustments are made, including (1) "equalization of the standardized amounts for urban and other areas," (2) adjustments "depending on whether a hospital submits quality data . . . and is a meaningful [Electronic Health Records] user," (3) a BNA "for DRG recalibration and reclassification," (4) a BNA "to ensure the wage index and labor-related share changes . . . are budget neutral," (5) a BNA "to ensure the effects of geographic reclassification are budget neutral," (6) a "positive adjustment of 0.5 percent . . . as required under section 414 of the [Medicare Access and CHIP Reauthorization Act of 2015,]" (7) a BNA "to ensure the effects of the Rural Community Hospital Demonstration program . . . are budget neutral," and (8) a BNA to maintain budget neutrality for high cost outliers

in IPPS. *See* 83 Fed. Reg. 41144, at 41712-13 (RR5979-80). Plaintiffs' view is apparently that each of these amounts is itself an adjustment to the site neutral rate. But Plaintiffs are wrong. And, in any event, it was certainly within the Secretary's wide discretion to follow a different approach to budget neutrality than that suggested by Plaintiffs. *See* Cross-Mot. at 21 (discussing the Secretary's discretion).

Plaintiffs insist that "the IPPS outlier BNA . . . must be accounting for outlier payments to LTCHs or it is meaningless." Reply at 6. Plaintiffs appear to assume that the values used to compute the IPPS standardized amount and the IPPS Federal rate must have some independent function within the LTCH PPS. But the IPPS standardized amount and IPPS Federal rate are simply numbers that Congress borrowed from the IPPS to use as a starting point for the site neutral rate calculation in the LTCH PPS. Congress never suggested that the math underlying those numbers necessarily was applicable to the LTCH PPS. Indeed, as the Secretary has explained, the IPPS BNA is *not* applicable to the LTCH PPS – it is based on the *IPPS* outlier target and has nothing to do with outlier payments in the LTCH PPS. *See* Cross-Mot. at 19-20. Similarly, other adjustments to the IPPS standardized amount also relate only to the IPPS and have no applicability to the LTCH PPS. For example, the IPPS standardized amount includes a "positive adjustment of 0.5 percent . . . as required under section 414 of the [Medicare Access and CHIP Reauthorization Act of 2015.]" 83 Fed. Reg. at 41713 (RR5980). That adjustment is used to offset reductions required to recoup overpayments that had been made in IPPS several years before the site neutral payment even existed and therefore could not possibly have any applicability to site neutral payments. *See id*. at 41156-57.

Plaintiffs contend that if the IPPS BNA "has no purpose in the LTCH site neutral payment calculation," then it is "arbitrary." Reply at 6. To the extent Plaintiffs are arguing that it was arbitrary for *the Secretary* to use the IPPS standardized amount and Federal rate, that argument

fails because Congress specifically required those amounts be used in the site neutral payment calculation. *See* Cross-Mot. at 16-18. To the extent Plaintiffs are arguing that it was arbitrary for *Congress* to select the IPPS standardized amount and Federal rate as inputs to the site neutral payment calculation, any statutory challenge is beyond the scope of this lawsuit. In any event, it makes good sense to borrow the IPPS rates for use in the LTCH PPS. Congress created the site neutral rate precisely because some of the cases treated in LTCHs could be treated in lower cost settings such as by hospitals reimbursed under the IPPS. Cross-Mot. at 6-7. Because IPPS cases are similar to site neutral cases, 83 Fed. Reg. at 41736-37 (RR6003-04), the IPPS rates provide a useful starting point for calculating site neutral payments, even if the adjustments underlying those rates do not necessarily relate to site neutral payments.

Next, Plaintiffs simply repeat arguments already refuted by Defendants in prior briefing. Plaintiffs claim that the "agency's math is flawed" because CMS allegedly "reduc[ed] the LTCH site neutral payments by the 5.1% IPPS outlier BNA" and thereby "already offset site neutral payments by the required 5.1% to maintain budget neutrality" such that an "additional BNA is an arbitrary and unwarranted payment cut." Reply at 5. But that is incorrect. The Secretary did not reduce site neutral payments using the IPPS BNA. As explained, the Secretary appropriately applied the inputs to the site neutral calculation as specified by statute. Cross-Mot. at 20-21. The fact that some of those inputs were computed using the IPPS BNA is irrelevant to the issue of budget neutrality in the LTCH PPS.

Plaintiffs also take issue with the Secretary's description of the IPPS standardized amount and Federal rate as "inputs" to the site neutral rate calculation because Congress did not "actually call these inputs." Reply at 6. Nomenclature aside, there is no dispute that the IPPS rates *function* as inputs. *See id*. at 2 (agreeing that the IPPS rates "are used to determine the IPPS comparable per diem amount under the LTCH PPS site neutral payment rate.") (internal quotation marks

omitted). Plaintiffs' fretting over the term "inputs" is particularly odd given that Plaintiffs themselves have described the IPPS rates as "the amounts used to calculate site neutral payments[.]" Compl. ¶ 1.

Similarly, Plaintiffs fail to rebut the presumption that Congress was aware, when it established the site neutral payment rate, of CMS's approach to budget neutrality in the analogous context involving short stay outliers ("SSOs"). The Secretary has explained that for many years, CMS budget neutralized projected outlier payments to SSO cases even though certain inputs to the SSO payment calculation incorporate the IPPS BNA. Cross-Mot. at 23-24. Surprisingly, Plaintiffs question whether "the LTCH PPS short stay outlier calculation includes an IPPS BNA." Reply at 7 (stating that "no authority is cited for this claim"). But the calculation of the IPPS comparable per diem amount for short stay outliers is precisely the same calculation used for site neutral payments. *See* 42 C.F.R. § 412.529(d)(4). The idea that that calculation incorporates the IPPS BNA is one of the central points of Plaintiffs' claims in this lawsuit. *See, e.g.*, Reply at 1-2.

Even though the SSO payments calculated pursuant to Section 412.529(d)(4) use inputs that incorporate the IPPS BNA, CMS has for many years applied a BNA to adjust for high cost outlier payments made to SSO cases. It has done so through an 8% reduction to the LTCH PPS standard Federal rate. 42 C.F.R. § 412.523(d)(1). That 8% reduction adjusts for projected high cost outlier payments payable for all LTCH PPS standard Federal rate cases in the LTCH PPS. *See id*. (8% adjustment represents the estimated proportion of high cost outlier payments "payable for discharges described in § 412.522(a)(2)"); *id*. § 412.522(a)(2) ("Discharges that meet the criteria for exclusion from site neutral payment rate . . . are paid based on the standard Federal prospective payment rate"). This includes SSO cases, which incorporate adjustments to the LTCH PPS standard Federal rate. *See id*. § 412.529(b). Plaintiffs respond that the SSO payment for a discharge may not be entirely based on the LTCH PPS standard Federal rate, Reply at 8, but that

is irrelevant. The important point is that CMS reduces a payment rate to adjust for high cost outlier payments that are projected to be made in SSO cases even though the SSO payments are calculated using inputs that incorporate the IPPS BNA. Accordingly, when Congress instructed the Secretary to calculate site neutral payments using the calculation described at 42 C.F.R. § 412.539(d)(4), it did so with the knowledge that CMS had interpreted the same provision to not preclude application of a BNA for outlier payments. *See* Cross-Mot. at 23-24 (citing cases concerning when Congress may be presumed to have knowledge of the interpretation of a regulation).

## II. Plaintiffs' Remaining Arguments Concerning Substantive APA Claims Are Meritless

In the later sections of their Reply, Plaintiffs simply repeat many of the same arguments that they make elsewhere in their Reply or have made in their prior briefing. *See* Reply at 14-25. Those arguments fail for the reasons that have been discussed extensively in the Secretary's Cross-Motion and above. For instance, Plaintiffs argue again that CMS has applied "double the required adjustment" and that the allegedly "duplicative" adjustment is unreasonable. *Id*. at 14-15; *see also id*. at 19, 24. Those arguments fail for all the reasons the Secretary has set forth above and in the Cross-Motion.

Likewise, Plaintiffs' repeated assertions that the Secretary's reasoning is "internally inconsistent," Reply at 17-18, fail for the reasons previously explained, Cross-Mot. at 25-26. Plaintiffs are mistaken when they claim that "CMS is actually paying LTCHs less" for site neutral cases "than what it pays for the same cases treated at IPPS hospitals." Reply at 17. Because LTCHs are currently being paid a blended rate equal to one-half of the site neutral payment rate and one-half of the LTCH PPS standard Federal payment rate, their payments are likely *higher* than what the hospitals would be paid for a similar stay under the IPPS. *See* 42 U.S.C. § 1395ww(m)(6)(B)(ii). To the extent that Plaintiffs are referring to differences between the *site-*

*neutral portion* of the blended rate and an IPPS payment for a similar stay, the Secretary has explained the many reasons why the two payments need not be identical. Cross-Mot. 30-31.

Next, Plaintiffs disagree with the Secretary's view on what the appropriate baseline is for measuring budget neutrality. Reply at 18. The appropriate baseline is the site neutral payment rate resulting from the calculation at 42 C.F.R. § 412.529(d)(4) because that is the payment rate, according to the formula set by Congress, before any outlier payment is added. *See* 42 U.S.C. § 1395ww(m)(6)(B)(II)(ii). Because adding outlier payments on top of that rate will increase aggregate Medicare payments above that baseline, it is necessary to apply a BNA to offset the outlier payments and maintain budget neutrality. *See* Ex. B. Plaintiffs offer no support for their belief that the appropriate budget neutrality baseline is the site neutral payment rate *with the IPPS BNA arbitrarily removed*.

Regarding Plaintiffs' argument that the Secretary's decision is not supported by substantial evidence, Reply at 21-22, the Secretary has explained why that standard does not apply here but would be met even if it did apply, Cross-Mot. at 27-28. Plaintiffs' response completely ignores the decision cited by the Secretary squarely holding that the "substantial evidence standard . . . does not apply in the rulemaking context." *Select Specialty Hosp. - Akron, LLC v. Sebelius*, 820 F. Supp. 2d 13, 27 (D.D.C. 2011). More fundamentally though, Plaintiffs still have not explained how the "substantial evidence" standard makes any sense in this context, which does not involve an evidentiary determination in any conventional sense.

Next, Plaintiffs try to interpret the decision in *Abington Crest Nursing and Rehabilitation Ctr. v. Sebelius*, 575 F.3d 717 (D.C. Cir. 2009) to save their argument that the challenged BNA violates the anti-cross-subsidization principle. Reply at 24. Plaintiffs argue that the court's reasoning in *Abington* "indicates that the anti-cross subsidization principle does apply to the LTCH PPS, a Part A PPS." *Id.* But contrary to Plaintiffs' reasoning, a Medicare Part A prospective

payment system is *not* a "reasonable cost reimbursement system" to which the anti-cross-subsidization principle would apply. *See Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1227 (D.C. Cir. 1994) (indicating that in 1983, Congress "completely revised" the Medicare reimbursement system for inpatient services from "reasonable costs" to PPS). Plaintiffs cite to portions of the *Abington* decision discussing the distinction between a Medicare Part A prospective payment system and a Medicare Part B fee schedule, Reply at 24, but there the court was addressing whether the type of cost at issue was reimbursable by Medicare, not the applicability of the anti-cross-subsidization principle, *Abington*, 575 F.3d at 721. In addition, Plaintiffs conflate the concepts of costs and reasonable costs. In any event, Plaintiffs' argument that the challenged BNA violates the anti-cross-subsidization principle assumes that the BNA is duplicative, which it is not.

Lastly, Plaintiffs appear to retreat from their position complaining about differences between the amount of site neutral and IPPS payments. Reply at 25. Plaintiffs now argue, instead, that the outlier BNAs for IPPS and site neutral cases "must be identical." *Id*. Although unclear, Plaintiffs appear to be repeating their same argument challenging the site neutral BNA as duplicative and that argument fails for the reasons discussed.

### III. The Secretary Sufficiently Responded to Comments During the Rulemaking

Plaintiffs have failed to show any deficiency in CMS's responses to comments concerning the challenged BNA. Reply at 16, 20-21, 22-23. Importantly, despite all of the briefing on this issue, Plaintiffs still have not identified even one point raised by any commenter for which CMS failed to provide a response. Instead, Plaintiffs merely repeat vague criticisms such as that CMS supposedly did not provide a "reasoned analysis" and that the responses allegedly were "terse" and "dismissive." Reply at 16, 22. Plaintiffs also claim that CMS did not address "new evidence and information," but Plaintiffs never say what "evidence and information" they are referring to.

*Id*. at 16. Plaintiffs' vague criticisms are wholly insufficient to show any procedural violation of the APA. Those criticisms are also contradicted by the record, which clearly shows that CMS provided detailed responses to commenters' objections concerning the challenged BNA. *See* 80 Fed. Reg. 49326, 49622 (Aug. 17, 2015) (RR1264); 81 Fed. Reg. 56762, 57308-09 (Aug. 22, 2016) (RR2908-09); 82 Fed. Reg. 37990, 38545-46 (Aug. 14, 2017) (RR4612-13); 83 Fed. Reg. at 41738 (RR6005). Those responses easily met the Secretary's obligation to respond. *See Simpson v. Young*, 854 F.2d 1429, 1435 (D.C. Cir. 1988) ("the agency need only state the main reasons for its decision and indicate it has considered the most important objections"). That Plaintiffs may disagree with CMS's position expressed in its responses does not make the responses inadequate.

Plaintiffs also contend without support that CMS did not carefully consider comments objecting to the BNA. Reply at 16, 20. But where "CMS's responses" to comments "identified the reasons" for the agency's decision, the responses "demonstrate[e] that CMS considered the comments" and "satisfied the APA requirements." *Lee Mem'l Health Sys. v. Burwell*, 206 F. Supp. 3d 307, 332 (D.D.C. 2016). As discussed, the agency's comments identified – in considerable detail – the reasons for the agency's decision and thereby showed that CMS appropriately considered the comments.

Plaintiffs also insist there is a "glaring deficiency" in CMS's responses to a comment from MedPAC. Reply at 23. But Plaintiffs are wrong. First, this case is limited to the Fiscal Year 2019 rulemaking, *see* Section IV below, and yet MedPAC submitted a comment on this issue only for the Fiscal Year 2017 rulemaking and did not repeat the concern in subsequent years. *See* RR1864-84. CMS was not required to respond in the Fiscal Year 2019 rulemaking to MedPAC's comment regarding the Fiscal Year 2017 rulemaking. But even if the Court were to consider the merits of Plaintiffs' argument, it should reject it. Plaintiffs contend that "CMS has never responded to MedPAC's concerns or even acknowledged that MedPAC submitted these comments." Reply at

23. However, CMS *did* respond to MedPAC's concerns. MedPAC raised precisely the same objection as other commenters, RR1879-80, as Plaintiffs acknowledge, *see* Compl. ¶ 2 ("The Plaintiffs, other hospitals, hospital trade associations, and the Medicare Payment Advisory Commission ('MedPAC') all told CMS in written comments during rulemaking that CMS is applying duplicative budget neutrality adjustments to LTCH site neutral payments[.]") (emphasis omitted); *id*. ¶ 30 ("MedPAC also criticized the BNA" for the reasons that "the Plaintiffs and hospital trade associations were telling CMS[.]"). Accordingly, the agency's lengthy response in the Fiscal Year 2017 final rule was a sufficient response to all significant comments received that year, including the comment from MedPAC. *See* 81 Fed. Reg. at 57308-09 (RR2908-09).

Lastly, Plaintiffs contend that "at a minimum, CMS' responses in FY 2019 and FY 2018 did not meet" the APA requirements to respond to comments, apparently realizing that the responses in Fiscal Years 2016 and 2017 cannot seriously be questioned. Reply at 22. Plaintiffs' challenge to the agency's responses in Fiscal Years 2018 and 2019 is that "most" of the agency's responses those years supposedly were "dismissive and simply referred back to responses from previous years." Reply at 22. Plaintiffs are referring to the fact that for Fiscal Year 2019, for example, CMS cross-referenced its prior years' responses to nearly identical comments and cited specific Federal Register pages containing those prior responses, instead of repeating those responses word-for-word in the new rule. 83 Fed. Reg. at 41738 (RR6005). There is, of course, nothing in the APA prohibiting an agency from cross-referencing prior responses to nearly identical comments and Plaintiffs provide no authority whatsoever to support their unusual argument.[1]

[1] Plaintiffs raise this argument for the Fiscal Year 2018 and 2019 rulemakings. Reply at 22. As discussed above and below, however, the Court's jurisdiction extends only to the Fiscal Year 2019 rulemaking.

## IV. The Court Lacks Jurisdiction Over Claims Other Than Those Concerning Fiscal Year 2019

Plaintiffs' Reply fails to establish that the Provider Reimbursement Review Board ("PRRB") granted expedited judicial review for their claims based on fiscal years other than Fiscal Year 2019. All claims other than those based on Fiscal Year 2019 therefore should be dismissed for lack of subject matter jurisdiction. *See* Cross-Mot. at 13-15; *see also Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998) ("Without jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.").

The Secretary's Cross-Motion explained that Plaintiffs had expressly limited their administrative appeal and request for expedited judicial review ("EJR") to claims for Fiscal Year 2019. *See* Cross-Mot. at 15. Plaintiffs do not dispute that fact but argue that they nevertheless met the presentment requirement because "[t]he PRRB's decision and the Plaintiffs' request for Expedited Judicial Review noted the Plaintiffs' objection to the BNA that CMS began applying in FY 2016." Reply at 10-11. But merely noting in an EJR request that the plaintiffs had submitted comments objecting to prior years' rules is wholly insufficient to confer federal court jurisdiction, particularly where the plaintiffs expressly limited the administrative claims to a particular fiscal year. *See Heartland Regional Medical Center v. Leavitt*, 415 F.3d 24, 31-32 (D.C. Cir. 2005) (holding that a particular claim was "the sole issue to be resolved" through a grant of EJR "because it was the sole basis for [the plaintiff's administrative] appeal"). Plaintiffs are bound by their litigation decisions made during the administrative phase of this case, and whatever regrets they may have for not administratively appealing additional claims is no basis on which to expand this Court's jurisdiction.

The Court's jurisdiction is also circumscribed by the scope of the PRRB's EJR grant, which was expressly limited to Fiscal Year 2019. Cross-Mot. at 14-15. In response, Plaintiffs misstate the legal question that the PRRB approved for judicial review, claiming it was "CMS' duplicative BNA." Reply at 12. But the PRRB was very clear that the EJR grant was limited to Fiscal Year 2019. *See* AR8 (authorizing EJR only for "the legal question of [whether] the Secretary incorrectly applied the outlier budget neutrality adjustment twice to the LTCH site neutral case payments for FFY [Federal fiscal year] 2019 as delineated in the August 17, 2018 Federal Register"). Notably, Plaintiffs' articulation of the pertinent legal question is contrary to their position during the administrative proceedings, in which they stated that "the legal question in these appeals is a challenge to the substantive and procedural validity of a regulation – the BNA in the FY 2019 Final Rule." AR59.

Next, similarities between the various years' rules do not justify excusing Plaintiffs' noncompliance with the requirements to establish jurisdiction in this Court. Reply at 12. The D.C. Circuit has explained that the presentment requirement "is not waivable." *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 823 (D.C. Cir. 2018). Moreover, permitting Plaintiffs to litigate claims never presented to the PRRB would undercut the PRRB's "role in shaping the controversy that is subject to judicial review." *Bethesda Hosp. Ass'n v. Bowen*, 485 U.S. 399, 407 (1988).

Plaintiffs also suggest that any relief ordered in this case could extend to other time periods. Reply at 11-12. But neither of the cases cited by Plaintiffs on this issue support their position. *NLRB v. Express Publishing Co.*, 312 U.S. 426 (1941) is a decision concerning the scope of injunctive relief that the National Labor Relations Board may order for violations of the National Labor Relations Act. Here, if the Court were to rule in Plaintiffs' favor, "the appropriate course [would be] simply to identify a legal error and then remand to the agency," *Am. Hosp. Ass'n v. Azar*, 2019 U.S. Dist. LEXIS 75728, *16-17 (D.D.C. May 6, 2019) (quoting *N. Air Cargo v. USPS*,

674 F.3d 852, 861 (D.C. Cir. 2012)), not to order any injunctive relief and especially not to order injunctive relief for time periods not covered by the Court's jurisdiction. And in the other case cited by Plaintiffs, *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 214 (D.C. Cir. 2011), the Court did not order relief for fiscal years over which there was no jurisdiction. Rather, the question in that case was whether CMS could "ignore prior errors in calculating rural-floor budget-neutrality adjustments when those errors are built into the formula used to calculate current Medicare payments." *Id*. at 216. In other words, the alleged errors made in prior years were only relevant to the extent they impacted the payments in the fiscal years at issue in that case.

Plaintiffs also discuss their reasons for not challenging rules issued before Fiscal Year 2019. Reply at 13. Plaintiffs' excuses for failing to seek administrative review, however, are irrelevant to the question of jurisdiction.

Finally, Plaintiffs' contention (Reply at 11) that their challenge to the Fiscal Year 2020 rule – which is not even final yet – is somehow already ripe is contrary to the D.C. Circuit's guidance that "the presentment requirement generally prevents anticipatory legal challenges to Medicare rules and regulations." *Am. Hosp. Ass'n*, 895 F.3d at 826 (finding no jurisdiction over challenge to regulation where "the new regulation had not yet even become effective" when the plaintiffs filed the lawsuit). If Plaintiffs want to challenge the Fiscal Year 2020 rule, they must wait until the rule is final and then follow the appropriate administrative process.

## V. The Court's Review is Highly Deferential

Plaintiffs' assertion that the Secretary's rulemaking is not entitled to high deference, Reply at 13, is incorrect. First, review of agency action challenged as arbitrary or capricious is by its nature deferential. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). So long as the Secretary considered the relevant factors and data, articulated an explanation for his decisions that establishes a rational connection between the facts

and the decisions, and made no clear error of judgment, his decisions should be upheld. *See Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 378 (1989). Second, D.C. Circuit precedent establishes that heightened deference is warranted in review of the Secretary's expertise-based judgments and implementation of the Medicare statute. *See Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994) (added deference to review of decisions implementing Medicare statute in light of its complexity). Third, because the pertinent statute specifies that the Secretary "shall examine and may provide for appropriate adjustments to the long-term hospital payment system," Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"), Pub. L. No. 106-554, § 307(b)(1), 114 Stat. 2763, 2763A497 (2000) (codified at 42 U.S.C. § 1395ww, note), and does not specify any particular method the Secretary must use to adjust for budget neutrality, the Court's review is necessarily limited. *See Adirondack Med. Ctr. v. Burwell*, 782 F.3d 707, 710 (D.C. Cir. 2015) (holding that statutory language similar to the language in the BIPA afforded the Secretary "wide discretion" to determine "how to meet Medicare's budget neutrality requirements" within IPPS). Accordingly, Plaintiffs have demonstrated no basis to depart from this highly deferential standard of review in this case.

## CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' Motion for Summary Judgment and grant Defendant's Cross-Motion for Summary Judgment.

Respectfully submitted,

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Exhibit B – IPPS Comparable Per Diem Amount Calculation