UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Federal Rule of Civil Procedure 56, Defendant Alex M. Azar II, U.S. Secretary of Health and Human Services, respectfully moves for summary judgment and opposes Plaintiffs' Motion for Summary Judgment, ECF No. 21. This motion is accompanied by a memorandum of law, exhibit, and proposed order.

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

JENNIFER D. RICKETTS
Director, Federal Programs Branch

JEAN LIN
Special Counsel, Federal Programs Branch

/s/ *Joshua Kolsky*
JOSHUA M. KOLSKY
Trial Attorney
D.C. Bar No. 993430
United States Department of Justice
Civil Division, Federal Programs Branch

1100 L Street NW Washington, DC 20005
Tel.: (202) 305-7664
Fax: (202) 616-8470
E-mail: joshua.kolsky@usdoj.gov

Attorneys for Defendant

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MEMORANDUM IN SUPPORT OF DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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GLOSSARY

BNA	Budget Neutrality Adjustment
BIPA	Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000
CMS	Centers for Medicare & Medicaid Services
HCO	High Cost Outlier
IPPS	Inpatient Prospective Payment System
LTCH	Long Term Care Hospital
PPS	Prospective Payment System
SSO	Short Stay Outlier

INTRODUCTION

Within Medicare payment systems, the principle of budget neutrality requires that certain increases in Medicare payments be offset by equivalent reductions in other payments so that the net effect on payments overall is projected to be neutral. One example of this is the longstanding practice by the Secretary of Health and Human Services ("the Secretary"), through the Centers for Medicare & Medicaid Services ("CMS"), to budget neutralize high cost outlier payments, which are additional payments made to health care providers for patient stays with exceptionally high costs. To maintain budget neutrality, CMS, in effect, reallocates some money and uses that money to fund the payment of outliers. This approach benefits hospitals because they are protected financially when they have exceptionally expensive patient stays, and it benefits patients because hospitals are incentivized to treat patients requiring expensive care. Budget neutrality helps to ensure that providing additional payments for high cost outlier cases is not projected to increase aggregate Medicare payments.

Plaintiffs, a group of long-term care hospitals ("LTCHs"), take issue with the Secretary's use of a budget neutrality adjustment ("BNA") to fund high cost outlier payments in the Long Term Care Hospital Prospective Payment System ("LTCH PPS") for "site neutral" payment rate cases—cases that Congress has determined should be reimbursed at the lower of the two rates applicable to LTCH patients because the patients otherwise could be safely and efficiently treated in an alternative lower-cost setting. Plaintiffs insist that the BNA for site neutral payments is unnecessary and duplicative because in Plaintiffs' view, a BNA made within a different Medicare payment system, the Inpatient Prospective Payment System ("IPPS"), that is incorporated into inputs to the site neutral payment calculation, already maintains budget neutrality within the separate LTCH PPS. Plaintiffs, however, are mistaken and their substantive and procedural

challenges under the Administrative Procedure Act, all of which are predicated on this false premise, fail.

First, Congress defined the site neutral payment calculation in such a way as to incorporate the IPPS BNA as an adjustment to certain inputs to that calculation. Specifically, Congress requires the Secretary to calculate site neutral payments using, among other values, two values from the IPPS: the operating IPPS standardized amount and the capital IPPS Federal rate. Those amounts are calculated each fiscal year through a complex process that involves a variety of mathematical adjustments, including the IPPS BNA. Accordingly, when the Secretary follows the statutory formula to calculate site neutral payment rates, the numbers he uses already incorporate the IPPS BNA. But simply because the IPPS BNA is incorporated into the statutory formula for calculating the site neutral payment rate does not mean that the IPPS BNA accounts for outliers in the LTCH PPS. To the contrary, the IPPS BNA accounts only for outlier payments in IPPS. Therefore, to ensure that outlier payments for site neutral payment cases do not upset budget neutrality in LTCH PPS, the Secretary applies a BNA that is specific to LTCH PPS site neutral payments. The Secretary's decision is consistent with the governing statutes, reasonable, and entitled to deference.

Plaintiffs' half-hearted procedural challenge as to the adequacy of the Secretary's explanation fares no better. For years, the Secretary provided detailed, substantive responses to comments complaining that the BNA for site neutral payments allegedly was duplicative. Plaintiffs' criticism appears to be that in the rulemaking for fiscal year 2019, the year at issue here, the Secretary referenced prior years' responses to nearly identical comments instead of quoting those responses in full. But the Secretary's explanation has not changed, and thus the APA does not require more.

Lastly, Plaintiffs' claims based on fiscal years other than 2019 fall outside this Court's jurisdiction. In the administrative proceedings leading to this suit, Plaintiffs expressly challenged only "a budget neutrality adjustment published in the August 17, 2018 FY 2019 IPPS/LTCH PPS Final Rule." AR1078.[1] And the Provider Reimbursement Review Board likewise authorized expedited judicial review only for claims relating to Fiscal Year 2019. This lawsuit does not properly include Plaintiffs' claims based on other fiscal years, including Fiscal Year 2020, for which the agency rule is not even final.

For each of these reasons, as discussed in greater detail below, the Court should deny Plaintiffs' Motion for Summary Judgment and grant summary judgment to the Secretary.

BACKGROUND

I. Statutory and Regulatory Background

A. Inpatient Prospective Payment System, Outlier Payments, and Budget Neutrality

Medicare "provides federally funded health insurance for the elderly and disabled." *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1226-27 (D.C. Cir. 1994). It sets out a "complex statutory and regulatory regime," *Good Samaritan Hospital v. Shalala*, 508 U.S. 402, 404 (1993), under which hospitals can obtain payments from CMS for services provided to Medicare beneficiaries.

For many years, Medicare reimbursed participating hospitals for inpatient services furnished to Medicare beneficiaries based on the "reasonable costs" the hospitals incurred. *Methodist Hospital*, 38 F.3d at 1227 (quoting 42 U.S.C. § 1395f(b) (1988)). Because this system gave hospitals insufficient incentive to reduce costs, in 1983 Congress directed HHS to implement

[1] Citations in the format "AR__" are to pages in the administrative record of the proceedings before the Provider Reimbursement Review Board. Citations in the format "RR__" are to pages in the administrative rulemaking record.

a "prospective payment system" under which hospitals would instead generally receive fixed payments for different kinds of inpatient services, regardless of their actual costs. *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 205 (D.C. Cir. 2011).

CMS pays most hospitals for inpatient services furnished to Medicare beneficiaries at fixed rates through the IPPS, or Inpatient Prospective Payment System. *See generally Dist. Hosp. Partners, L.P. v. Burwell*, 786 F.3d 46, 49 (D.C. Cir. 2015); *Banner Health v. Burwell*, 126 F. Supp. 3d 28, 39 (D.D.C. 2015). The IPPS divides reimbursable medical conditions into groups of related illnesses called "diagnosis-related groups" ("DRGs"). *Dist. Hosp. Partners*, 786 F.3d at 49. For a given inpatient discharge from a hospital reimbursed under the IPPS ("IPPS hospitals"), Medicare reimburses the hospital at a preset rate that depends on the patient's DRG and other factors, such as regional labor costs. *See* 42 U.S.C. §§ 1395ww(d), (g); 42 C.F.R. §§ 412.64, 412.312; *Cape Cod*, 630 F.3d at 205-06. The payment amount for each DRG is intended to reflect the estimated average cost of treating a patient whose condition falls within that DRG, *see* 42 U.S.C. § 1395ww(d), even though the actual cost the hospital incurs in treating that patient may be higher or lower. Recognizing that some cases are exceptionally costly, Congress provided for additional "high cost outlier" ("HCO") payments to partly offset extremely high costs that hospitals incur in particular cases. Accordingly, an IPPS hospital may request additional payments for outlier cases in certain statutorily defined circumstances. 42 U.S.C. § 1395ww(d)(5)(A)(ii).

IPPS outlier payments, however, cannot be projected to increase the overall Medicare payment obligations of the federal government under the IPPS. *See id.* § 1395ww(d)(3)(B). Therefore, to account for the higher outlier payments, CMS reduces the IPPS payment rates by, each fiscal year, prospectively estimating the proportion of IPPS outlier payments and then prospectively reducing IPPS payment rates to account for those IPPS outlier payments. The limitation on such adjustment is Congress's requirement that the IPPS high cost outlier payments

for a given year must be projected to be between 5 and 6 percent of the total projected IPPS payments for that year. *Id*. § 1395ww(d)(5)(A)(iv). For Fiscal Year 2019, CMS set an outlier target of 5.1% for IPPS. 83 Fed. Reg. 41144, 41717 (Aug. 17, 2018) (RR5984). CMS then reduced the IPPS payment rates by 5.1% to adjust for the expected high cost outlier payments under the IPPS. *Id*. at 41723 (RR5990).

B. Long Term Care Hospitals Prospective Payment System, Outlier Payments, and Budget Neutrality

When Congress created the IPPS in 1983, it limited the application of the new payment scheme to short-term acute care general hospitals. 42 U.S.C. § 1395ww(d)(1)(B); *see also Transitional Hosps. Corp. of La. v. Shalala*, 222 F.3d 1019, 1021 (D.C. Cir. 2000) (the IPPS was "developed for short-term acute care general hospitals"). LTCHs and certain other types of hospitals were excluded from the IPPS and instead continued to receive reimbursement for inpatient services under the reasonable-cost system. *Id*. Long Term Care Hospitals are defined as hospitals with "an average inpatient length of stay . . . of greater than 25 days[.]" 42 U.S.C. § 1395ww(d)(1)(B)(iv).

In 1999, Congress directed the Secretary to "develop a per discharge prospective payment system for payment for inpatient hospital services of long term care hospitals[.]" Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 ("BBRA"), Pub. L. No. 106-113, § 123, 113 Stat. 1501, 1501A330 (1999) (codified at 42 U.S.C. § 1395ww, note). Congress granted the Secretary broad discretion in developing the new LTCH prospective payment system. *Id*. The following year, Congress further provided that the Secretary "shall examine and may provide for appropriate adjustments to the long-term hospital payment system, including . . . outliers[.]" 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). Accordingly, CMS may make outlier payments within the LTCH PPS and may do so in a budget neutral manner.[2]

CMS implemented LTCH PPS on October 1, 2002, which marked the beginning of Federal Fiscal Year 2003. 67 Fed. Reg. 55954 (Aug. 30, 2002). The Secretary modeled the LTCH PPS after IPPS. *See generally* 42 C.F.R. ch. IV, subch. B, pt. 412, subpt. O (setting forth the rules governing LTCH PPS). As in IPPS, the Secretary established a flat national rate for LTCH PPS, now known as the "standard Federal rate." *Id*. § 412.523(c)(1). Also since Fiscal Year 2003, in conjunction with the implementation of the LTCH PPS, CMS has made a budget neutrality adjustment for estimated high cost outlier payments under the standard Federal rate every year. Pursuant to the Secretary's broad authority under section 123 of Public Law 106-113, BBRA, and section 307 of Public Law 106-554, BIPA, CMS has always adjusted the standard Federal rate by a reduction factor of 8%, which is the estimated proportion of outlier payments paid to standard Federal rate cases under the LTCH PPS. *See* 42 C.F.R. § 412.523(d)(1). That BNA is not challenged in this case.

In 2013, concerned that LTCHs were admitting some patients who instead could be safely and efficiently treated in a lower-cost setting, Congress required the Secretary to create a separate payment rate for such patients at a rate generally lower than the standard Federal rate, known as the "site neutral" rate. *See* Bipartisan Budget Act of 2013, Pub. L. No. 113-67, § 1206, 127 Stat. 1165; 80 Fed. Reg. 49326, 49601-23 (Aug. 17, 2005) (RR1243-65). Pursuant to this congressional mandate, CMS implemented this dual-rate payment structure for the LTCH PPS in 2015 (for Fiscal Year 2016), and the structure remains in place today. Under that structure, generally a LTCH is

[2] Although the BBRA requires that the LTCH PPS be budget neutral, the requirement applied only to the first year of the LTCH PPS. *See* 77 Fed. Reg. 53258, 53494 (Aug. 31, 2012). Nevertheless, the Secretary is authorized to maintain budget neutrality within LTCH PPS pursuant to Section 307(b)(1) of the BIPA.

no longer reimbursed at the standard Federal rate if the patient did not spend at least three days in a hospital's intensive care unit immediately preceding the LTCH care or did not receive at least 96 hours of respiratory ventilation services during the LTCH stay. 42 U.S.C. § 1395ww(m)(6)(A).[3] To allow LTCHs to transition to the dual rate payment structure, Congress directed that for discharges in cost reporting periods beginning in Fiscal Year 2019 or earlier, LTCHs are paid at a blended rate for site neutral cases, 42 U.S.C. § 1395ww(m)(6)(B)(i)(I), which is equal to one-half of the site neutral payment rate and one-half of the LTCH PPS standard Federal payment rate. *Id*. § 1395ww(m)(6)(B)(ii). Effective for discharges in cost reporting periods beginning in Fiscal Year 2020 or later, site neutral cases will be paid at 100 percent of the site neutral payment rate.

The site neutral payment rate is statutorily defined as the lower of (1) "the IPPS comparable per diem amount determined under [42 C.F.R. § 412.529(d)(4)], including any applicable outlier payments under [42 C.F.R. § 412.525]" or (2) "100 percent of the estimated cost for the services involved." 42 U.S.C. § 1395ww(m)(6)(B)(ii); *see also* 42 C.F.R. § 412.522(c)(1). The "IPPS comparable per diem amount" in turn is determined based on a formula that uses IPPS rates – the operating IPPS standardized amount and the capital IPPS Federal rate – as inputs for the calculation. *See* 42 C.F.R. § 412.529(d)(4). Those IPPS rates are nationally-applicable values set annually by CMS through a complex computation. *See* 83 Fed. Reg. at 41724-25 (RR5991-92) (identifying FY 2019 operating standardized amounts); *id*. at 41729 (RR5996) (identifying FY 2019 capital Federal rate). The rates reflect the application of several adjustments, *see id*. at 41712-13, 41727-29 (RR5979-80, RR5994-96), including the IPPS BNA for outliers, *see id*. at 41723,

[3] There are additional factors that affect whether payment is made at the site neutral rate or the standard Federal rate, such as whether the patient discharge has a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation, 42 U.S.C. § 1395ww(m)(6)(A)(ii)(II), but those details are not relevant here.

41728 (RR5990, RR5995); *see also* 42 C.F.R. § 412.64(f) (IPPS BNA is applied when calculating standardized amount); *id*. § 412.308(c)(2) (IPPS BNA is applied when calculating Federal rate).

Just as it has done for the standard Federal rate, CMS makes certain adjustments to the site neutral payment rate, including an adjustment to account for outlier payments paid to site neutral cases in the LTCH PPS. 42 C.F.R. § 412.522(c)(2); *id*. § 412.525(a) (providing for high-cost outlier payments to LTCHs). The adjustment is equal to "the estimated proportion of outlier payments . . . payable for discharges from a long-term care hospital [payable at the site neutral payment rate]. . . to total estimated payments under the long-term care hospital prospective payment system to discharges from a long-term care hospital [payable at the site neutral payment rate.]" *Id*. § 412.522(c)(2)(i).

II. Factual Background Pertaining to Rulemakings

As noted before, CMS first implemented the site neutral payment rate for LTCHs in Fiscal Year 2016. 80 Fed. Reg. at 49601-23 (RR1243-65). CMS adopted a 5.1% BNA for site neutral payments "so that the estimated HCO [High Cost Outlier] payments payable to site neutral payment rate cases do not result [in] any increase in aggregate LTCH PPS payments." *Id*. at 49622 (RR1264); *see also id*. at 49621 (RR1263) ("In accordance with the current LTCH PPS HCO policy budget neutrality requirement, we believe that the HCO policy for site neutral payment rate cases should also be budget neutral, meaning that the proposed site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments."); *id*. at 49623 (RR1265) ("[W]e estimate that this will result in an estimated proportion of HCO payments to total LTCH PPS payments for site neutral payment rate cases of 5.1 percent."). CMS adopted the same percentage as the factor used to adjust payments for budget neutrality in the IPPS due to its projection that site neutral payment rate cases would mirror similar IPPS cases. *Id*. at 49621-49622 (RR1263-64).

Some "[c]ommenters objected to the proposed site neutral payment rate HCO budget neutrality adjustment, claiming that it would result in savings [to Medicare] instead of being budget neutral." *Id*. at 49622 (RR1264). "The commenters' primary objection was based on their belief that, because the IPPS base rates used in the IPPS comparable per diem amount calculation of the site neutral payment rate include a budget neutrality adjustment for IPPS HCO payments (for example, a 5.1 percent adjustment on the operating IPPS standardized amount), an 'additional' budget neutrality factor is not necessary and is, in fact, duplicative." *Id*.[4] CMS disagreed and explained that there was no duplication:

> While the commenters are correct that the IPPS base rates that are used in site neutral payment rate calculation include a budget neutrality adjustment for IPPS HCO payments, that adjustment is merely a part of the calculation of one of the inputs (that is, the IPPS base rates) that are used in the LTCH PPS computation of site neutral payment rate. The HCO budget neutrality factor that is applied in determining the IPPS base rates is intended to fund estimated HCO payment made under the IPPS, and is therefore determined based on estimated payments made under the IPPS. As such, the HCO budget neutrality factor that is applied to the IPPS base rates does not account for the additional HCO payments that would be made to site neutral payment rate cases under the LTCH PPS.

Id. CMS further explained why the 5.1% BNA was necessary to account for outlier payments in LTCH PPS:

> Without a budget neutrality adjustment when determining payment for a case under the LTCH PPS, any HCO payment payable to site neutral payment rate cases would increase aggregate LTCH PPS payments above the level of expenditure if there were no HCO payments for site neutral payment rate cases. Therefore, our proposed approach appropriately results in LTCH PPS payments to site neutral payment rate cases that are budget neutral relative to a policy with no HCO payments to site neutral payment rate cases.

Id.

[4] Plaintiffs' motion quotes a Fiscal Year 2016 comment letter and claims that "[t]he Defendant admits that this information from the comment letter is accurate." Mot. at 8 (citing Answer ¶ 23). Of course, Defendant has not admitted that any such information is accurate. Defendant's Answer merely admits that commenters submitted a comment letter containing the text quoted in Plaintiffs' complaint, not that any of the information in the letter is accurate. *See* Compl. ¶ 23; Answer ¶ 23.

For Fiscal Year 2017, commenters again objected to the proposed 5.1% BNA for the LTCH site neutral payment rate on the same and similar grounds as in the prior year. Compl. ¶¶ 29-30. CMS continued to explain why commenters were wrong:

> Section 1206 of Public Law 113-67 defined the site neutral payment rate as the lower of the estimated cost of the case or the IPPS comparable per diem amount determined under paragraph (d)(4) of § 412.529, including any applicable outlier payments under § 412.525. The term "IPPS comparable per diem amount" was not new at the time of enactment. That term had already previously been defined under § 412.529(d)(4), which has been in effect since July 1, 2006, and used as a component of the payment adjustment formula for LTCH PPS SSO [short stay outlier] cases. From the July 1, 2006 inception of the IPPS comparable component of the LTCH PPS' SSO payment formula, we have budget neutralized the estimated HCO payments that we expected to pay to SSO cases including those paid based on the IPPS comparable per diem amount. Congress was also well aware of how we had implemented our "IPPS comparable per diem amount" concept in the SSO context at the time of the enactment of section 1206 of Public Law 113-67. As such, we believe Congress left us with the discretion to continue to treat the "IPPS comparable per diem amount" in the site neutral payment rate context as we have historically done with respect to LTCH PPS HCO payments made to discharges paid using the "IPPS comparable per diem amount," that is, to adopt a policy in the site neutral context to budget neutralize HCO payments made to LTCH PPS discharges including those paid using the "IPPS comparable per diem amount."

81 Fed. Reg. 56762, 57308 (Aug. 22, 2016) (RR2908). Moreover, CMS explained that applying a BNA to site neutral rate is consistent with its treatment of standard Federal rate within the LTCH PPS:

> We have made a budget neutrality adjustment for estimated HCO payments under the LTCH PPS under § 412.525 every year since its inception in FY [Federal fiscal year] 2003. Specifically, at § 412.523(d)(1), under the broad authority provided by section 123 of Public Law 106-113 and section 307 of Public Law 106-554, which includes the authority to establish adjustments, we established that the standard Federal rate (now termed the LTCH PPS standard Federal payment rate under the new dual rate system) would be adjusted by a reduction factor of 8 percent, the estimated proportion of outlier payments under the LTCH PPS (67 FR 56052). Thus, Congress was well aware of how we had implemented our HCO policy under the LTCH PPS under § 412.525 at the time of the enactment of section 1206 of Public Law 113-67.

Id.

For Fiscal Year 2018, CMS again proposed and later finalized a 5.1% BNA for the LTCH site neutral payment rate and again received similar objections as in prior years. Compl. ¶ 32. CMS again explained its disagreement:

> As we discussed in response to similar comments (81 FR 57308 through 57309 and 80 FR 49621 through 49622), we have the authority to adopt the site neutral payment rate HCO policy in a budget neutral manner. More importantly, we continue to believe this budget neutrality adjustment is appropriate for reasons outlined in our response to the nearly identical comments in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57308 through 57309) and our response to similar comments in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49621 through 49622).

82 Fed. Reg. 37990, 38545-38546 (Aug. 14, 2017) (RR4612-4613).

For Fiscal Year 2019, commenters similarly objected to CMS's proposal of a 5.1% BNA for the LTCH site neutral payment rate. Compl. ¶¶ 34-36. CMS responded as follows:

> We continue to disagree with the commenters that a budget neutrality adjustment for site neutral payment rate HCO payments is inappropriate, unnecessary, or duplicative. As we discussed in response to similar comments (82 FR 38545 through 38546, 81 FR 57308 through 57309, and 80 FR 49621 through 49622), we have the authority to adopt the site neutral payment rate HCO policy in a budget neutral manner. More importantly, we continue to believe this budget neutrality adjustment is appropriate for reasons outlined in our response to the nearly identical comments in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57308 through 57309) and our response to similar comments in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49621 through 49622).

83 Fed. Reg. at 41738 (RR6005). CMS finalized the proposal in August 2018, and the Rule became effective on October 1, 2018. 83 Fed. Reg. at 41144 (RR5411).

STANDARD OF REVIEW

In this action proceeding under the Medicare statute, 42 U.S.C. § 1395oo(f)(1), judicial review is governed by the standards of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706, and decided on an administrative record. *Southeast Ala. Med. Ctr. v. Sebelius*, 572 F.3d 912, 916-17 (D.C. Cir. 2009). Accordingly, "'the district court does not perform its normal role' but instead 'sits as an appellate tribunal'" resolving legal questions. *Cty. of L.A. v. Shalala*, 192 F.3d 1005,

1011 (D.C. Cir. 1999) (quoting *PPG Indus., Inc. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995)). Although the parties move for summary judgment, the "standard set forth in Rule 56(c) . . . does not apply." *Gentiva Healthcare Corp. v. Sebelius*, 857 F. Supp. 2d 1, 6 (D.D.C. 2012) *aff'd*, 723 F.3d 292 (D.C. Cir. 2013). Rather, summary judgment "serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Id.*

The APA provides for courts to "hold unlawful and set aside agency action, findings, and conclusions" if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C. § 706(2)(A), or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C). Under the APA's "arbitrary or capricious" standard, the Court "must consider whether the [agency's] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 378 (1989). An agency is required 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." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983); *accord, e.g.*, *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610, 626 (1986). "[A]n agency cannot 'fail[] to consider an important aspect of the problem' or 'offer[] an explanation for its decision that runs counter to the evidence' before it," *Dist. Hospital Partners*, 786 F.3d at 57 (quoting *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43), and it must "consider 'significant and viable and obvious alternatives,'" *id.* at 59 (quoting *Nat'l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 215 (D.C. Cir. 2013)). However, a decision that is not fully explained may be upheld "if the agency's path may reasonably be discerned." *Bowman Transp., Inc. v. Ark.–Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974).

The "arbitrary or capricious" standard is "narrow . . . as courts defer to the agency's expertise." *Ctr. for Food Safety v. Salazar*, 898 F. Supp. 2d 130, 138 (D.D.C. 2012) (quoting *Motor Vehicle Mfrs. Ass'n*, 463 U.S. at 43). The court "is not to substitute its judgment for that of the agency." *Id.* In Medicare cases such as this, the "'tremendous complexity of the Medicare statute . . . adds to the deference which is due to the Secretary's decision.'" *Dist. Hosp. Partners*, 786 F.3d at 60 (quoting *Methodist Hospital*, 38 F.3d at 1229); *see also Alaska Airlines, Inc. v. TSA*, 588 F.3d 1116, 1120 (D.C. Cir. 2009) (agency decisions involving "complex judgments about . . . data analysis that are within the agency's technical expertise" receive "an extreme degree of deference") (citation omitted). Finally, the court reviews the disputed rulemaking based on the administrative record that was before the agency at the time of rulemaking. *See Citizens to Pres. Overton Park v. Volpe*, 401 U.S. 402, 420 (1971).

ARGUMENT

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

"To obtain judicial review of claims arising under the Medicare Act, a plaintiff must first present the claims to the Secretary of Health and Human Services." *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 823 (D.C. Cir. 2018); *see also Am. Chiropractic Ass'n, Inc. v. Leavitt*, 431 F.3d 812, 816 (D.C. Cir. 2005) ("Judicial review may be had only after the claim has been presented to the Secretary and administrative remedies have been exhausted."). Although Plaintiffs purport to challenge the BNA for fiscal years 2016 through 2020, they have satisfied the presentment requirement only with respect to the Fiscal Year 2019 BNA.

Hospitals' payments for Medicare services are calculated and processed by Medicare administrative contractors. *See* 42 U.S.C. § 1395h(a). After receiving a determination as to the amount of a hospital's payments, the hospital can appeal the determination to the Provider

Reimbursement Review Board ("PRRB"), an administrative tribunal within HHS. *Id.* § 1395oo(a); *see also id.* § 1395oo(b) (providing for group appeals by multiple providers). If a hospital believes the PRRB lacks authority to decide some "question of law or regulations relevant to the matters in controversy," it can request that the PRRB make a determination "that it is without authority to decide the question" and authorize expedited judicial review in federal district court. *Id.* § 1395oo(f)(1). In seeking the PRRB's authorization, the Medicare provider must specify each "question of law or regulations" that it intends to present to the district court. *Id.* The regulation implementing the statute similarly speaks of a provider obtaining review of individual "legal question[s]." 42 C.F.R. § 405.1842(a)(1); *see also id.* § 405.1842(g)(2) ("If the Board grants EJR [expedited judicial review], the provider may file a complaint in a Federal district court in order to obtain EJR of the legal question."). The consequence of this statutory and regulatory requirement is that a grant of expedited judicial review permits judicial review only of the particular "questions of law" or "legal questions" identified in the provider's request for expedited judicial review and the PRRB's notice granting expedited judicial review. Legal questions that the PRRB did not approve for expedited judicial review are outside the Court's subject matter jurisdiction. *See* 42 U.S.C. § 1395oo(f)(1). Such questions have not been presented to the agency as required to establish jurisdiction. *Am. Hosp. Ass'n*, 895 F.3d at 825-26. As the Supreme Court has observed, the expedited judicial review approval process gives the Board "a role in shaping the controversy that is subject to judicial review." *Bethesda Hosp. Ass'n v. Bowen*, 485 U.S. 399, 407 (1988).

Here, the PRRB granted the request for expedited judicial review only on "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." AR8. Accordingly, the only budget neutrality adjustment at issue, and the only relief that can be granted by the Court, concerns the adjustment for Fiscal

Year 2019. *See* 42 U.S.C. § 1395oo(f)(1); *see also Shands Jacksonville Med. Ctr. v. Azar*, 2019 U.S. Dist. LEXIS 42423, at *53 (D.D.C. Mar. 15, 2019) (PRRB limited its grant of expedited judicial review to the "subject year" and the "administrative remedies that the providers exhausted before filing suit were limited to the 'subject year'").

Nevertheless, Plaintiffs insist that the Court has jurisdiction over claims for fiscal years prior to Fiscal Year 2019 because "Plaintiffs objected to the duplicative BNA that CMS applied in FY 2016 and subsequent years." Pl's Mot. for Summ. J. ("Mot.") at 20. Although Plaintiffs' PRRB Appeal Request and their request for expedited judicial review did mention that CMS applied a BNA to site neutral payments in years prior to Fiscal Year 2019, the record is clear that Plaintiffs appealed only the BNA for Fiscal Year 2019. Their Appeal Request expressly stated: "The Providers in this group are challenging a budget neutrality adjustment published in the August 17, 2018 FY 2019 IPPS/LTCH PPS Final Rule." AR1078. Likewise, their Request for Expedited Judicial Review stated that the "Providers are directly challenging the FY 2019 LTCH PPS site neutral HCO budget neutrality adjustment in the final rule." AR58; *see also* AR59 ("[T]he 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"). It should come as no surprise then that the PRRB granted expedited judicial review only for Fiscal Year 2019. *See* AR8 (granting review on "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").

Because Plaintiffs never sought judicial review for any claims other than for Fiscal Year 2019 and because the PRRB's grant of expedited judicial review was limited to Fiscal Year 2019, Plaintiffs' claims based on other fiscal years fall outside the Court's subject matter jurisdiction. This includes claims based on Fiscal Year 2020, which have never been presented to the PRRB.

Indeed, as CMS's rule for Fiscal Year 2020 is not yet final, those claims are not yet ripe for presentment to the PRRB, much less to this Court.

II. Plaintiffs' Substantive APA Challenges Fail as a Matter of Law

Plaintiffs' various substantive challenges to the Secretary's decision to apply a budget neutrality adjustment to site neutral payments in LTCH PPS for Fiscal Year 2019 fail because they are each based on the faulty premise that the 5.1% BNA is duplicative. But there is no duplication. First, the language of 42 U.S.C. § 1395ww(m)(6)(B)(ii) and the regulation to which it directs the Secretary plainly require him to calculate site neutral payments using specified values that were generated using various adjustments, including the IPPS BNA. Indeed, instead of requiring the Secretary to use a complex formula to calculate site neutral payments, Congress could have supplied a specified amount. The effect on LTCH PPS outliers would be the same; neither situation accounts for outliers unless and until the Secretary adjusts payments for that purpose. Second, the Secretary appropriately concluded that Section 307(b)(1) of the BIPA authorizes him to apply a budget neutrality adjustment within LTCH PPS to offset for outlier payments paid to site neutral payment cases. He accordingly did so. The Secretary's payment methodology is entirely consistent with the governing statutes and reflects a reasonable determination to which deference is due. As discussed in greater detail below, Plaintiffs offer no coherent theory to the contrary.

A. Congress Required the Secretary to Calculate Site Neutral Payments Using Amounts that Incorporate the IPPS BNA

Although Plaintiffs characterize the IPPS BNA as an adjustment that is made directly to site neutral payments, Mot. at 26 n.32, it is actually embedded into amounts that Congress directed the Secretary to use when calculating site neutral payments. In other words, the Secretary is statutorily required to calculate site neutral payments using defined amounts that already

incorporate the IPPS BNA. Specifically, the site neutral payment rate is defined by statute as the lower of:

> (I) the IPPS comparable per diem amount determined under paragraph (d)(4) of section 412.529 of title 42, Code of Federal Regulations, including any applicable outlier payments under section 412.525 of such title; or
>
> (II) 100 percent of the estimated cost for the services involved.

42 U.S.C. § 1395ww(m)(6)(B)(ii).

Through this provision, Congress directed the Secretary to compute the "IPPS comparable per diem amount" using the calculation described at 42 C.F.R. § 412.529(d)(4). That regulation requires the Secretary, first, to add two amounts together, "the applicable operating inpatient prospective payment system standardized amount and the capital inpatient prospective payment system Federal rate in effect at the time of the LTCH discharge." 42 C.F.R. § 412.529(d)(4)(A). Those two amounts – the IPPS standardized amount and the IPPS Federal rate – are values set annually by CMS through a complex computation. *See* 83 Fed. Reg. at 41724-25 (RR5991-92) (identifying FY 2019 IPPS operating standardized amounts); *id*. at 41729 (RR5996) (identifying FY 2019 IPPS capital Federal rate). They reflect the application of several adjustments, *see id*. at 41712-13, 41727-29 (RR5979-80, RR5994-96), including the IPPS BNA, *see id*. at 41723, 41728 (RR5990, RR5995); s*ee also* 42 C.F.R. § 412.64(f) (IPPS BNA is applied when calculating standardized amount); *id*. § 412.308(c)(2) (IPPS BNA is applied when calculating Federal rate).

Accordingly, the IPPS BNA is applied as part of the complex process by which CMS determines the IPPS standardized amount and IPPS Federal rate prior to the start of each fiscal year. Therefore, when Congress instructed the Secretary to compute the "IPPS comparable per diem amount" by adding the IPPS standardized amount and IPPS Federal rate in accordance with

42 C.F.R. § 412.529(d)(4), it understood that certain inputs to the calculation would already incorporate the IPPS BNA.[5]

Notwithstanding Congress's express instruction to calculate site neutral payments using the IPPS standardized amount and the IPPS Federal rate (both of which incorporate the IPPS BNA), Plaintiffs insist that the Secretary should alter those amounts by somehow deducting the IPPS BNA from them when calculating site neutral payments. Mot. at 29-30. But Plaintiffs' position is at odds with the statutory language. Again, Congress instructed the Secretary to follow the calculation described at 42 C.F.R. § 412.529(d)(4), which expressly requires the Secretary to use "the applicable operating inpatient prospective payment system standardized amount and the capital inpatient prospective payment system Federal rate in effect at the time of the LTCH discharge." In using the amounts specified, the Secretary is doing exactly what Congress directed. Plaintiffs' only textual argument is that Section 412.529(d)(4) "does *not* say to use the outlier BNAs from the IPPS operating and capital amounts in this calculation of the IPPS comparable per diem amount[.]" Mot. at 26. But, as noted, that regulation does say to use the IPPS standardized amount and IPPS Federal rate, which are further defined as incorporating the IPPS BNA. *See* 42 C.F.R. § 412.64(f); *id*. § 412.308(c)(2).

For these reasons, the Secretary appropriately uses inputs to the site neutral payment calculation that already reflect application of the IPPS BNA, as required by statute.

[5] The diagram attached hereto as Exhibit A summarizes the site neutral payment calculation and demonstrates how the IPPS BNA is incorporated into certain inputs to the site neutral payment calculation, namely, the IPPS standardized amounts (labor and non-labor share) and the IPPS Federal rate.

B. To Maintain Budget Neutrality Within LTCH PPS, the Secretary Must Apply the LTCH PPS BNA to Site Neutral Payments

The Secretary reasonably concluded that, to the extent LTCH PPS provides additional payments for outliers for site neutral cases, it is necessary to apply a BNA to site neutral payments in order to maintain budget neutrality within LTCH PPS. The Secretary's determination is reasonable and entitled to deference under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 845 (1984), particularly given the Secretary's "wide discretion" in "determining how to meet Medicare's budget neutrality requirements," *Adirondack Med. Ctr. v. Burwell*, 782 F.3d 707, 710 (D.C. Cir. 2015) (addressing budget neutrality under IPPS).

It is undisputed that the Secretary is authorized to maintain budget neutrality with regard to outlier payments in LTCH PPS. *See* Mot. at 23 ("Plaintiffs do not dispute that CMS can apply a BNA to LTCH site neutral case payments so that overall LTCH payments do not increase due to high cost outlier payments for qualifying site neutral cases."); *see also* BIPA, § 307(b)(1) (authorizing the Secretary to "provide for appropriate adjustments to the long-term hospital payment system"). Plaintiffs, however, argue that the Secretary is prohibited from applying the LTCH PPS BNA to site neutral payments because the IPPS BNA is incorporated into certain inputs to the site neutral rate calculation. In other words, Plaintiffs believe that the IPPS BNA already budget neutralizes payments within LTCH PPS such that an LTCH PPS-specific BNA is duplicative. But Plaintiffs misunderstand the function of the IPPS BNA, which does not promote budget neutrality in LTCH PPS.

Contrary to Plaintiffs' mistaken view, the IPPS BNA does not in any way account for outlier payments that are made in LTCH PPS. Rather, the amount of the IPPS BNA is set based on the amount of outlier payments in IPPS, an altogether different payment system than LTCH PPS. Specifically, the IPPS BNA is defined as an amount equal to the proportion of payments

estimated to be used for high cost outlier payments *within IPPS*. 42 U.S.C. § 1395ww(d)(3)(B). For Fiscal Year 2019, CMS set an outlier target of 5.1% for IPPS, which fell within Congress's requirement that the IPPS high cost outlier payments for a given year must be projected to be between 5 and 6 percent of the total IPPS payments. *See* 83 Fed. Reg. at 41717 (RR5984); *see also* 42 U.S.C. § 1395ww(d)(5)(A)(iv). In other words, CMS's projection is that 5.1% of total IPPS payments in Fiscal Year 2019 will be for high cost outliers in IPPS. After setting the IPPS outlier target at 5.1%, CMS likewise set the IPPS BNA at 5.1% to neutralize the effect on the total payments for the year for the IPPS. *See* 83 Fed. Reg. at 41723 (RR5990) (explaining that CMS "reduced the FY 2019 standardized amount by the same [5.1%] percentage to account for the projected proportion of payments paid as outliers [in IPPS]"). Accordingly, the IPPS BNA was determined according to features of outlier payments specific to IPPS; it has no relevance to the LTCH PPS outliers.

Although CMS used the same 5.1% figure for the site neutral payment BNA as for the IPPS BNA, that was due to its projection that costs and resource use for site neutral payment rate cases would mirror similar IPPS cases. 83 Fed. Reg. at 41736-37 (RR6003-04). Importantly, CMS has explained that, in the future, it may use different figures for the two BNAs if necessary based on CMS's continuing review of payment data. *See* 80 Fed. Reg. at 49621-22 (RR1263-64). The fact that the two BNAs do not necessarily have to match underscores that they serve to maintain budget neutrality in two distinct payment systems.

Plaintiffs' erroneous contention that the IPPS BNA maintains budget neutrality within LTCH PPS also ignores the fact that, as discussed above, the IPPS BNA is simply one of many adjustments to certain figures that are later used in the site neutral payment calculation. Indeed, Plaintiffs' motion is filled with inaccurate claims that CMS "uses the IPPS outlier BNA to adjust site neutral payments to LTCH hospitals." Mot. at 26 n.32. The IPPS BNA is not, as Plaintiffs

claim, "applie[d] . . . to the LTCH PPS site neutral payment rate." Mot. at 25. Rather, it is applied annually by CMS to determine the IPPS standardized amount and IPPS Federal rate for that year, 83 Fed. Reg. at 41712-13, 41727-29 (RR5979-80, RR5994-96), and it is those figures that are later used, along with other figures, to calculate site neutral payments, 42 C.F.R. § 412.529(d)(4)(A). It is therefore inaccurate for Plaintiffs to describe the IPPS BNA as an adjustment that is made within LTCH PPS.

For these reasons, the Secretary has repeatedly explained that the IPPS BNA is not relevant to the issue of budget neutrality within LTCH PPS. Principles of budget neutrality do not require CMS to disassemble the inputs to the site neutral payment calculation and treat each component of those inputs as adjustments that are made in the LTCH PPS. Particularly in light of CMS's substantial discretion in implementing budget neutrality, its decision to consider only adjustments made within LTCH PPS when analyzing LTCH PPS budget neutrality was entirely reasonable. *See* BIPA, § 307(b)(1) (granting discretion to the Secretary to "provide for appropriate adjustments to the long-term hospital payment system"); *Adirondack Med. Ctr.*, 782 F.3d at 710 (addressing the Secretary's "wide discretion" in "determining how to meet Medicare's budget neutrality requirements" in IPPS). But even assuming an alternative approach to budget neutrality in LTCH PPS exists and could be considered preferable to the Secretary's approach, an agency "is not required to choose the best solution, only a reasonable one." *Petal Gas Storage, L.L.C. v. FERC*, 496 F.3d 695, 703 (D.C. Cir. 2007); *see also North Carolina v. FERC*, 112 F.3d 1175, 1190 (D.C. Cir. 1997) (stating that although estimates that the agency used to select growth rates might have been less reasonable than other available data, "the fact that these estimates were less 'reasonable' does not necessarily make them unreasonable or arbitrary"); *Deaf Smith Cnty. Grain Processors, Inc. v. Glickman*, 162 F.3d 1206, 1215 (D.C. Cir. 1998) (noting that the arbitrary and capricious standard demands a reasonable decision, not the best or most reasonable decision).

As CMS has explained, while "the IPPS base rates that are used in site neutral payment rate calculation include a budget neutrality adjustment for IPPS HCO [high cost outlier] payments, that adjustment is merely a part of the calculation of one of the inputs (that is, the IPPS base rates) that are used in the LTCH PPS computation of site neutral payment rate." 80 Fed. Reg. at 49622 (RR1264). Again, "[t]he HCO budget neutrality factor that is applied in determining the IPPS base rates is intended to fund estimated HCO payment made under the IPPS," and "[a]s such, the HCO budget neutrality factor that is applied to the IPPS base rates does not account for the additional HCO payments that would be made to site neutral payment rate cases under the LTCH PPS." *Id.* To maintain budget neutrality within LTCH PPS, the Secretary reasonably determined that it is not sufficient to merely rely on adjustments incorporated into certain of the inputs for the calculation of the site neutral payment rate because those adjustments account only for outliers in IPPS hospitals. To properly adjust for outlier payments in LTCH PPS, the Secretary determined that CMS must adjust the site neutral payment rate amount itself. 42 C.F.R. § 412.522(c)(2). As CMS further explained, "[w]ithout a budget neutrality adjustment when determining payment for a case under the LTCH PPS, any HCO payment payable to site neutral payment rate cases would increase aggregate LTCH PPS payments" to a level that upsets budget neutrality. 80 Fed. Reg. at 49622 (RR1264).

Plaintiffs contend that CMS "calls" the IPPS BNA "an 'input' to avoid the appearance of duplication." Mot. at 26; *see also id*. at 28 (arguing that the IPPS BNA is not a "meaningless input"). Plaintiffs are wrong in two respects. First, the IPPS BNA is not itself an input to the site neutral calculation. The inputs include, among other things, the IPPS standardized amount and IPPS Federal rate, 42 C.F.R. § 412.529(d)(4)(A), which are adjusted prior to each fiscal year by the IPPS BNA, among many other adjustments, 83 Fed. Reg. at 41712-13, 41727-29 (RR5979-80, RR5994-96). Second, CMS's description of the standardized amount and Federal rate as inputs is

accurate. Congress determined that those would be the inputs to the site neutral rate calculation. 42 U.S.C. § 1395ww(m)(6)(B)(ii).

Plaintiffs also argue that Congress was not aware that the Secretary would budget neutralize the high cost outlier payments made to site neutral payment cases. Mot. at 27. But Congress conferred broad authority on CMS and, given CMS's longstanding practice of budget neutralizing outlier payments throughout the various Medicare payment systems, including within the LTCH PPS (for standard Federal rate cases), Congress surely expected the Secretary to do so here as well. Furthermore, as CMS has explained, the term "IPPS comparable per diem amount" was not new when Congress, in 2013, directed CMS to compute that amount using the calculation described at 42 C.F.R. § 412.529(d)(4). 81 Fed. Reg. at 57308 (RR2908). That regulation has been used since 2006 to calculate short stay outlier ("SSO") payments. *Id.* Short stay outliers are cases where the length of stay is significantly less than the average, 42 C.F.R. § 412.529(a), and those cases may be eligible for high cost outlier payments if their costs are sufficiently high, *id*. § 412.525(a). To maintain budget neutrality for high cost outlier payments for SSO cases (and also for high cost outlier payments for non-SSO standard Federal rate cases), CMS applies a BNA to the standard Federal rate, reducing it by 8%. *id*. § 412.523(d)(1). CMS does so even though the short stay outlier calculation uses inputs that already reflect application of the IPPS BNA. Congress was well aware of how CMS had implemented the "IPPS comparable per diem amount" language in the short stay outlier context. Thus, in using that same term to define the site neutral payment rate and in providing that the IPPS comparable per diem amount is to include "any applicable outlier payments," Congress presumably understood that CMS would budget neutralize the high cost outlier payments for site neutral cases, just as CMS had been doing for years for SSO cases. *See Lorillard v. Pons*, 434 U.S. 575, 581 (1978) ("[W]here, as here, Congress adopts a new law incorporating sections of a prior law, Congress normally can be presumed to have had

knowledge of the interpretation given to the incorporated law, at least insofar as it affects the new statute."); *Orton Motor, Inc. v. HHS*, 884 F.3d 1205, 1213 (D.C. Cir. 2018) (court may rely on regulations to interpret authorizing statute where Congress legislated with particular regulations in mind).[6]

Plaintiffs next point to the fact that CMS removes the impact of the prior year's IPPS BNA when calculating IPPS payment rates each year, and suggest that CMS should proceed similarly when calculating site neutral payments. Mot. at 30. But the two situations are not comparable. CMS updates IPPS payment rates each year based, in part, on the prior year's payment rates. 42 U.S.C. § 1395ww(d)(3)(A)(iv). In doing so, CMS removes the prior year's IPPS BNA before applying the current year's BNA, so that the impact of the BNA is not cumulative. 83 Fed. Reg. at 41729 (RR5996). In contrast, when CMS calculates site neutral payments, it is not merely updating the prior year's rates but instead is determining reimbursements for particular discharges based on a calculation defined by Congress.

For these reasons, the Secretary reasonably determined that the BNA for site neutral payments is an "appropriate adjustment[]" that maintains budget neutrality within LTCH PPS. BIPA, § 307(b)(1); *see also Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 218 (2009) (the agency's "view governs if it is a reasonable interpretation of the statute—not necessarily the only possible interpretation, nor even the interpretation deemed *most* reasonable by the courts.").

[6] Plaintiffs observe that CMS's Medicare Claims Processing Manual's discussion of SSO payment calculations does not discuss any BNA for SSO payments. Mot. at 26-27. From that, Plaintiffs conclude that a BNA should not be applied when calculating the IPPS comparable per diem amount. *Id*. But the reason the manual does not discuss a BNA is because the SSO payment rates discussed in that manual are not adjusted to account for high cost outliers. Instead, as discussed above, budget neutrality for high cost outliers in SSO cases is maintained by adjusting the standard Federal rate.

C. The Secretary Engaged in a Reasoned Analysis

Next, Plaintiffs contend that CMS did not engage in a reasoned analysis and did not take a "hard look" at the issue. Mot. at 31-32. The record shows otherwise. For years, CMS has carefully considered comments that the BNA for LTCH site neutral payments is duplicative of the IPPS BNA and has explained why those concerns are incorrect. *See* Background Section. Given that CMS's responses on this issue are discussed and quoted in Plaintiffs' own complaint, Compl. ¶¶ 27, 31, 32, 37, it is perplexing for Plaintiffs to claim that CMS has "entirely failed to consider an important aspect of the problem." Mot. at 23.

Plaintiffs also claim that "CMS believes that a separate BNA for LTCH site neutral HCO cases will 'reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS and promote fairness between the two systems.'" Mot. at 32 (quoting 83 Fed. Reg. at 41737). But CMS did not say that. In the language that Plaintiffs quote, CMS was explaining why it used the same fixed-loss amount—the amount that a case must exceed before it is eligible for a high cost outlier payment, 83 Fed. Reg. at 41734 (RR6001)—for site neutral payment cases as for IPPS cases. *Id*. at 41737 (RR6004). That language did not address the reason for applying a BNA to site neutral payments, which as CMS explained separately, is to maintain budget neutrality with respect to outlier payments made to site neutral payment cases. *Id*. at 41737 (RR6004) (BNA is necessary "to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2019 would not result in any increase in estimated aggregate FY 2019 LTCH PPS payments").

D. The Secretary's Decision is Not Internally Inconsistent

Nor is the Secretary's reasoning "internally inconsistent," as Plaintiffs claim. Mot. at 33-35. First, the fact that CMS uses the same threshold and targets for outliers in IPPS as in LTCH PPS does not mean that the BNA for outliers in the LTCH PPS is duplicative. As discussed, CMS

set the outlier threshold based on the IPPS outlier threshold because of its projection that site neutral payment rate cases would mirror similar IPPS cases. 83 Fed. Reg. at 41736-37 (RR6003-04). That is no surprise because the reason the site neutral rate was developed was that certain LTCH patients could be treated appropriately in a lower cost IPPS setting. But to maintain budget neutrality within LTCH PPS, CMS must account for outlier payments within LTCH PPS. CMS reasonably determined that the BNA for site neutral payments is necessary to maintain budget neutrality within LTCH PPS, just as a BNA is necessary to maintain budget neutrality in IPPS.

Second, there is no internal inconsistency in the Secretary's reasoning concerning budget neutrality for standard Federal rate cases and site neutral cases in LTCH PPS. Mot. at 34. Plaintiffs' perceived "inconsistency" is simply that Congress defined the site neutral payment calculation to use inputs that reflect the prior application of the IPPS BNA, whereas it has not required such inputs when calculating the standard Federal rate. Moreover, Plaintiffs' argument is based on their mistaken view that "CMS applies two BNAs to the site neutral payment rate." *Id*. As discussed, CMS applies only one BNA to site neutral payments (and uses inputs to the payment calculation that incorporate another BNA, among many other adjustments, as required by statute). *See* Section II(A).

Third, Plaintiffs claim the BNA is internally inconsistent "because it is contrary to the intent of budget neutrality." Mot. at 35. Plaintiffs believe the challenged BNA "reduces aggregate site neutral payments to LTCHs to a level that is *below* the budget neutral baseline." *Id*. The flaw in Plaintiffs' reasoning is the invalid assumption that the budget neutral baseline is the inputs to the site neutral payment calculation (*i.e.*, the IPPS standardized amount and IPPS Federal rate) *adjusted to remove the impact of the IPPS BNA*. But Plaintiffs offer no sound reason why that should be considered the relevant baseline for budget neutrality. In fact, Congress effectively has mandated the opposite.

E. The Secretary Did Not Make a Clear Error of Judgment

Repeating the same incorrect arguments made elsewhere in their motion, Plaintiffs contend that the Secretary's decision involved a "clear error of judgment." Mot. at 35-38. The "clear error of judgment standard" is no less deferential than ordinary arbitrary and capricious review and courts find a clear error of judgment "only if the error is so clear as to deprive the agency's decision of a rational basis." *Ethyl Corp. v. EPA*, 541 F.2d 1, 34 n.74 (D.C. Cir. 1976). Plaintiffs have identified no error of judgment here, much less an error that meets that very high standard.

Furthermore, the agency plainly did not "ignore[] evidence," Mot. at 37, but rather it carefully considered comments that the challenged BNA was duplicative and reasonably determined that there was no duplication. Likewise, there were no "computational errors" in CMS's determination of payment rates for LTCHs. *Id*. at 38. The LTCH PPS reimbursements are based on CMS's reasoned analysis and its proper application of Medicare payment policy pursuant to statutory requirements and broad authority conferred by Congress. Once again, the Secretary properly determined that the BNA for site neutral payments is necessary to maintain budget neutrality within LTCH PPS.

F. The Substantial Evidence Standard Does Not Apply Here

Plaintiffs next argue that the Secretary's decision "is not supported by substantial evidence." Mot. at 38. "The substantial evidence standard, however, does not apply in the rulemaking context." *Select Specialty Hosp. - Akron, LLC v. Sebelius*, 820 F. Supp. 2d 13, 27 (D.D.C. 2011). The APA provides that a reviewing court "shall hold unlawful and set aside agency action, findings, and conclusions found to be . . . unsupported by substantial evidence in a case subject to sections 556 and 557 of [the APA] or otherwise reviewed on the record of an agency hearing provided by statute." 5 U.S.C. § 706(2)(E). Sections 556 and 557 of the APA govern agency hearings at which evidence is taken. *See* 5 U.S.C. §§ 556, 557. "In other words, the

substantial evidence standard applies only to agency findings of fact made after a hearing, rather than the rulemaking process that is at issue in this case." *Select Specialty Hospital*, 820 F. Supp. 2d at 27.

Plaintiffs cite the Supreme Court's decision in *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 414 (1971) to argue that the substantial evidence standard applies to agency actions taken pursuant to a rulemaking. Mot. at 39. "Although the Supreme Court in *Citizens to Preserve Overton Park v. Volpe* referred to the substantial evidence test in connection with rule-making proceedings under 5 U.S.C. § 553, it later made clear in *Hynson* that this standard applies only to proceedings which are the subject of hearing provisions provided by 5 U.S.C. §§ 556 and 557 or to review of the record of an agency hearing provided by statute[.]" *Nat'l Nutritional Foods Asso. v. Weinberger*, 512 F.2d 688, 700-01 (2d Cir. 1975) (internal citation omitted; citing *Weinberger v. Hynson, Westcott & Dunning, Inc*., 412 U.S. 609, 622 n.19 (1973); *Camp v. Pitts*, 411 U.S. 138, 140-41 (1973)).

Even if the Court were to apply the substantial evidence standard here, the Secretary still should prevail, as the distinction between that standard and the arbitrary and capricious standard "is mostly academic." *Miley v. Lew*, 42 F. Supp. 3d 165, 170 n.2 (D.D.C. 2014) (citing *Assoc. of Data Processing Service Orgs., Inc. v. Board of Governors*, 745 F.2d 677, 684 (D.C. Cir. 1984) (noting "that the distinction between the substantial evidence test and the arbitrary and capricious test is 'largely semantic'")). For all the reasons why the Secretary's decision survives arbitrary and capricious review, it would also survive under a substantial evidence standard, were that standard applicable.

III. Plaintiffs' Procedural APA Challenges Fail as a Matter of Law

Plaintiffs also contend that the Secretary failed to respond adequately to comments on the BNA for site neutral payments. Mot. at 40-41. The Secretary's response to those comments, however, easily met his obligation to respond.

The D.C. Circuit has recognized that an agency's obligation to respond to comments on a proposed rulemaking is "not 'particularly demanding.'" *Ass'n of Private Sector Colls. & Univs. v. Duncan*, 681 F.3d 427, 441–42 (D.C. Cir. 2012) (quoting *Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993)). "[T]he agency's response to public comments need only 'enable [courts] to see what major issues of policy were ventilated . . . and why the agency reacted to them as it did.'" *Pub. Citizen, Inc.*, 988 F.2d at 197 (quoting *Auto. Parts & Accessories Ass'n v. Boyd*, 407 F.2d 330, 338 (D.C. Cir. 1968)); *cf. 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 that it has considered the most important objections.").

As discussed above, for the past several years, CMS has repeatedly considered comments that the BNA for LTCH site neutral payments was duplicative of the IPPS BNA and has explained why those concerns are incorrect. *See* Background Section. Plaintiffs' own complaint acknowledges the responses. Compl. ¶¶ 27, 31, 32, 37. Nevertheless, Plaintiffs argue that CMS's response in the Fiscal Year 2019 rulemaking was inadequate because it allegedly did not offer "a substantive response" and did not "explain why the BNA is not duplicative" of the IPPS BNA. Mot. at 40. Plaintiffs' argument is meritless because CMS's Fiscal Year 2019 rulemaking expressly referenced CMS's earlier substantive responses and incorporated the "reasons outlined in [CMS's] response to the nearly identical comments in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57308 through 57309) and [CMS's] response to similar comments in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49621 through 49622)." 83 Fed. Reg. at 41738 (RR6005).

Plaintiffs do not argue that the prior years' responses failed to address any issue raised by the commenters or were inadequate in any other respect. Accordingly, the Secretary need not do more under the APA. *See Pub. Citizen, Inc.*, 988 F.2d at 197.

IV. The Challenged BNA Does Not Violate Any Law

Plaintiffs argue that the challenged BNA is not an "appropriate adjustment" under Section 307 of the BIPA because it allegedly duplicates the impact of the IPPS BNA. Mot. at 42-43. The argument is again premised on the ill-conceived duplication theory, and accordingly, fails for the same reasons as discussed previously. As discussed above, the statutory scheme grants the Secretary broad discretion to make appropriate adjustments within LTCH PPS. BIPA, § 307(b)(1). In light of that broad discretion, his determinations easily pass muster under the deferential APA and *Chevron* standards. *See Chevron*, 467 U.S. at 845. The same is true with Plaintiffs' theory that the challenged BNA shifts Medicare costs to non-beneficiaries. Mot. at 44-45. Additionally, the anti-cross-subsidization principle applies only to reimbursement systems based on "reasonable costs" and therefore does not apply here. *See Abington Crest Nursing and Rehabilitation Ctr. v. Sebelius*, 575 F.3d 717, 720-21 (D.C. Cir. 2009).

Next, Plaintiffs argue that the challenged BNA violates the dual-rate structure for LTCH PPS. Although unclear, Plaintiffs' argument appears to be twofold: (1) that CMS allegedly is not paying LTCHs at the site neutral rate and (2) that CMS allegedly is paying LTCHs at a rate lower than similar cases would be paid under the IPPS. Mot. at 43-44. But for all the reasons discussed previously, CMS is paying hospitals at the appropriate rate calculated pursuant to the methodology required by Congress. And Plaintiffs' second argument hinges on a mistaken view—that the site neutral payment must be identical to the IPPS payment for similar cases. But the statute does not require identical payments under these two distinct payment systems; rather, it calls for calculation

of a "comparable" amount. 42 U.S.C. § 1395ww(m)(6)(B)(ii).[7] As CMS has explained, "differing statutory requirements between the two payment systems result in comparable LTCH PPS site neutral payment rate cases and IPPS cases not being paid exactly the same amount[.]" 80 Fed. Reg. at 49619 (RR1261). Indeed, the statutory requirement in 42 U.S.C. § 1395ww(m)(6)(B)(ii) that CMS pays the estimated cost for the services involved for a site neutral case if that cost is lower than the comparable IPPS per diem amount already creates a differential. *See* 80 Fed. Reg. at 49619 (RR1261). In addition, the statute specifies that the IPPS comparable amount is calculated as a per diem capped at the full amount as set forth under 42 C.F.R. § 412.529(d)(4), which also creates a differential. *Id*. Thus, the statute does not require exact payment equality between IPPS and LTCH PPS, and CMS's application of the site neutral BNA is proper under the statutory scheme. In any event, 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, 42 U.S.C. § 1395ww(m)(6)(B)(ii), which is likely higher than what the hospitals would be paid for a similar stay under the IPPS.

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,

JOSEPH H. HUNT
Assistant Attorney General

JENNIFER D. RICKETTS

[7] In contrast, other language in the same statute does instruct the Secretary to pay, in some circumstances, certain LTCHs an "amount that would apply under [the subsection pertaining to IPPS hospitals] for the discharge if the hospital were a [IPPS hospital.]" 42 U.S.C. § 1395ww(m)(6)(C). Accordingly, where Congress wanted LTCHs to be paid equivalently to IPPS hospitals, it used language clearly requiring identical payments, unlike here where Congress required only a "comparable" amount.

Director, Federal Programs Branch

JEAN LIN
Special Counsel, Federal Programs Branch

/s/ *Joshua Kolsky*
JOSHUA M. KOLSKY
Trial Attorney
D.C. Bar No. 993430
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW Washington, DC 20005
Tel.: (202) 305-7664
Fax: (202) 616-8470
E-mail: joshua.kolsky@usdoj.gov

Attorneys for Defendant

Exhibit A – Site Neutral Payment Calculation

The only fiscal year for which this Court has jurisdiction is Fiscal Year 2019. For Fiscal Year 2019, as in prior years, a blended rate applies. (The rate is not proposed to be blended for Fiscal Year 2020 due to a statutory requirement).

The blended site neutral payment = 50% of the site neutral payment rate amount + 50% of the LTCH PPS standard Federal rate.[1]

Site-neutral payment rate amount is the lower of:

(1) the IPPS comparable per diem amount determined under 42 C.F.R. § 412.529(d)(4), including any applicable outlier payments under 42 C.F.R. § 412.525, or

(2) 100 percent of the estimated cost for the services involved.[2]

[1] 42 C.F.R. § 412.522(c)(3).
[2] 42 U.S.C. § 1395ww(m)(6)(B)(ii); 42 C.F.R. § 412.522(c)(1).

IPPS Comparable Per Diem Amount Calculation

IPPS Comparable Payment Amount = Adjusted Operating IPPS Standardized Amount + Adjusted Capital IPPS Federal Rate[3]

Adjusted Operating IPPS Standardized Amount = ((**IPPS Labor-Share Standardized Amount*** x IPPS Wage Index)[4] + (**IPPS Non Labor-Share Standardized Amount*** x COLA for Operating Costs)[5]) x (IPPS DRG Relative Weight)[6] x (1 + Indirect Medical Education Adjustment for Operating Costs + Disproportionate Share Hospital Adjustment for Operating Costs)[7]

Adjusted Capital IPPS Federal Rate = (**IPPS Capital Federal Rate***) x (IPPS DRG Relative Weight)[8] x (Geographic Adjustment Factor)[9] x (COLA for Capital Costs)[10] x (1 + Indirect Medical Education Adjustment for Capital Costs + Disproportionate Share Hospital Adjustment for Capital Costs)[11]

IPPS Comparable Per Diem Amount Before Site-Neutral Budget Neutrality Adjustment is Applied[12] = (IPPS Comparable Payment Amount / IPPS Average Length of Stay for the DRG) x Covered Length of Stay[13]

IPPS Comparable Per Diem Amount = (IPPS Comparable Per Diem Amount Before Site-Neutral Budget Neutrality Adjustment is Applied x Site-Neutral BNA)[14] + Any Applicable High Cost Outlier Payment[15]

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* The IPPS BNA (*i.e.*, the 5.1% adjustment) is incorporated into the IPPS Comparable Per Diem Amount through the bolded figures above. *See* 42 C.F.R. § 412.64(f) (reduction of IPPS standardized amounts to account for IPPS outlier payments); 42 C.F.R. § 412.308(c)(2) (reduction of IPPS Federal rate to account for IPPS outlier payments).

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[3] 42 C.F.R. §§ 412.529(d)(4)(i)(A).
[4] 42 C.F.R. § 412.529(d)(4)(ii)(B).
[5] 42 C.F.R. § 412.529(d)(4)(ii)(B).
[6] 42 C.F.R. § 412.529(d)(4)(ii)(A).
[7] 42 C.F.R. § 412.529(d)(4)(ii)(C).
[8] 42 C.F.R. § 412.529(d)(4)(iii)(A).
[9] 42 C.F.R. § 412.529(d)(4)(iii)(B).
[10] 42 C.F.R. § 412.529(d)(4)(iii)(B).
[11] 42 C.F.R. § 412.529(d)(4)(iii)(C).
[12] This amount shall not exceed the IPPS Comparable Payment Amount (42 C.F.R. § 412.529(d)(4)(i)(C)).
[13] 42 C.F.R. § 412.529(d)(4)(i)(B).
[14] 42 C.F.R. § 412.522(c)(2)(i).
[15] 42 C.F.R. § 412.525.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

ORDER

Upon consideration of Defendant's Cross-Motion for Summary Judgment and Plaintiffs' Motion for Summary Judgment, the parties' briefing on such motions, and the entire record herein, it is hereby **ORDERED** that Defendant's Cross-Motion is **GRANTED** and Plaintiffs' Motion is **DENIED**.

It is **SO ORDERED** this ____day of _____, 2019.

_____
United States District Judge