IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NEW LIFECARE HOSPITALS OF CHESTER COUNTY LLC, *et al.*, Plaintiffs, v. ALEX M. AZAR II, Secretary U.S. Department of Health and Human Services Defendant.	Civil Action No. 19-cv-705 (EGS)

PLAINTIFFS' APPLICATION FOR A PRELIMINARY INJUNCTION AND REQUEST FOR EXPEDITED HEARING

Plaintiffs, 101 Medicare certified long-term care hospitals ("LTCHs") operated by LifeCare Health Partners ("LifeCare Hospitals"), Post Acute Medical, LLC ("Post Acute Medical"), Vibra Healthcare, LLC ("Vibra Healthcare"), and Kindred Healthcare, Inc. ("Kindred Healthcare"), hereby move the Court, under Rule 65 of the Federal Rules of Civil Procedure and Local Civil Rule 65.1, for a preliminary injunction enjoining Defendant's Centers for Medicare & Medicaid Services ("CMS") from enforcing, applying, or implementing the duplicative 5.1% budget neutrality adjustment ("BNA") to Medicare site neutral payments under the LTCH prospective payment system ("LTCH PPS") in FY 2019 and subsequent years.

Plaintiffs meet the test for the issuance of a preliminary injunction. There is a substantial likelihood that Plaintiffs will prevail on the merits of their case. Plaintiffs challenge CMS' adoption and application of a duplicative BNA that reduces the Medicare payments to LTCHs for site neutral payment rate cases under the LTCH PPS. CMS' decision to apply this duplicative BNA violates the Administrative Procedure Act ("APA") because the BNA is arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law, is unsupported by

substantial evidence, and violates the APA's notice and comment rulemaking requirements. Moreover, the duplicative BNA violates the Social Security Act ("SSA") and other federal laws.

Further, CMS' application of the BNA poses an imminent threat of irreparable harm to Plaintiffs. CMS is already applying the duplicative BNA to Plaintiffs' Medicare reimbursement. Although the exact monetary consequences will not be known until the conclusion of the Plaintiffs' FY 2019 cost reporting periods, the Plaintiffs estimate the duplicative BNA deprives them of $9,388,544 in the aggregate in FY 2019, but no less than $3,358,322.00. The loss of these funds forces Plaintiffs to reallocate their other revenues to subsidize the treatment that the Plaintiffs provide Medicare beneficiaries. Plaintiffs have also discontinued important services and programs as a result of the lost reimbursement. Dozens of LTCHs, including 21 of Plaintiffs' LTCHs, have already closed as a result of the lost Medicare reimbursement from the site neutral payment rate that has been arbitrarily reduced further by the duplicative BNA. If CMS continues to apply the duplicative BNA to site neutral payments, there will be even more LTCH closures. In addition, the harm to the Plaintiffs will become even greater in FY 2020 when the transition period for the LTCH site neutral payment rate ends and the monetary consequences of the BNA *double*. The lost Medicare reimbursement from the duplicative BNA is a windfall for the Medicare program that causes irreparable harm to Plaintiffs because it threatens the very existence of Plaintiffs' LTCHs.

In contrast, there is no hardship to CMS in enjoining the application of the duplicative BNA. These are funds that CMS is not entitled to as a matter of law. Additionally, there is no burden on CMS to comply with an injunction that prevents application of the duplicative BNA. An injunction is also in the public interest because it would ensure CMS is complying with its obligations under the APA, the SSA, and other federal laws. The public interest is also served if

CMS is required to make accurate payments for the services LTCHs provide to Medicare beneficiaries.

For the reasons stated in their accompanying Memorandum of Law and the supporting affidavits and exhibits attached thereto (filed concurrently herewith), Plaintiffs respectfully request that the Court issue an order: (1) granting the Plaintiffs' Application for a Preliminary Injunction; and (2) enjoining Defendant's CMS from enforcing, applying, or implementing the duplicative LTCH site neutral BNA in FY 2019 and subsequent years.

The undersigned counsel for Plaintiffs was unable to confer with counsel for Defendants, in accordance with Local Civil Rule 7(m), because no counsel has entered an appearance for Defendant as of the time of this filing.

Plaintiffs' Request for Preliminary Hearing. Under LCvR 65.1(d), Plaintiffs respectfully request that the Court set an expedited hearing on Plaintiffs' Application for a Preliminary Injunction at the Court's earliest convenience, other than April 15-19, 2019, but no later than 21 days after the filing of Plaintiffs' Application. LCvR 65.1(d). A statement of facts which make expedition essential is contained in the attached Memorandum in Support of Plaintiffs' Application for a Preliminary Injunction. *See* Memorandum, filed concurrently herewith, at Statement of Material Facts, 6-19.

Dated: April 5, 2019 Respectfully Submitted,

/s/ *Jason M. Healy*

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MEMORANDUM IN SUPPORT OF PLAINTIFFS' APPLICATION FOR A PRELIMINARY INJUNCTION

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Plaintiffs, 101 Medicare certified long-term care hospitals ("LTCHs") operated by LifeCare Health Partners ("LifeCare Hospitals"), Post Acute Medical, LLC ("Post Acute Medical"), Vibra Healthcare, LLC ("Vibra Healthcare"), and Kindred Healthcare, Inc. ("Kindred Healthcare"), hereby submit the following memorandum of points and authorities in support of their Application for a Preliminary Injunction to set aside and enjoin a duplicative budget neutrality adjustment ("BNA") that the Defendant's Centers for Medicare & Medicaid Services ("CMS") applies to the site neutral payment rate under the Long-Term Care Hospital Prospective Payment System ("LTCH PPS").

I. INTRODUCTION

Plaintiffs are Medicare certified LTCHs located throughout the United States. The 101 Plaintiffs represent more than one-quarter of the total number of LTCHs nationwide. Plaintiffs' LTCHs provide care for medically complex patients who require acute care hospital services for an extended period of time. Plaintiffs bring this action to challenge the Defendant's unlawful adoption and implementation of a negative 5.1 percent outlier BNA that Defendant is applying *twice* to LTCH PPS site neutral case payments. Defendant's duplicative BNA improperly reduces Medicare payments to the Plaintiffs and results in a windfall for the Medicare program. Plaintiffs explained the Defendant's error in comments submitted to CMS during the notice-and-comment rulemaking process. The Defendant has dismissed these comments and has refused to take a "hard look" at this issue. Moreover, the duplicative BNA is not the product of reasoned decisionmaking and reflects a clear error in judgment by Defendant's CMS. This erroneous BNA is therefore a textbook violation of the arbitrary and capricious standard under the Administrative Procedure Act ("APA"). 5 U.S.C. § 705(2)(A). In addition, this duplicative BNA violates the Social Security Act ("SSA") and other federal laws.

The duplicative BNA poses an imminent threat of irreparable harm to Plaintiffs. Without any legitimate basis, the Defendant is using the duplicative BNA to arbitrarily reduce Plaintiffs' Medicare reimbursement. As a result, the Defendant is withholding millions of dollars in Medicare reimbursement to the Plaintiffs each year. The loss of these funds is requiring Plaintiffs to reallocate other revenues to subsidize the treatment of medically complex Medicare beneficiaries and other patients, make cuts to programs or staff, and in some cases close the hospital entirely. In contrast, there is no hardship on Defendant from enjoining the duplicative BNA because these are funds that the Defendant is not entitled to as a matter of law. Moreover, Defendant's compliance with the APA, SSA, and other federal laws also serves a compelling public interest.

If the duplicative BNA is not enjoined, the harm to Plaintiffs will continue during the pendency of this lawsuit. Plaintiffs will not receive the full Medicare site neutral payments they are entitled to receive in fiscal year ("FY") 2019. Moreover, without an injunction, the financial impact of the duplicative BNA will *double* in FY 2020. More LTCHs are likely to close as a result. Therefore, Plaintiffs seek an order enjoining Defendant from enforcing, applying, or implementing the duplicative site neutral budget neutrality adjustment in FY 2019 and subsequent years.

II. LEGAL BACKGROUND

A. Site Neutral Payment

For LTCH Part A discharges in cost reporting periods beginning on or after October 1, 2015, Congress established a new dual-rate payment structure under the Medicare payment system for LTCHs, the LTCH PPS, with two distinct payment rates. 42 U.S.C. § 1395ww(m)(6) (SSA § 1886(m)(6)). The first payment rate is the LTCH PPS standard Federal payment rate, discussed above. *Id.* at § 1395ww(m)(6)(A)(ii) (SSA § 1886(m)(6)(A)(ii)). This first payment

rate only applies to discharges that meet one of the two patient criteria established by section 1206 of the Pathway for SGR Reform Act of 2013 ("PSRA"), Pub. L. No. 113-67, Div. B, 127 Stat. 1165 (2013)[1]—3 or more days in a "subsection (d) hospital"[2] intensive care unit ("ICU") or LTCH ventilator services of at least 96 hours—and a principal diagnosis that is not psychiatric or rehabilitation. *Id.* at §§ 1395ww(m)(6)(A)(ii),(iii),(iv) (SSA §§ 1886(m)(6)(A)(ii),(iii),(iv)). All other LTCH Part A discharges are reimbursed at the site neutral payment rate, which is the lesser of the IPPS comparable per diem amount (including any applicable outlier payments) or 100 percent of the estimated cost of the services involved. *Id.* at § 1395ww(m)(6)(B)(ii) (SSA § 1886(m)(6)(B)(ii)).

CMS implemented the site neutral payment rate through the regulation at 42 C.F.R. § 412.522. The IPPS comparable per diem amount used for determining LTCH site neutral payments is calculated by adding the adjusted standardized IPPS operating amount to the adjusted capital IPPS Federal rate, divided by the geometric average length of stay of the specific MS-DRG under the IPPS, and multiplying that amount by the covered days of the LTCH stay, but no higher than the full IPPS payment amount. FY 2016 IPPS/LTCH PPS Final Rule, 80 Fed. Reg. 49326, 49608-09 (Aug. 17, 2015).

LTCHs are transitioning to the new LTCH PPS dual-rate structure with a blended payment rate that applies to site neutral case discharges in cost reporting periods beginning on or

[1] Congress has amended Section 1206 of the Pathway for SGR Reform Act of 2013 on several occasions. However, none of the amendments are at issue in this case. *See* Bipartisan Budget Act of 2018, Pub. L. No. 115-123, § 51005, 132 Stat. 64 (2018); 21st Century Cures Act, Pub. L. No. 114-255, §§ 15009(a), 15010(a), 130 Stat. 1033 (2016); Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 231, 129 Stat. 2242 (2015); Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, § 112(a), 128 Stat. 1040 (2014).

[2] A reference to section 1861(d)(1)(B) of the SSA (42 U.S.C. § 1395x(d)(1)(B)). These are primarily general short-term acute care hospitals paid by Medicare under the IPPS.

after October 1, 2015 and on or before September 30, 2019. 42 U.S.C. § 1395ww(m)(6)(B)(i)(I) (SSA § 1886(m)(6)(B)(i)(I)). During this transition period, the blended payment rate for site neutral cases is equal to one-half the site neutral payment rate and one-half the LTCH PPS standard Federal payment rate. *Id.* at § 1395ww(m)(6)(B)(ii) (SSA § 1886(m)(6)(B)(ii)). FY 2019 is the last year of the transition period. LTCH site neutral case discharges in cost reporting periods beginning on or after October 1, 2019 will be paid at 100 percent of the site neutral payment rate.

B. High Cost Outlier Payments

In addition to the standard Federal payment rate for a Medicare discharge, Medicare makes additional payments for high cost outlier ("HCO") cases that have extraordinarily high costs relative to the costs of most discharges. These high cost outlier payments are a feature of both the IPPS and the LTCH PPS. 42 U.S.C. § 1395ww(d)(5)(A)(ii) (SSA § 1886(d)(5)(A)(ii)); 42 C.F.R. § 412.525(a)(1). CMS sets a threshold each year at the maximum loss that a provider can incur for a case with unusually high costs before the provider will receive an additional high cost outlier payment.

Like LTCH cases that are paid the standard Federal payment rate, site neutral cases paid at the IPPS comparable per diem amount may include a LTCH outlier payment. 42 U.S.C. § 1395ww(m)(6)(B)(ii)(I) (SSA § 1886(m)(6)(B)(ii)(I)). For LTCH site neutral cases, CMS sets the same target amount of total HCO payments and fixed-loss amount as they do for IPPS hospitals. 83 Fed. Reg. at 41734 ("For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount.").

III. STATEMENT OF MATERIAL FACTS

A. FY 2016 Rulemaking

CMS first implemented the site neutral payment rate for LTCHs during the FY 2016 IPPS/LTCH PPS rulemaking. In the FY 2016 IPPS/LTCH PPS Final Rule, CMS adopted a budget neutrality factor (adjustment) (the "BNA") for the site neutral portion of the LTCH site neutral blended payment rate. FY 2016 IPPS/LTCH PPS Final Rule, 80 Fed. Reg. 49326, 49805 (Aug. 17, 2015). CMS claimed that this BNA was necessary "to ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2016 do not result [in] any increase in estimated aggregate FY 2016 LTCH PPS payments . . . ." *Id.* CMS finalized this BNA to reduce the LTCH site neutral payment rate amount by 5.1%. *Id.* In the same FY 2016 Final Rule, CMS finalized high cost outlier BNAs of negative 5.1% to the IPPS operating standardized amount and approximately the same amount to the IPPS capital Federal rate.[3] *Id.* at 49785, 49794-95. The IPPS payment rate, as reduced by these IPPS outlier BNAs, is used to determine the IPPS comparable per diem amount under the LTCH PPS site neutral payment rate discussed above.

During the comment period for the FY 2016 LTCH PPS rulemaking, the Plaintiffs and other stakeholders submitted comments to CMS objecting to the BNA. The Plaintiffs explained to CMS that the proposed BNA was duplicative of the outlier BNAs already applied to the IPPS payment rate. For example, Kindred Healthcare, the parent company of many of the Plaintiffs, and another LTCH company submitted a comment letter to CMS that stated:

> Specifically, CMS already reduced the operating standardized payment amount under the IPPS and the capital federal rate under the capital PPS for outliers. In determining these payment rates for FY 2016, CMS reduced the IPPS payment rate by a factor of 0.948999 and CMS reduced the capital PPS payment rate by a

[3] Payment rates for operating and capital costs are handled separately under the IPPS, but combined under the LTCH PPS. Each year, the IPPS operating standardized amount budget neutrality adjustment is 5.1% and the IPPS capital outlier budget neutrality adjustment is approximately 5.1%. Accordingly, for the sake of clarity, this Memorandum In Support Of Plaintiffs' Application for a Preliminary Injunction will generally refer to both IPPS adjustments as a budget neutrality adjustment of 5.1%.

> factor of 0.935731. **It would be duplicative (*i.e.*, CMS would be removing outlier payments twice) if CMS also applies the proposed site neutral HCO BNA. This would be the case because the IPPS comparable per diem amount will be based on the FY 2016 IPPS payment rate, which has already been adjusted by the 5.1 percent outlier target. Since CMS has already reduced the FY 2016 IPPS payment rate by the 5.1 percent of estimated outlier payments in FY 2016, it would be inappropriate for CMS to reduce LTCH payments that are based on the IPPS rate again for site neutral cases that qualify as HCOs. Therefore, we object to CMS' proposal to apply a separate HCO BNA to LTCH site neutral payments.**[4]

Post Acute Medical and Vibra Healthcare, the parent companies of other Plaintiffs, also submitted comments to CMS objecting to the duplicative BNA.[5] Vibra Healthcare's FY 2016 comment letter explained that Vibra Healthcare objected to the BNA because the IPPS comparable per diem amount was already reduced by the same 5.1%. *See* Vibra Healthcare, Comment Letter on FY 2016 IPPS/LTCH PPS Proposed Rule at 21.

Leading hospital trade associations also submitted comments to CMS during the FY 2016 rulemaking opposing the erroneous BNA. The American Hospital Association ("AHA") submitted a comment letter to CMS objecting to the "two outlier-related BNAs for site-neutral rates."[6] The AHA explained:

> Specifically, the inpatient PPS rates used as the basis for site-neutral payment rates are already subject to a BNA for the inpatient PPS's 5.1 percent outlier pool. However, within the LTCH payment framework, CMS proposes a second BNA of 2.3 percent for the site-neutral outlier pool. CMS's rationale for this second BNA

[4] Kindred Healthcare, Inc. & Select Medical Holdings Corp., Comment Letter on FY 2016 IPPS/LTCH PPS Proposed Rule at 39 (June 16, 2015), https://www.regulations.gov/contentStreamer?documentId=CMS-2015-0049-0222&attachmentNumber=1&contentType=pdf (footnote omitted).

[5] Post Acute Medical, Comment Letter on FY 2016 IPPS/LTCH PPS Proposed Rule at 23-25 (June 16, 2015), https://www.regulations.gov/contentStreamer?documentId=CMS-2015-0049-0199&attachmentNumber=1&contentType=pdf; Vibra Healthcare, Comment Letter on FY 2016 IPPS/LTCH PPS Proposed Rule at 19-21 (June 15, 2015).

[6] American Hospital Association, Comment Letter on FY 2016 IPPS/LTCH PPS Proposed Rule at 7 (June 15, 2015), https://www.regulations.gov/contentStreamer?documentId=CMS-2015-0049-0121&attachmentNumber=1&contentType=pdf.

> is to ensure that site-neutral HCO payments do not increase aggregate LTCH PPS payments. **However, we strongly disagree that the additional 2.3 percent BNA is necessary to achieve this goal; rather, it was already achieved when the 5.1 percent BNA was applied to the inpatient PPS rates used as the basis for the site-neutral rates. We recommend that CMS calculate standard LTCH PPS and site-neutral rates separately, without any co-mingling of these payments, as mentioned previously.** Furthermore, the second BNA prevents LTCH site-neutral payments from aligning with inpatient PPS payments for associated MS-DRG and MS-LTC-DRGs, which would counter the goals of BiBA.[7]

The Federation of American Hospitals ("FAH") submitted similar comments in response to the FY 2016 Proposed Rule. The FAH opposed the outlier BNA for LTCH site neutral cases because "CMS has already accounted for estimated outlier payments for site neutral cases when it adjusted the IPPS payment rate for FY 2016."[8] The FAH explained that because LTCH site neutral cases are already paid at the IPPS comparable rate, the additional BNA is "an additional unwarranted reduction in payment." Federation of American Hospitals, Comment Letter on FY 2016 IPPS/LTCH PPS Proposed Rule at 67.

In the FY 2016 Final Rule, CMS acknowledged that it received comments objecting to the site neutral outlier BNA. 80 Fed. Reg. at 49622. In response to these objections, CMS stated:

> We disagree with the commenters that a budget neutrality adjustment for site neutral payment rate HCO payments is unnecessary or duplicative. 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

[7] American Hospital Association, Comment Letter on FY 2016 IPPS/LTCH PPS Proposed Rule at 7 (emphasis in original). The AHA's FY 2016 comment letter references a 2.3% budget neutrality adjustment. CMS initially proposed a 2.3% adjustment in the FY 2016 Proposed Rule because CMS planned to apply a budget neutrality adjustment to all LTCH PPS payments. FY 2016 IPPS/LTCH PPS Proposed Rule, 80 Fed. Reg. 24324, 24649 (Apr. 30, 2015). However, in the FY 2016 Final Rule, CMS decided that it would instead apply a 5.1% adjustment only to site neutral case payments. *See* FY 2016 IPPS/LTCH PPS Final Rule, 80 Fed. Reg. at 49805.

[8] Federation of American Hospitals, Comment Letter on FY 2016 IPPS/LTCH PPS Proposed Rule at 67 (June 16, 2015), https://www.regulations.gov/contentStreamer?documentId=CMS-2015-0049-0188&attachmentNumber=1&contentType=pdf.

> 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. 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. For these reasons, we are not adopting the commenters' recommendation to change the calculation of the IPPS comparable per diem amount to adjust the IPPS operating standardized amount used in that calculation to account for the application of the IPPS HCO budget neutrality adjustment.

Id. Despite admitting that 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," CMS kept this HCO BNA and the separate LTCH site neutral outlier BNA of negative 5.1 percent in the calculation of the LTCH site neutral payment rate. *Id.*

B. FY 2017 Rulemaking

A similar process played out during the FY 2017 LTCH PPS rulemaking. However, this time the Medicare Payment Advisory Commission ("MedPAC") also strongly opposed the duplicative BNA. CMS proposed a 5.1% BNA to the LTCH site neutral payment rate portion of the blended payment rate. FY 2017 IPPS/LTCH PPS Proposed Rule, 81 Fed. Reg. 24946, 25288-89 (Apr. 27, 2016). MedPAC's FY 2017 comment letter objected to this separate BNA for LTCH site neutral high-cost outliers because, as the Plaintiffs and hospital trade associations were telling CMS, "the IPPS standard payment amount is already adjusted to account for HCO

payments."[9] MedPAC explained why it was incorrect for CMS to apply another BNA to the LTCH site neutral payment rate:

> CMS proposes to use the IPPS fixed-loss amount to determine if a discharge paid under the site-neutral rate qualifies to receive an HCO payment again for FY 2017. CMS sets the IPPS fixed-loss amount each year at a level that it estimates will result in aggregate HCO payments equal 5.1 percent of total IPPS payment. **To account for the spending attributed to these outlier payments, CMS reduces the IPPS base payment rates to maintain budget neutrality in the IPPS. The IPPS-comparable rate used to pay for site-neutral cases in LTCHs includes an adjustment for budget neutrality to account for spending associated with HCOs.**
>
> With the Commission's payment principles in mind, **MedPAC urges CMS to eliminate the proposed payment adjustment for discharges paid the site-neutral rate to account for outlier payments under this payment methodology. Given that the IPPS standard payment amount is already adjusted to account for HCO payments, CMS' proposal to reduce the site-neutral portion of the LTCH payment by a budget neutrality adjustment of 0.949 is duplicative and exaggerates the disparity in payment rates across provider settings. Given this duplication, CMS should not adjust the site-neutral rate further.**

MedPAC, Comment Letter on FY 2017 IPPS/LTCH PPS Proposed Rule at 16-17 (emphasis added).

Kindred Healthcare,[10] LifeCare Hospitals,[11] Post Acute Medical,[12] and Vibra HealthCare[13] each submitted comments objecting to the proposed BNA in the FY 2017

[9] MedPAC, Comment Letter on FY 2017 IPPS/LTCH PPS Proposed Rule at 16 (May 31, 2016), https://www.regulations.gov/contentStreamer?documentId=CMS-2016-0053-0123&attachmentNumber=1&contentType=pdf.

[10] Kindred Healthcare & Select Medical Holdings Corporation, Comment Letter on FY 2017 IPPS/LTCH PPS Proposed Rule at 18-25 (June 17, 2016), https://www.regulations.gov/contentStreamer?documentId=CMS-2016-0053-0521&attachmentNumber=1&contentType=pdf.

[11] LifeCare Hospitals, Comment Letter on FY 2017 IPPS/LTCH PPS Proposed Rule at 7-11 (June 15, 2016), https://www.regulations.gov/contentStreamer?documentId=CMS-2016-0053-0315&attachmentNumber=1&contentType=pdf.

Proposed Rule. Kindred Healthcare included a table that clearly shows the duplication using the components of the site neutral payment rate. Kindred Healthcare & Select Medical Holdings Corporation, Comment Letter on FY 2017 IPPS/LTCH PPS Proposed Rule at 20-22, Table 1. Without making this change, the duplicative BNA not only "exaggerates the disparity in payment rates across provider settings," as MedPAC states, but it is also purely punitive. *Id.* at 22. The AHA[14] and FAH[15] also opposed the proposed site neutral BNA in the FY 2017 Proposed Rule. Many of these comments requested that CMS not only fix the erroneous calculation of the BNA for FY 2017, but also correct the adjustment CMS applied in FY 2016 because the hospitals were systematically underpaid. *See e.g.*, Kindred Healthcare & Select Medical Holdings Corporation, Comment Letter on FY 2017 IPPS/LTCH PPS Proposed Rule at 23 ("CMS must reverse this adjustment to all FY 2016 payments, or make an equivalent prospective increase in payments to FY 2017 site neutral rate cases to account for this underpayment.").

Despite these strong objections from MedPAC, the Plaintiffs, other hospitals and hospital trade associations in written comments to the agency, CMS again dismissed these concerns and

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[12] Post Acute Medical, Comment Letter on FY 2017 IPPS/LTCH PPS Proposed Rule at 14-21 (June 17, 2016), https://www.regulations.gov/contentStreamer?documentId=CMS-2016-0053-1262&attachmentNumber=1&contentType=pdf.

[13] Vibra Healthcare, Comment Letter on FY 2017 IPPS/LTCH PPS Proposed Rule at 14-21 (June 17, 2016), https://www.regulations.gov/contentStreamer?documentId=CMS-2016-0053-0483&attachmentNumber=1&contentType=pdf.

[14] American Hospital Association, Comment Letter on FY 2017 IPPS/LTCH PPS Proposed Rule at 5-8 (June 17, 2016), https://www.aha.org/system/files/advocacy-issues/letter/2016/160617-let-nickels-slavitt-ltch.pdf.

[15] Federation of American Hospitals, Comment Letter on FY 2017 IPPS/LTCH PPS Proposed Rule at 48-49 (June 17, 2016), https://www.regulations.gov/contentStreamer?documentId=CMS-2016-0053-0575&attachmentNumber=1&contentType=pdf.

finalized the BNA for FY 2017. *See* FY 2017 IPPS/LTCH PPS Final Rule, 81 Fed. Reg. 56762, 57308-09 (Aug. 22, 2016).[16]

C. FY 2018 Rulemaking

In FY 2018, CMS continued applying the BNA over the objections of the Plaintiffs and others. The FY 2018 IPPS/LTCH PPS Final Rule contained an identical BNA. FY 2018 IPPS/LTCH PPS Final Rule, 82 Fed. Reg. 37990, 38544-46 (Aug. 14, 2017). During the FY 2018 comment period, Kindred Healthcare,[17] LifeCare Hospitals,[18] Post Acute Medical,[19] and Vibra HealthCare[20] each submitted comments opposing the proposed adjustment for FY 2018. The Plaintiffs also continued to request that CMS correct the duplicative adjustment that CMS already applied to FY 2016 and FY 2017 LTCH site neutral payments.[21] In addition to the Plaintiffs, the AHA and FAH again objected to the FY 2018 BNA.[22] Despite these objections for

[16] In the FY 2017 IPPS/LTCH PPS Final Rule, CMS did make one change to the BNA. CMS decided that the budget neutrality adjustment would not be applied to the HCO payment itself for site neutral payment rate cases. 81 Fed. Reg. at 57309.

[17] Kindred Healthcare & Select Medical Holdings Corporation, Comment Letter on FY 2018 IPPS/LTCH PPS Proposed Rule at 5-12 (June 13, 2017), https://www.regulations.gov/contentStreamer?documentId=CMS-2017-0055-4033&attachmentNumber=1&contentType=pdf.

[18] LifeCare Hospitals, Comment Letter on FY 2018 IPPS/LTCH PPS Proposed Rule at 14-18 (June 13, 2017), https://www.regulations.gov/contentStreamer?documentId=CMS-2017-0055-3745&attachmentNumber=1&contentType=pdf.

[19] Post Acute Medical, Comment Letter on FY 2018 IPPS/LTCH PPS Proposed Rule at 4 (June 12, 2017), https://www.regulations.gov/contentStreamer?documentId=CMS-2017-0055-3620&attachmentNumber=1&contentType=pdf.

[20] Vibra Healthcare, Comment Letter on FY 2018 IPPS/LTCH PPS Proposed Rule at 20-23 (June 13, 2017), https://www.regulations.gov/contentStreamer?documentId=CMS-2017-0055-3729&attachmentNumber=1&contentType=pdf.

[21] *See e.g.*, Kindred Healthcare & Select Medical Holdings Corporation, Comment Letter on FY 2018 IPPS/LTCH PPS Proposed Rule at 12 ("CMS should reverse this adjustment to all FY 2016 and FY 2017 payments, or make an equivalent prospective increase in payments to FY 2018 site neutral rate cases to account for this underpayment.").

[22] American Hospital Association, Comment Letter on FY 2018 IPPS/LTCH PPS Proposed Rule at 4-7 (June 13, 2017), https://www.regulations.gov/contentStreamer?documentId=CMS-2017-

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a third year, CMS again finalized the BNA without any change. *See* FY 2018 IPPS/LTCH PPS Final Rule, 82 Fed. Reg. 37990, 38544-46 (Aug. 14, 2017).

D. FY 2019 Rulemaking

In the FY 2019 IPPS/LTCH PPS Proposed Rule, CMS again proposed the BNA for all LTCH site neutral payment rate cases. CMS claimed that this adjustment is necessary so that HCO payments for such cases do not result in any change to estimated aggregate LTCH payments. FY 2019 IPPS/LTCH PPS Proposed Rule, 83 Fed. Reg. 20164, 20596 (May 7, 2018). The proposed BNA would reduce the LTCH site neutral payment rate amount by 5.1% to offset the cost of LTCH site neutral HCO payments in FY 2019. *Id.* In addition to this BNA for LTCH site neutral HCO cases, CMS again proposed adjusting the IPPS payment rate to account for projected IPPS outlier payments. 83 Fed. Reg. at 20583. Specifically, CMS proposed a BNA to reduce the IPPS payment rate by 5.1%. *Id.* As in prior years, the IPPS rate is used to determine the IPPS comparable per diem amount for LTCH site neutral payment rate cases.

In response to the FY 2019 IPPS/LTCH PPS Proposed Rule, the Plaintiffs and other commenters again objected to the BNA on the grounds that the adjustment is duplicative of the BNA CMS proposed to apply to the IPPS payment rate. Kindred Healthcare stated that CMS' calculation of the 5.1 percent LTCH PPS site neutral BNA did not account for the BNA CMS already proposed for the IPPS payment rate:

> Consistent with MedPAC's and the AHA's comments, we strongly disagree with the proposed 0.949 budget neutrality adjustment for site neutral cases that qualify as high-cost outliers. CMS already reduced the FY 2019 site neutral payment

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0055-3995&attachmentNumber=1&contentType=pdf; Federation of American Hospitals, Comment Letter on FY 2018 IPPS/LTCH PPS Proposed Rule at 62-63 (June 13, 2017), https://www.regulations.gov/contentStreamer?documentId=CMS-2017-0055-4057&attachmentNumber=1&contentType=pdf.

> amount for estimated outlier payments via the IPPS HCO outlier factor and the capital PPS outlier factor. CMS should *not* reduce LTCH site neutral payments by *another 5.1%*.[23]

LifeCare Hospitals explained to CMS that the proposed LTCH site neutral adjustment was duplicative of the adjustments already included in the LTCH site neutral payment rate:

> This BNA is duplicative and unwarranted because CMS has *already* applied budget neutrality adjustments to reduce the operating and capital portions of the IPPS standard Federal payment rate by the same 5.1%, before using that rate to determine the IPPS comparable per diem amount for site neutral payment cases.[24]

Similarly, Vibra Healthcare submitted comments to CMS explaining CMS' error in calculating the BNA.[25] As in prior years, the AHA and FAH also objected to the BNA.[26] The comment letters to the proposed rule specifically asked CMS to take a fresh look at this issue and consider the detrimental effect the duplicative adjustment would have on LTCHs in FY 2019, as well as the harm that already occurred by applying the BNA in FYs 2016 through 2018.[27]

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[23] Kindred Healthcare & Select Medical Holdings Corporation, Comment Letter on FY 2019 IPPS/LTCH PPS Proposed Rule at 42 (June 25, 2018), https://www.regulations.gov/contentStreamer?documentId=CMS-2018-0046-1349&attachmentNumber=1&contentType=pdf.

[24] LifeCare Hospitals, Comment Letter on FY 2019 IPPS/LTCH PPS Proposed Rule at 14 (June 21, 2018), https://www.regulations.gov/contentStreamer?documentId=CMS-2018-0046-1055&attachmentNumber=1&contentType=pdf.

[25] Vibra Healthcare, Comment Letter on FY 2019 IPPS/LTCH PPS Proposed Rule at 21-25 (June 25, 2018), https://www.regulations.gov/contentStreamer?documentId=CMS-2018-0046-1360&attachmentNumber=1&contentType=pdf.

[26] American Hospital Association, Comment Letter on FY 2019 IPPS/LTCH PPS Proposed Rule at 6-8 (June 25, 2018), https://www.regulations.gov/contentStreamer?documentId=CMS-2018-0046-1495&attachmentNumber=1&contentType=pdf; Federation of American Hospitals, Comment Letter on FY 2019 IPPS/LTCH PPS Proposed Rule at 42-43 (June 25, 2018), https://www.regulations.gov/contentStreamer?documentId=CMS-2018-0046-1468&attachmentNumber=1&contentType=pdf.

[27] LifeCare Hospitals, Comment Letter on FY 2019 IPPS/LTCH PPS Proposed Rule at 15; Kindred Healthcare & Select Medical Holdings Corporation, Comment Letter on FY 2019 IPPS/LTCH PPS Proposed Rule at 36, 42.

In spite of these comments, CMS finalized the duplicative BNA for all LTCH site neutral payment rate cases in the FY 2019 IPPS/LTCH PPS Final Rule. 83 Fed. Reg. 41144, 41737-38 (Aug. 17, 2018). At the same time, CMS finalized the 5.1% BNA to the IPPS payment rate. *Id.* at 41723, 41728. CMS offered only a brief response to the Plaintiffs' comments objecting to the duplicative BNA, essentially repeating what it had said in the FY 2018 Final Rule:

> 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).

Id. at 41738.

Accordingly, CMS is applying a BNA factor of 0.949 (5.1%) to reduce the site neutral payment rate portion of the LTCH PPS blended payment rate for all site neutral cases, despite the fact that the IPPS comparable per diem amount has already been reduced by the same percentage by the IPPS outlier BNA. This BNA reduces site neutral case payments by an *additional* 5.1% for all LTCHs, including the Plaintiffs' LTCHs. The Plaintiffs gave CMS ample opportunity to correct the flawed methodology for determining the BNA. The Plaintiffs clearly spelled out the duplication in their comments, and MedPAC agreed that a separate BNA should not be applied for this reason. However, CMS has been dismissive of the Plaintiffs' concerns.

The Plaintiffs had hoped that CMS would correct the error before the end of the LTCH site neutral transition period because when the transition period ends on September 30, 2019, the financial impact of CMS' error will double. *See* 42 U.S.C. § 1395ww(m)(6)(B)(i)(I) (SSA § 1886(m)(6)(B)(i)(I)). Starting in FY 2020, the entire payment for site neutral cases will be the

lesser of the IPPS comparable per diem amount or 100% of the estimated costs of the case. *Id.* at §§ 1395ww(m)(6)(B)(i)-(ii). If CMS continues to insist on applying the duplicative outlier BNA in FY 2020, the adjustment will apply to the entire payment for site neutral cases. The Plaintiffs' LTCHs are already experiencing significantly reduced Medicare payments under the site neutral payment policy for many of their patients. Applying a BNA twice to site neutral payments only increases the financial pressure on these hospitals and unnecessarily deters care for Medicare patients in LTCHs. The Plaintiffs have no choice but to seek relief from the courts.

E. Plaintiffs' Irreparable Harm

In support of this Application for a Preliminary Injunction, Plaintiffs have attached to this memorandum, and reference below, the following affidavits provided by experts on Medicare reimbursement from within Plaintiffs' parent companies: (i) Michael Cronin, Senior Vice President of Finance and Government Relations for LifeCare Health Partners ("Cronin Aff.") (attached as **Exhibit 1**); (ii) Karick Stober, Chief Financial Officer for Post Acute Medical, LLC ("Stober Aff.") (attached as **Exhibit 2**); (iii) Clint Fegan, Chief Financial Officer for Vibra Healthcare, LLC ("Fegan Aff.") (attached as **Exhibit 3**); and (iv) Richard L. Algood, Senior Vice President of Reimbursement for Kindred Healthcare, Inc. ("Algood Aff.") (attached as **Exhibit 4**).

As discussed above, CMS is currently applying the duplicative BNA to Plaintiffs' site neutral case payments. The Plaintiffs have already lost over one million dollars in Medicare reimbursement during FY 2019 to date as a direct result of the duplicative BNA. Cronin Aff. ¶7; Stober Aff. ¶ 7; Fegan Aff. ¶ 7; Algood Aff. ¶ 7. These losses are on top of the millions of dollars in losses sustained by Plaintiffs in FYs 2016 through 2018 due to the duplicative BNA. Cronin Aff. ¶ 6; Stober Aff. ¶ 6; Fegan Aff. ¶ 6; Algood Aff. ¶ 6. The harm to the Plaintiffs is not a speculative loss of minor profits. Rather, the duplicative BNA results in a certain and

material reduction of funds available to the Plaintiffs. Cronin Aff. ¶ 9; Stober Aff. ¶ 9; Fegan Aff. ¶ 9; Algood Aff. ¶ 9. These are funds that are necessary for the Plaintiffs to carry out their mission of providing healthcare services to medically complex patients. Cronin Aff. ¶ 9; Stober Aff. ¶ 9; Fegan Aff. ¶ 9; Algood Aff. ¶ 9.

The Plaintiffs' operations are very dependent on receiving accurate payments from Medicare because the vast majority of Plaintiffs' patients are Medicare beneficiaries. Cronin Aff. ¶ 4; Stober Aff. ¶ 4; Fegan Aff. ¶ 4; Algood Aff. ¶ 4. Fifty-seven to seventy percent of the patients at Plaintiffs' LTCHs are covered by Medicare. Cronin Aff. ¶ 4 (59%); Stober Aff. ¶ 4 (70%); Fegan Aff. ¶ 4 (57%); Algood Aff. ¶ 4 (66%).

Fifty LTCHs across the country—more than 10 percent of the sector—have already closed as a result of CMS' site neutral payment rate,[28] which includes the duplicative BNA. Twenty-one of Plaintiffs' LTCHs have closed since the duplicative BNA was adopted. Cronin Aff. ¶ 10; Stober Aff. ¶ 11; Fegan Aff. ¶ 10; Algood Aff. ¶ 10. An additional five of Plaintiffs' LTCHs are scheduled to close this year. Cronin Aff. ¶ 10; Stober Aff. ¶ 11; Fegan Aff. ¶ 10. If CMS' error is not corrected, many more LTCHs will close. Cronin Aff. ¶ 10; Stober Aff. ¶ 11; Fegan Aff. ¶ 10; Algood Aff. ¶ 10. Moreover, without these funds, Plaintiffs are forced to reallocate their revenues to subsidize the care and treatment of Medicare beneficiaries. Cronin Aff. ¶ 9; Stober Aff. ¶ 9 ("We have already been forced to reallocate other revenues to subsidize the treatment of Medicare patients . . . ."); Fegan Aff. ¶ 9; Algood Aff. ¶ 9. The Plaintiffs have

[28] MedPAC, Presentation Slides, *Mandated report: Changes in post-acute and hospice care following the implementation of the long-term care hospital dual payment-rate structure* 6 (Mar. 8, 2019), http://www.medpac.gov/docs/default-source/default-document-library/ltch-mandated-report-march-final.pdf?sfvrsn=0; MedPAC, *March 8, 2019 Public Meeting Transcript* 74 (Mar. 8, 2019), http://www.medpac.gov/docs/default-source/default-document-library/medpac-march-2019-meeting-transcript.pdf?sfvrsn=0.

also had to reduce staff and discontinue certain services and programs offered to their patients. Cronin Aff. ¶ 9; Stober ¶ 9 (noting that the company has had to "limit hiring, reduce corporate positions, cut services and programs, and close some LTCHs altogether."); Fegan Aff. ¶ 9 (explaining that the company has "cut staffing levels" and "cut services and programs"); Algood ¶ 9 ("The company has also had to reduce the number of Medicare site neutral patients by nearly 50% given the financial condition those patients would place on our hospitals. Reductions in administrative and other overhead staff have been absorbed, in part, due to the reductions in reimbursement from Medicare.").

The Plaintiffs face even greater harm when the monetary effect of the duplicative BNA *doubles* in FY 2020. Cronin Aff. ¶ 11; Stober Aff. ¶ 12; Fegan Aff. ¶ 11; Algood Aff. ¶ 11. CMS has provided no indication that it plans to fix the error in the calculation of the BNA prior to the start of FY 2020. Cronin Aff. ¶ 11; Stober Aff. ¶ 12; Fegan Aff. ¶ 11; Algood Aff. ¶ 11.

IV. PROCEDURAL HISTORY

The Plaintiffs submitted an Initial Group Appeal Request and a Request for Expedited Judicial Review to the Provider Reimbursement Review Board ("PRRB") on November 20, 2018. Dkt. 1-1 at 2. The PRRB granted Plaintiffs' request for Expedited Judicial Review on January 28, 2019. Dkt. 1-1. The Plaintiffs filed the Complaint challenging the duplicative BNA on March 13, 2019. Dkt. 1.

V. STANDARD OF REVIEW

A plaintiff seeking a preliminary injunction must demonstrate that: (1) the plaintiff is likely to succeed on the merits; (2) the plaintiff is likely to suffer irreparable harm absent an injunction; (3) the balance of equities tips in the plaintiff's favor; and (4) a preliminary injunction is in the public interest. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008).

Historically, courts in this circuit use a sliding scale analysis when evaluating whether to grant an application for a preliminary injunction:

> In applying this four-factored standard, district courts may employ a sliding scale under which a particularly strong showing in one area can compensate for weakness in another. . . . [I]f the showing in one area is particularly strong, an injunction may issue even if the showings in other areas are rather weak.

Brady Campaign To Prevent Gun Violence v. Salazar, 612 F. Supp. 2d 1, 11-12 (D.D.C. 2009) (internal quotation marks and citations omitted). Some courts have questioned whether the sliding scale analysis still applies after the Supreme Court's *Winter* decision. *See e.g., Alcresta Therapeutics, Inc. v. Azar*, 318 F. Supp. 3d 321, 324 (D.D.C. 2018) (expressing "strong doubts" regarding the survival of the sliding scale approach after *Winter*). However, the D.C. Circuit has not yet decided to abandon the sliding scale approach for evaluating the preliminary injunction factors. *See Archdiocese of Washington v. Washington Metro. Area Transit Auth.*, 897 F.3d 314, 334 (D.C. Cir. 2018) ("[T]this court has not yet decided whether *Winter v. Natural Resources Defense Council* . . . is properly read to suggest a 'sliding scale' approach to weighing the four factors be abandoned . . . .").

VI. ARGUMENT

A. Plaintiffs are Likely to Succeed on the Merits of their Claims

To obtain a preliminary injunction, a plaintiff must show that it is likely to succeed on the merits. *Winter*, 555 U.S. at 20. Here, Plaintiffs allege multiple violations of law against Defendant's duplicative BNA to Plaintiffs' site neutral outlier payments: (1) CMS violated the APA by adopting a BNA that is arbitrary and capricious (Complaint ¶ 48(a)); (2) CMS violated the APA by adopting a BNA that is not supported by substantial evidence (Complaint ¶ 48(b)); (3) CMS violated the APA's notice and comment rulemaking requirements (5 U.S.C. §§ 553(b)-(d)) by failing to provide a sufficient response to comments (Complaint ¶ 48(c)); and (4) CMS'

duplicative BNA violates the Social Security Act and other federal laws (Complaint ¶ 48(e)). Plaintiffs are likely to succeed on each of these claims.

The 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. What the Plaintiffs dispute is a BNA that *reduces* overall LTCH payments *below* what they would otherwise be in the absence of high cost outlier payments for qualifying site neutral cases. This is not budget neutrality. It is a payment cut that is completely arbitrary and unsupported, and results in a windfall to the Medicare program.

CMS set the target amount of LTCH HCO payments at 5.1% of total LTCH site neutral payments. The simple math is clear that CMS can only reduce total LTCH site neutral payments by 5.1% to maintain budget neutrality. Yet, the extra BNA at issue here reduces total LTCH site neutral payments by *another* 5.1% in the name of budget neutrality.

The Plaintiffs, hospital trade associations and MedPAC have repeatedly told CMS not to apply the extra BNA. CMS has stubbornly refused, with unconvincing attempts to recast the IPPS outlier BNA as "inputs" that only relate to the IPPS. But this form over function argument does not change the math. CMS has continued setting the LTCH site neutral payment rate based upon an erroneous calculation that includes *double* the budget neutrality adjustment for HCO payments.

1. The BNA Is Arbitrary and Capricious Because CMS Did Not Account For the Budget Neutrality Adjustments Already Included in the IPPS Comparable Amount

CMS' promulgation of the duplicative BNA is a textbook violation of the Administrative Procedure Act's arbitrary and capricious standard. For several reasons, it is very clearly "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." 5 U.S.C. § 706(2)(A). First, the duplicative BNA is arbitrary and capricious because it is

unreasonable. *See U.S. Postal Serv. v. Postal Regulatory Comm'n*, 785 F.3d 740, 750 (D.C. Cir. 2015) (recognizing that agency action must be reasonable to survive arbitrary and capricious review under the APA). Second, the duplicative BNA is arbitrary and capricious because "the agency . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983); *see also Summer Hill Nursing Home LLC v. Johnson*, 603 F. Supp. 2d 35, 39 (D.D.C. 2009) (concluding that "the Secretary entirely failed to consider an important aspect of the problem" and "the Secretary's decision provide[d] no basis upon which [the Court] could conclude that it was the product of reasoned decisionmaking" because CMS did not explain why Summer Hill's subsequent receipt of remittance advices was insufficient to establish that the bad debts were actually uncollectible when claimed) (internal quotation marks omitted). Third, the duplicative BNA is arbitrary and capricious because CMS' reasoning is "internally inconsistent." *See District Hosp. Partners v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015) (finding agency action arbitrary and capricious when it is "internally inconsistent and inadequately explained"). Finally, the duplicative BNA is arbitrary and capricious because it reflects a clear error of judgment. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971) (noting that agency action is arbitrary and capricious when "there has been a clear error of judgment" by the agency). Each of these reasons is discussed more fully below.

a. CMS' Unwarranted BNA is Arbitrary and Capricious Because it is Unreasonable

To survive arbitrary and capricious review under the APA, an agency's "exercise of its authority must be 'reasonable and reasonably explained.'" *U.S. Postal Serv. v. Postal Regulatory*

Comm'n, 785 F.3d 740, 750 (D.C. Cir. 2015) (quoting *Mfrs. Ry. Co. v. Surface Transp. Bd.*, 676 F.3d 1094, 1096 (D.C .Cir. 2012)). Agency action must be set aside if "the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion . . . ." *Cty. of L.A. v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999); *see also FiberTower Spectrum Holdings, LLC v. F.C.C.*, 782 F.3d 692, 699 (D.C. Cir. 2015) (stating that if an agency's "interpretation is 'plainly erroneous or inconsistent with the regulation[s]' or there is any other 'reason to suspect that the interpretation does not reflect the agency's fair and considered judgment on the matter in question,'" courts will not "defer to an agency's interpretation of its regulations").

CMS' unreasonable decision to apply a second outlier BNA to the LTCH site neutral payment rate is a textbook violation of the APA's arbitrary and capricious standard. It is not reasonable for CMS to apply a 5.1% BNA to the LTCH site neutral payment rate to offset the cost of high cost outlier payments *after* CMS already applied the same 5.1% BNA to the IPPS payment rate. CMS uses the IPPS payment rate, as reduced by the BNAs of 5.1%, to determine the LTCH site neutral payment rate. It was not reasonable for CMS to ignore the BNA already included in the IPPS comparable per diem amount (which is the basis for the LTCH site neutral payment rate in most cases) when adopting the additional BNA. Under a reasonable approach, CMS would have *either* applied the negative 5.1% BNAs to the IPPS rate when calculating the LTCH site neutral payment rate, *or* applied the separate negative 5.1% BNA to that calculation, *but not both*. Instead of adopting either of these approaches, CMS used both, resulting in a negative 10.2% adjustment to the LTCH site neutral payment rate—*double* the amount needed to maintain budget neutrality.

CMS has trivialized the comments and evidence submitted during the comment period about this duplication, and insisted on a second adjustment to the LTCH site neutral payment

rate. As a result, Medicare has arbitrarily cut aggregate payment to all LTCHs by tens of millions of dollars each year.[29] This is clearly unreasonable. Accordingly, the duplicative BNA is arbitrary and capricious under the APA.

b. CMS Did Not Engage in a Reasoned Analysis When It Implemented the Duplicative BNA without Accounting for the Adjustments Already Applied to the IPPS Comparable Per Diem Amount

An agency violates the APA's reasoned analysis requirement if it fails to consider an important aspect of the problem. *See Wood v. Betlach*, 922 F. Supp. 2d 836 (D. Ariz. 2013) (finding that HHS failed to address an important aspect of the problem because the record contains no evidence that HHS considered or responded to plaintiffs' expert opinion that none of the demonstration project's hypotheses test anything new); *St. James Hosp. v. Heckler*, 760 F.2d 1460 (7th Cir. 1985), *accord*, *Walter O. Boswell Mem'l Hosp. v Heckler*, 628 F. Supp. 1121 (D.D.C. 1985) (holding that malpractice rule was arbitrary and capricious because HHS entirely failed to consider an important aspect of the problem by making no attempt to examine the relationship between actual malpractice loss experience and premium costs, and its rule was not adequately supported by the study it relied on); *see also Shays v. Fed. Election Comm'n*, 337 F. Supp. 2d 28, 72 (D.D.C. 2004) (concluding that the FEC's regulation implementing the Bipartisan Campaign Reform Act ("BCRA") was arbitrary and capricious because the FEC "did not adequately explain its decision to exclude 'apparent authority' from the scope of its definition of 'agent'" and provided "no indication that [it] considered how [its] decision might facilitate circumvention or perpetuate the appearance of corruption, two policies Congress

[29] The AHA's analysis of FY 2016 MedPAR data found that the duplicative budget neutrality adjustment reduces aggregate payments by approximately $28 million per year. American Hospital Association, Comment Letter on FY 2019 IPPS/LTCH PPS Proposed Rule at 6.

definitely sought to advance in passing BCRA," demonstrating that the FEC "'entirely failed to consider an important aspect of the problem'") (quoting *State Farm Mut. Auto. Ins.*¸ 463 U.S. at 43). Although courts typically exercise restraint in reviewing agency action, the courts will intervene if "the agency has not really taken a 'hard look' at the salient problems, and has not genuinely engaged in reasoned decision-making." *Greater Boston Television Corp. v. F.C.C.*, 444 F.2d 841, 851 (D.C. Cir. 1970).

The Plaintiffs do not dispute that CMS has the authority to apply a BNA to reduce LTCH site neutral payments to account for HCO payments for LTCH site neutral payment rate cases. However, the Plaintiffs do object to a BNA on top of BNAs of the same size.[30] The BNA is duplicative of the adjustments CMS borrows from the IPPS payment rates. CMS' refusal to seriously consider whether the adjustment is duplicative shows that the agency has not taken a "hard look" to ensure that the math behind the calculation of the BNA is valid. *See Greater Boston Television Crop.*, 444 F.2d at 851. A serious examination of the way the IPPS comparable per diem amount is calculated for LTCH site neutral payments would reveal the fact that this extra LTCH BNA results in underpayments to LTCHs and a savings for the Medicare program. Accordingly, CMS has "entirely failed to consider an important aspect of the problem" because the agency refuses to recognize that it is applying a duplicative BNA. *See State Farm Mut. Auto. Ins.*¸ 463 U.S. at 43.

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." 83 Fed. Reg. at

[30] *See* Kindred Healthcare & Select Medical Holdings Corporation, Comment Letter on FY 2019 IPPS/LTCH PPS Proposed Rule at 37; LifeCare Hospitals, Comment Letter on FY 2019 IPPS/LTCH PPS Proposed Rule at 16.

41737. However, by aligning this policy with the IPPS payment system—and making the IPPS comparable per diem amount and the IPPS fixed-loss amount the primary components—CMS did not adequately consider the adjustment that it *already* made to the IPPS payment rate to account for outlier payments. Specifically, CMS already reduced the IPPS payment rate for outlier budget neutrality. For FY 2019, CMS reduced the operating portion of the IPPS payment rate by a factor of 0.948999 and the capital portion of the IPPS payment rate by a factor of 0.949431. *Id.* at 41723. As CMS explains, these budget neutrality factors result in a 5.1% outlier adjustment that already reduces the IPPS payment rate. *Id.* at 41723-24. CMS has therefore not taken a "hard look" at the salient problem and is not engaging in reasoned decisionmaking because CMS is unwilling to consider the duplicative effect of the extra BNA. *See Greater Boston Television Corp.*, 444 F.2d at 851. Moreover, this extra 5.1% adjustment to LTCH site neutral payments in the name of budget neutrality does not "reduce differences between HCO payments for similar cases under the IPPS and site neutral payment rate cases under the LTCH PPS"—it exacerbates differences—and it does not "promote fairness between the two systems"—it is patently unfair to LTCHs.

Accordingly, CMS' decision to adopt the BNA for FY 2019 is arbitrary and capricious because CMS did not engage in reasoned decisionmaking when the agency's adoption of the BNA failed to account for the budget neutrality adjustment to the IPPS standard Federal payment rate that is used in the calculation of the LTCH site neutral payment rate.

c. CMS' Decision to Apply a Duplicative Budget Neutrality Adjustment is Arbitrary and Capricious Because CMS' Reasoning is Internally Inconsistent

An agency's decision is also arbitrary and capricious if it is "internally inconsistent and inadequately explained." *District Hosp. Partners v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015) (citing *General Chem. Corp. v. United States*, 817 F.2d 844, 846 (D.C. Cir. 1987). CMS'

rationale for the duplicative BNA suffers from "internal inconsistency" for several reasons. First, the BNA is "internally inconsistent" because CMS chose to make the LTCH site neutral outlier policy identical to the IPPS outlier policy, but adds an extra BNA to LTCH site neutral payments. CMS uses the same outlier policy as the IPPS for LTCH site neutral cases because CMS actuaries "projected that the costs and resource use for cases paid at the site neutral payment rate . . . would likely mirror the costs and resource use for IPPS cases assigned to the same MS-DRG" and "site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount," rather than 100% of the estimated costs of the case. FY 2019 IPPS/LTCH PPS Final Rule, 83 Fed. Reg. at 41737. CMS therefore uses the same IPPS fixed-loss amount for LTCH site neutral outlier cases. *Id.* ("[W]e continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2019 is the IPPS fixed-loss amount for FY 2019."). CMS also uses the same target amount of 5.1% of total payments for outlier cases. *Id.* To be internally consistent, the LTCH site neutral payment rate would be considered budget neutral after applying the negative 5.1% IPPS outlier BNA. *See id.* at 41723, 41728 (establishing a 0.948999 outlier adjustment factor to the IPPS operating standardized amount and a 0.949431 outlier adjustment factor to the IPPS capital federal rate). But CMS did not stop there. The agency applied an additional BNA of 5.1%, thereby doubling the reduction to LTCH site neutral payments. *Id.* at 41737. This approach is very clearly "internally inconsistent."

Second, CMS' LTCH PPS outlier policies are "internally inconsistent" because LTCH PPS standard rate payments are subject to a single outlier BNA, yet CMS applies two BNAs to the site neutral payment rate. The AHA explained this issue in their comments to CMS on the FY 2017 and FY 2018 LTCH PPS rulemakings. The AHA's FY 2017 comment letter states:

> When calculating any of the LTCH PPS standard rate payments[], only one BNA applies. Similarly, when pricing out the LTCH PPS short-stay outliers . . . that are paid either an IPPS comparable amount or cost (similar to what site-neutral cases are being paid), only one BNA applies. However, by contrast, when calculating rates for site-neutral cases paid the IPPS comparable amount, two BNAs apply.

American Hospital Association, Comment Letter on FY 2017 IPPS/LTCH PPS Proposed Rule at 6 (footnote omitted). The AHA's comment letter included a chart that diagrams the BNA CMS applies to other LTCH PPS payment rates and the two BNAs CMS applies to the LTCH site neutral payment rate. *Id.* at 7. CMS' deviation from its standard practice of applying only one outlier BNA indicates that CMS' outlier policies are "internally inconsistent."

Finally, the BNA is "internally inconsistent" because it is contrary to the intent of budget neutrality. The intent of budget neutrality is to ensure that a particular payment policy does not raise *or lower* the aggregate payments to providers. In fact, CMS states in the FY 2019 Final Rule that the LTCH site neutral HCO policy should be budget neutral, "meaning that estimated site neutral payment rate HCO payments should not result in *any change* in estimated aggregate LTCH PPS payments." FY 2019 IPPS/LTCH PPS Final Rule, 83 Fed. Reg. at 41737 (emphasis added). However, CMS' implementation of the BNA reduces aggregate site neutral payments to LTCHs to a level that is *below* the budget neutral baseline. In other words, the BNA the Plaintiffs are challenging in these appeals is not an adjustment that achieves budget neutrality at all—it is purely a payment cut. This unwarranted reduction is therefore "internally inconsistent" with the goals of budget neutrality.

Each of these examples of "internal inconsistency" on their own renders CMS' duplicative BNA arbitrary and capricious. *Banner Health v. Price*, 867 F.3d 1323 (D.C. Cir. 2017); *District Hosp. Partners v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015). CMS' rationale for the duplicative budget neutrality adjustment is fatally defective.

d. CMS' Decision to Apply a Duplicative Budget Neutrality Adjustment is Arbitrary and Capricious Because it Reflects a Clear Error of Judgment

Review of agency action under the APA's arbitrary and capricious standard requires consideration of "whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971). A "clear error of judgment" is evaluated by looking at the substance of the agency's decision, not just the agency's procedures for promulgating the rule. *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1098 (D.C. Cir. 1996).

In *James Madison Ltd.*, the D.C. Circuit stated that "judicial review of agency action under the APA must go beyond the agency's procedures to include the substantive reasonableness of its decision." *Id.* Relying on the Supreme Court's decision in *Overton Park*, the D.C. Circuit stated: "Although the reasonableness of the agency's procedures is relevant to the court's inquiry, reasonable procedures alone cannot absolve a court from making a 'thorough, probing, in-depth review' to determine if the agency has considered the relevant factors or committed a clear error of judgment." *Id.* (citing *Overton Park*, 401 U.S. at 415-16). According to the D.C. Circuit, the agency's action would amount to a substantive violation of the APA if the agency ignored salient facts or offered "patently implausible justifications." *Id.* In other circuits, there is a "clear error of judgment" that is "sufficient to constitute arbitrary and capricious agency action . . . when 'the agency offer[s] an explanation that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Sierra Club v. E.P.A.*, 346 F.3d 955, 961 (9th Cir. 2003) (alteration in original) (quoting *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983)).

The "clear error of judgment" standard requires reversing the agency action "if the error is so clear as to deprive the agency's decision of a rational basis." *Ethyl Corp. v. Envtl. Prot. Agency*, 541 F.2d 1, 34-35 n. 74 (D.C. Cir. 1976), *cert. denied*, 426 U.S. 941, (1976). In the context of an agency's informal rulemaking, compared to agency decisions made after an evidentiary hearing, it is even more important that the record contain a rational basis for the agency's decision because it is easier for the agency to abuse informal rulemaking proceedings. *Almay, Inc. v. Califano*, 569 F.2d 674, 681 (D.C. Cir. 1977).

Here, CMS' duplicative BNA is arbitrary and capricious because the agency committed a "clear error of judgment" when it ignored evidence that the IPPS comparable per diem amount for LTCH site neutral payment cases already includes a 5.1% BNA to offset the cost of LTCH outlier cases. The Plaintiffs submitted comments to CMS explaining why the proposed BNA was unnecessary and duplicative because the IPPS comparable per diem amount already includes a BNA. *See e.g.*, Post Acute Medical, Comment Letter on FY 2016 IPPS/LTCH PPS Proposed Rule at 25 ("It would be duplicative (*i.e.*, CMS would be removing outlier payments twice) if CMS also applies the proposed site neutral HCO BNA. This would be the case because the IPPS comparable per diem amount will be based on the FY 2016 IPPS payment rate, which has already been adjusted by the 5.1 percent outlier target."). The Plaintiffs, and other stakeholders, submitted additional comments to CMS during the FY 2017, FY 2018, and FY 2019 LTCH PPS rulemakings making the same point. *See supra* Parts III.B.-D. Even MedPAC submitted a comment letter objecting to the BNA because it is "duplicative and exaggerates the disparity in payment rates across provider settings." MedPAC, Comment Letter on FY 2017 IPPS/LTCH PPS Proposed Rule at 16-17.

Based on these comments, CMS had more than enough information to know that the BNA was erroneous and unnecessary as early as FY 2016. In every rulemaking since FY 2016, commenters including the Plaintiffs explained to CMS that it erred when it failed to account for the outlier BNA already applied to the IPPS comparable per diem amount when calculating the LTCH PPS site neutral outlier BNA. *See e.g.*, LifeCare Hospitals, Comment Letter on FY 2017 IPPS/LTCH PPS Proposed Rule at 10 ("CMS already reduced the FY 2017 site neutral payment amount for estimated outlier payments via the IPPS HCO outlier factor and the capital PPS outlier factor. CMS should *not* reduce LTCH site neutral payments by *another 5.1%*."); Kindred Healthcare & Select Medical Holdings Corporation, Comment Letter on FY 2019 IPPS/LTCH PPS Proposed Rule at 42 ("CMS already reduced the FY 2019 site neutral payment amount for estimated outlier payments via the IPPS HCO outlier factor and the capital PPS outlier factor.").

The D.C. Circuit has stated that CMS cannot continue using payment rates based on computational errors. *See Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 214-15 (D.C. Cir. 2011) ("[W]e never suggested that even after the error in the data on which the Secretary had relied was brought to her attention, she could have chosen to continue using the inaccurate wage index in calculating future payments."). Here, CMS is setting the LTCH site neutral payment rate based upon an erroneous calculation that includes double the BNA for HCO payments, even after MedPAC, the Plaintiffs, and others repeatedly brought the error to CMS' attention. Accordingly, CMS has committed a "clear error of judgment" by refusing to correct this error in the FY 2016, FY 2017, FY 2018 and FY 2019 IPPS/LTCH PPS Final Rules.

2. CMS' Decision to Apply a Second Outlier Budget Neutrality Adjustment to the LTCH Site Neutral Payment Rate is Not Supported by Substantial Evidence

CMS' duplicative BNA should also be set aside because CMS' determination that a second adjustment is necessary to offset the cost of site neutral high cost outlier payments is not

supported by substantial evidence. Pursuant to 5 U.S.C. § 706(2)(E) of the APA, a reviewing court is required to "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 this title or otherwise reviewed on the record of any agency hearing provided by statute." 5 U.S.C. § 706(2)(E). According to the Supreme Court, this substantial evidence test applies "when the agency action is taken pursuant to a rulemaking provision of the Administrative Procedure Act itself, 5 U.S.C. § 553 . . . ." *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 414 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977). CMS' duplicative BNA at issue here was adopted through the APA's notice and comment rulemaking procedures. *See* 5 U.S.C. § 553.

Substantial evidence supports the agency's action when there is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Banner Health v. Sebelius*, 715 F. Supp. 2d 142, 153 (D.D.C. 2010). No such evidence exists here to support CMS' decision to apply a second outlier BNA to the LTCH site neutral payment rate. CMS claims that this second 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 . . . ." FY 2019 IPPS/LTCH PPS Final Rule, 83 Fed. Reg. at 41737. However, CMS offers no evidence in support of its claim that this second BNA is *not* duplicative of the adjustment already applied to the IPPS payment rate used to determine the IPPS comparable per diem amount for LTCH site neutral cases. Instead, the rulemaking record confirms that CMS is applying multiple outlier BNAs to the LTCH site neutral payment rate.

Specifically, the rulemaking record shows that CMS included the 5.1% BNA to reduce the IPPS payment rate amount used for the IPPS comparable per diem amount before applying

the separate negative 5.1% BNA. *Id.* at 41723, 41728. The site neutral payment rate for most LTCH site neutral cases is based on the IPPS comparable per diem amount. 42 U.S.C. § 1395ww(m)(6)(B)(ii)(I); FY 2019 IPPS/LTCH PPS Final Rule, 83 Fed. Reg. at 41737 ("[S]ite neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount . . . ."). Because there is no evidence to contradict that this second budget neutrality adjustment is duplicative, it must be set aside.

3. CMS Did Not Provide a Sufficient Response to Comments Raising Major Issues Regarding the Duplicative BNA in the FY 2019 IPPS/LTCH PPS Final Rule

In addition to the substantive deficiencies with CMS' adoption of the site neutral BNA, CMS' nominal response to comments in the FY 2019 IPPS/LTCH PPS Final Rule also violates the procedural requirements for notice and comment rulemaking at section 553(c) of the APA. The APA requires that the agency's response to comments, the basis and purpose statement, "must identify 'what major issues of policy were ventilated by the informal proceedings and why the agency reacted to them as it did.'" *St. James Hosp. v. Heckler*, 760 F.2d 1460, 1469 (7th Cir. 1985) (citing *Automotive Parts & Accessories Ass'n v. Boyd*, 407 F.2d 330, 338 (D.C. Cir. 1968)).

Here, CMS' three sentence response to commenters, including the Plaintiffs, in the FY 2019 IPPS/LTCH PPS Final Rule shows that the agency is disregarding major issues with the BNA raised by commenters. Just as the Secretary's response to comments in *St. James Hospital* made no effort to respond to comments regarding a statistically unreliable study, CMS' response here did not attempt to explain why the BNA is not duplicative. CMS only responded that it "continue[s] to disagree with the commenters that a budget neutrality adjustment for site neutral payment rate HCO payments is inappropriate, unnecessary, or duplicative" and referred readers to CMS' responses in prior years. 83 Fed. Reg. at 41738. There was no effort by CMS to develop

a substantive response to the commenters and explain why the BNA is *not* duplicative of the adjustment already applied to the IPPS payment rate used to determine the IPPS comparable per diem amount for LTCH site neutral cases. In sum, CMS did not even attempt to explain why commenters' criticisms of the BNA were invalid. *See St. James Hosp.*, 760 F.2d at 1470. CMS' lack of a reasoned response to comments regarding the duplicative nature of the BNA violates the procedural requirements for notice and comment rulemaking at section 553(c) of the APA.

The agency does not need to respond to every individual issue raised by commenters. *See Auto. Parts & Accessories Ass'n v. Boyd*, 407 F.2d 330, 338 (D.C. Cir. 1968) ("We do not expect the agency to discuss every item of fact or opinion included in the submissions . . . ."). However, the agency "must respond in a reasoned manner to those [comments] that raise significant problems." *Reytblatt v. U.S. Nuclear Regulatory Comm'n*, 105 F.3d 715, 722 (D.C. Cir. 1997). Here, the Plaintiffs submitted comment letters to CMS identifying a "significant problem." That is, CMS is underpaying LTCH site neutral cases due to a duplicative outlier BNA. The significance of this problem is only confirmed by the fact that many LTCH organizations, MedPAC, the AHA, and the FAH submitted comment letters to CMS objecting to the duplicative BNA. Although CMS may disagree with comments, it cannot simply dismiss comments from MedPAC and others as insignificant. Accordingly, the unwarranted reduction to the LTCH site neutral payment rate that resulted from the duplicative BNA was a "significant problem" that required a substantive response from CMS. Unfortunately, CMS' response in the FY 2019 Final Rule and the referenced prior rules cannot be considered a substantive response. CMS has not shown that the challenged budget neutrality adjustment is the only 5.1% outlier budget neutrality adjustment to the LTCH site neutral payment rate.

4. CMS' Duplicative BNA Violates the Social Security Act and Other Federal Laws

CMS' decision to apply a second outlier BNA to the LTCH site neutral payment rate violates several provisions of the SSA and other pieces of legislation. First, the duplicative BNA violates the Federal statutes authorizing the LTCH PPS because it is not an "appropriate adjustment." Second, the adjustment is contrary to the SSA's authorization of only two payment rates for LTCH cases, the standard federal payment rate and the site neutral payment rate. Finally, the unwarranted BNA violates the SSA's prohibition on cost-shifting.

In prior rulemakings, CMS asserted that it has "ongoing authority to make annual HCO budget neutrality adjustments for payments under the LTCH PPS . . . using the broad authority provided by section 123 of Public Law 106-113 and section 307 of Public Law 106-554." FY 2017 IPPS/LTCH PPS Final Rule, 81 Fed. Reg. at 57308. However, CMS' exercise of this authority in applying the duplicative BNA is contrary to the statutory text. Section 123 of the Balanced Budget Refinement Act of 1999 ("BBRA"), Pub. L. No. 106-113, 113 Stat. 1501 (1999), required CMS to develop and implement a LTCH PPS that "shall include an adequate patient classification system that is based on diagnosis-related groups (DRGs) and that reflects the differences in patient resource use and costs, and shall maintain budget neutrality."[31] BBRA § 123(a)(1). Section 307 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"), Pub. L. No. 106-554, 114 Stat. 2763 (2000), states that the Secretary "may provide for appropriate adjustment to the long-term hospital payment system." BIPA § 307(b)(1). The duplicative BNA is not an "appropriate adjustment."

[31] CMS interprets BBRA's "budget neutrality" requirement as applying only to the first year of the LTCH PPS. *See* FY 2013 IPPS/LTCH PPS Final Rule, 77 Fed. Reg. 53258, 53494 (Aug. 31, 2012) ("[I]t has been our consistent interpretation that the statutory requirement for budget neutrality applies exclusively to FY 2003 when the LTCH PPS was implemented.").

CMS claims that it has the authority to implement the additional BNA and that the BNA is necessary because "estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments." FY 2019 IPPS/LTCH PPS Final Rule, 83 Fed. Reg. at 41737. Plaintiffs do not dispute that CMS generally possesses the authority under BBRA section 123 and BIPA section 307 to apply a BNA to prevent LTCH high cost outlier payments from increasing aggregate LTCH payments. CMS applies such a BNA to account for outlier payments for LTCH standard rate cases. Similarly, CMS applies a BNA to the IPPS payment rate to account for IPPS outlier payments. However, CMS exceeded its statutory authority, in violation of BIPA section 307(b)(1), when it applied a duplicative BNA to the LTCH site neutral payment rate because this extra adjustment is not an "appropriate adjustment."

An "appropriate adjustment" to maintain budget neutrality for site neutral outlier payments would have achieved actual budget neutrality and ensured that LTCH site neutral outlier payments did not increase *or decrease* aggregate LTCH payments. This was already accomplished by the 5.1% outlier BNA from IPPS rate setting that CMS uses to calculate the IPPS comparable per diem amount for LTCH site neutral payments. This adjustment achieved the 5.1% offset (reduction) to LTCH site neutral payments equal to the target amount of LTCH site neutral outlier payments. The BNA from the IPPS is arguably an "appropriate adjustment" to the LTCH site neutral payment rate. Any additional adjustment to LTCH site neutral payments to maintain budget neutrality due to LTCH site neutral outlier payments cannot be considered an "appropriate adjustment" under BIPA section 307(b)(1). Therefore, the extra 5.1% BNA at issue here violates BIPA section 307(b)(1). It is budget neutral in name only. Instead of ensuring that site neutral outlier payments do not cause any change in aggregate Medicare payments to LTCHs, this adjustment actually saves the Medicare program tens of millions of dollars every

year. When Congress authorized CMS to make "appropriate adjustments" to the LTCH PPS, it could not have envisioned that CMS would apply a duplicative adjustment like the BNA at issue here. Accordingly, the adjustment must be set aside because it violates CMS' authority under BIPA section 307(b)(1) to apply "appropriate adjustments" to LTCH PPS payments.

CMS' duplicative BNA also violates the Social Security Act's dual-rate structure for the LTCH PPS. As discussed above, Congress established a new dual-rate payment structure under the LTCH PPS in section 1206 of the Pathway for SGR Reform Act of 2013. CMS has stated with regard to the dual rate LTCH PPS that it does "not have the authority to pay LTCH discharges that fail to meet the patient-level criteria for payment at the LTCH PPS standard Federal payment rate at a rate other than the site neutral payment rate . . . ." FY 2017 IPPS/LTCH PPS Final Rule, 81 Fed. Reg. at 57070. However, CMS is doing just that by applying the duplicative BNA. CMS is acting in direct contradiction of its own position on the dual rate LTCH PPS by paying LTCH site neutral cases a rate other than the site neutral payment rate contemplated by the statute. Furthermore, because CMS applies multiple BNAs to the site neutral payment rate, LTCHs may receive a *lower* Medicare payment for these cases than a short term acute care hospital would receive for the case under the IPPS. Therefore, the duplicative budget neutrality adjustment must be set aside because it is contrary to the SSA.

c. The Extra BNA Violates the Medicare Prohibition on Cost-Shifting

The Social Security Act prohibits CMS from shifting Medicare costs to non-beneficiaries (*i.e.*, "cost-shifting"). 42 U.S.C. § 1395x(v)(1)(A) (SSA § 1861(v)(1)(A)) ("[T]he necessary costs of efficiently delivering covered services to individuals covered by the insurance programs established by this title will not be borne by individuals not so covered . . . ."). Courts have regularly recognized Medicare's cost-shifting prohibition (sometimes referred to as "anti-cross-

subsidization provisions"). *E.g.*, *Abington Crest Nursing and Rehab. Ctr. v. Leavitt*, 541 F. Supp. 2d 99, 106 (D.D.C. 2008); *Foothill Hosp.-Morris L. Johnston Mem'l v. Leavitt*, 558 F. Supp. 2d 1, 3 (D.D.C. 2008). In *Howard Univ. v. Bowen*, No. 85-3342, 1988 WL 33508 (D.D.C. Mar. 29, 1988), the D.C. District Court found that the cost-shifting prohibition superseded a contrary Medicare regulation, stating ". . . the Secretary failed to note that the prohibition against cost-shifting is not merely a general regulation, but, as noted above, is an integral part of the Medicare statute itself and has been so found by numerous courts." *Id.* at *2.

Here, CMS' decision to apply a second outlier BNA to the LTCH site neutral payment rate violates the statutory prohibition on cost-shifting under 42 U.S.C. § 1395x(v)(1)(A)(i) because it results in Medicare costs being shifted to non-Medicare beneficiaries. This duplicative BNA reduces aggregate LTCH payments by approximately $28 million per year. *See* American Hospital Association, Comment Letter on FY 2019 IPPS/LTCH PPS Proposed Rule at 6. This is a windfall for the Medicare program that violates the Social Security Act's cost-shifting prohibition.

The duplicative outlier budget neutrality adjustment should be set aside because it violates the Social Security Act and other federal laws (*i.e.*, BIPA § 307(b)(1)). As a result of these statutory violations, the budget neutrality adjustment also must be set aside under the APA because the adjustment is "not in accordance with the law." 5 U.S.C. § 706(2)(A). For these reasons, and the others discussed above, the Plaintiffs are very likely to succeed on the merits of their claims that the duplicative budget neutrality adjustment is invalid and must be set aside.

B. Plaintiffs Will Suffer Imminent, Irreparable Harm if Defendant's Improper BNA is Not Enjoined

To obtain a preliminary injunction, a plaintiff must also demonstrate that it is "likely to suffer irreparable harm in the absence of preliminary relief." *Winter v. Nat. Res. Def. Council,*

Inc., 555 U.S. 7, 20 (2008). This requires the plaintiff to show that the harm is "both certain and great; it must be actual and not theoretical." *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam). The plaintiff's harm must also be imminent. *Id.* (citing *Ashland Oil, Inc. v. FTC*, 409 F. Supp. 297, 307 (D.D.C. 1976)). In general, a monetary loss is not typically sufficient for demonstrating irreparable harm. *See Va. Petroleum Jobbers Ass'n v. FPC*, 259 F.2d 921, 925 (D.C. Cir. 1958) ("Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay, are not enough."). However, the D.C. Circuit recognizes an exception to this general rule. A recoverable monetary loss may still establish irreparable harm for the purposes of obtaining a preliminary injunction "where the loss threatens the very existence of the movant's business." *Wis. Gas Co.*, 259 F.2d at 674.

Here, the Plaintiffs are facing a harm that is both "certain and great." *Wis. Gas Co.*, 259 F.2d at 674. The Plaintiffs' harm is certain because CMS is already applying the duplicative BNA to Plaintiffs' FY 2019 site neutral payments. CMS' BNA is documented in the *Federal Register*. *See* FY 2019 IPPS/LTCH PPS Final Rule, 83 Fed. Reg. 41144, 41738 (Aug. 17, 2018) ("[I]t is necessary to reduce the site neutral payment rate portion of the blended rate payment by 5.1% to account for the estimated additional HCO payments payment to those cases in FY 2019."). It is irrefutable that the Plaintiffs are and will continue to experience reduced Medicare payments as a result of the duplicative BNA. This is not a theoretical harm that Plaintiffs face. Rather, CMS' duplicative BNA is presently reducing the Medicare payment for every site neutral case that the Plaintiffs treat. Cronin Aff. ¶ 5 ("As a result, CMS is currently applying the duplicative BNA to LTCH site neutral payment rate cases during Vibra's FY 2019 cost reporting periods . . . ."); Stober Aff. ¶ 5; Fegan Aff. ¶ 5; Algood Aff. ¶ 5.

In addition to being certain, the harm to the Plaintiffs from the duplicative BNA is also great. In FY 2019 alone, the Plaintiffs estimate that the duplicative BNA reduces their aggregate Medicare payments by approximately $9,388,544 based on CMS data, but no less than $3,358,322.[32] Cronin Aff. ¶ 7; Stober Aff. ¶ 7; Fegan Aff. ¶ 7; Algood Aff. ¶ 7. The harm caused by the duplicative BNA is not merely the speculative loss of minuscule profit. Rather, the duplicative BNA results in the loss of millions of dollars in the aggregate. This is a material reduction to the Plaintiffs' Medicare reimbursement—funds that are necessary for the Plaintiffs to carry out their patient treatment missions for medically complex patients. Cronin Aff. ¶ 9; Stober Aff. ¶ 9; Fegan Aff. ¶ 9; Algood Aff. ¶ 9. The Plaintiffs' operations rely heavily on receiving accurate payments from Medicare because the vast majority (57 to 70 percent) of the Plaintiffs' patients are covered by Medicare. Cronin Aff. ¶ 4 ("LifeCare Hospitals' LTCHs rely heavily on obtaining timely and accurate payments from CMS for the Medicare patients that the LTCHs treat."); Stober Aff. ¶ 4; Fegan Aff. ¶ 4; Algood Aff. ¶ 4. The reduced Medicare reimbursement forces Plaintiffs to reallocate their revenues from other sources to subsidize their losses from treating Medicare beneficiaries that qualify for site neutral payment. Cronin Aff. ¶ 9; Stober Aff. ¶ 9 ("These artificially reduced payments have seriously compromised the ability of Post Acute Medical to operate their patient care programs for *all* patients."); Fegan Aff. ¶ 9; Algood Aff. ¶ 9 ("We have already been forced to reallocate other revenues to subsidize the treatment of Medicare patients.").

[32] The Plaintiffs can only provide an estimate of their losses at this time because it is impossible to know the exact reimbursement effect of the duplicative BNA until all of their claims for services provided in federal FY 2019, which ends on September 30, 2019, have been submitted and paid by Medicare. The estimated $9,388,544 aggregate impact is based on CMS data used to establish the FY 2019 LTCH PPS payment rates. CMS used the best available complete claims data during the FY 2019 rate setting, which was data from FY 2017. *See* 83 Fed. Reg. at 20595.

The magnitude of the Plaintiffs' monetary loss qualifies as an irreparable harm under D.C. Circuit law because the significant reduction in Medicare reimbursement "threatens the very existence" of the Plaintiffs' businesses (*i.e.*, operating Medicare-certified LTCHs). *Wis. Gas Co.*, 259 F.2d at 674. Over 50 LTCHs have already closed, representing more than 10% of the sector, since the adoption of the LTCH PPS site neutral payment rate with this duplicative BNA.[33] A total of 21 of Plaintiffs' LTCHs have closed during this period, and another five LTCHs are scheduled to close this year. Cronin Aff. ¶ 10; Stober Aff. ¶ 11; Fegan Aff. ¶ 10; Algood Aff. ¶ 10. Many of these LTCHs noted that recent reductions in Medicare payment led to their closure, referring to the implementation of site neutral payment with the duplicative BNA. *See e.g.*, **Exhibit 2-D** ("[G]iven the draconian changes imposed upon long-term acute care hospitals, it is simply impossible for the Hospital to continue to operate."); **Exhibit 3-A** at 1 (". . . reductions in healthcare reimbursement and changes in referral practices over the past twelve months have made continuing operations at this location unsustainable."); **Exhibit 3-B** at 1 ("The recent changes in healthcare reimbursement have made this hospital extremely difficult to maintain."). As a result of the lost LTCH reimbursement from the duplicative BNA, there will be even more LTCH closures.[34] Cronin Aff. ¶ 10; Stober Aff. ¶ 11 ("If CMS continues to apply the

[33] MedPAC, Presentation Slides, *Mandated report: Changes in post-acute and hospice care following the implementation of the long-term care hospital dual payment-rate structure* 6 (Mar. 8, 2019), http://www.medpac.gov/docs/default-source/default-document-library/ltch-mandated-report-march-final.pdf?sfvrsn=0; MedPAC, *March 8, 2019 Public Meeting Transcript* 74 (Mar. 8, 2019), http://www.medpac.gov/docs/default-source/default-document-library/medpac-march-2019-meeting-transcript.pdf?sfvrsn=0.

[34] *See* MedPAC, *November 1, 2018 Public Meeting Transcript* 48 (Nov. 1, 2018), http://www.medpac.gov/docs/default-source/default-document-library/november-2018-transcripts.pdf?sfvrsn=0 ("[Dr. Mathews] . . . I think the greater expectation is you might see further adaptation of the market in terms of reduced volume overall, possible additional closures of LTCHs, and all of this resulting from the focus on those patients who are most appropriate for this level of care.").

duplicative BNA, more LTCHs are likely to close."); Fegan Aff. ¶ 10; Algood Aff. ¶ 10 ("In addition, decisions to continue to operate LTCH facilities have been based on the viability of the hospital with reduced reimbursement for site neutral patients."). The closure of additional LTCHs affects not just the operators of the facilities, but also the Medicare beneficiaries and other patients receiving care at the closing facilities.

Finally, the irreparable harm factor for preliminary injunctions requires the plaintiff to show that "the alleged harm will directly result from the action which the movant seeks to enjoin." *Wisc. Gas. Co.*, 259 F.2d at 674. Here, the Plaintiffs' harm, lost Medicare reimbursement that threatens the existence of their businesses, is the direct result of the duplicative BNA. This BNA reduces all LTCH site neutral payments by an additional 5.1%. If not for the duplicative BNA, Plaintiffs estimate that their FY 2019 Medicare reimbursement would increase in the aggregate by approximately $9,388,544 (but no less than $3,358,322). Without these Medicare funds, it is clear that not all of the Plaintiffs will be capable of remaining operational to treat medically complex patients during this litigation. Cronin Aff. ¶ 10; Stober Aff. ¶ 11; Fegan Aff. ¶ 10; Algood Aff. ¶ 10.

The injury to the Plaintiffs from the duplicative BNA is already great. However, if the BNA is not enjoined, the financial impact of CMS's error will *double* during the pendency of this lawsuit. This is because the site neutral transition period ends at the conclusion of FY 2019. *See* 42 U.S.C. § 1395ww(m)(6)(B)(i) (SSA § 1886(m)(6)(B)(i)). Beginning on October 1, 2019, CMS will start paying site neutral cases the full site neutral payment rate instead of the transitional blended payment rate. *Id.* at §§ 1395(m)(6)(B)(ii), (iii). A preliminary injunction to prevent CMS from applying the duplicative BNA in FY 2019 and subsequent years, pending the outcome of this litigation, will prevent this great harm.

CMS has used the duplicative BNA to reduce Plaintiffs' Medicare reimbursement since the start of Plaintiffs' FY 2016 cost reporting periods. Plaintiffs estimate that they have lost $12,502,353 in Medicare reimbursement as a result of the duplicative BNA during their FY 2016 through FY 2018 cost reporting periods. Cronin Aff. ¶ 6; Stober Aff. ¶ 6; Fegan Aff. ¶ 6; Algood Aff. ¶ 6. As discussed above, these losses are continuing in FY 2019, and in FY 2020 the financial impact of the duplicative BNA will double. Therefore, this is a case where "the totality of the harm would not necessarily have been immediately apparent." *Texas Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 245 (D.D.C. 2014) (Sullivan, J.).

The Plaintiffs submitted comment letters to CMS during the LTCH PPS rulemaking processes and gave CMS multiple opportunities to correct the erroneous BNA. In addition, the Plaintiffs had hoped that Congress would step in and fix the duplicative BNA. The Plaintiffs now face irreparable harm as a result of the cumulative effect of the millions of dollars in lost Medicare reimbursement from previous years, the continuing losses in FY 2019, and the threat from the doubling of the BNA's impact in FY 2020. The Plaintiffs are therefore entitled to a preliminary injunction because their "ongoing, worsening injuries" constitute irreparable harm. *Arc of Cal. v. Douglas*, 757 F.3d 974, 990 (9th Cir. 2014); *see also id.* at 990-91 (noting that where the "harm alleged . . . related in part to the continued economic viability of service providers in the face of cuts in compensation . . . the actual impact of the various reductions in compensation might well become irreparable only over time."). Accordingly, a preliminary injunction is necessary because the Plaintiffs will suffer irreparable harm, a threat to their very existence, if CMS is allowed to continue applying the duplicative BNA to the Medicare payment for Plaintiffs' site neutral cases.

C. The Balance of Equities Tips in Favor of Plaintiffs

The third factor for obtaining a preliminary injunction requires the plaintiff to establish "that the balance of equities tips in his favor." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20. The "balance-of-equities factor directs the Court to 'balance the competing claims of injury and . . . consider the effect on each party of the granting or withholding of the requested relief.'" *Texas Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 245 (D.D.C. 2014) (Sullivan, J.) (quoting *ConverDyn v. Moniz*, 68 F. Supp. 3d 34, 52 (D.D.C. 2014)).

As discussed above, Plaintiffs face considerable hardship if the duplicative BNA is not enjoined. Plaintiffs will lose millions of dollars in Medicare reimbursement just in FY 2019 as a result of the duplicative BNA. This lost reimbursement "threatens the very existence" of the Plaintiffs' businesses. *Wis. Gas Co.*, 259 F.2d at 674. In contrast, there is no hardship or injury to Defendant from enjoining the duplicative BNA, pending the final outcome of this litigation. If the duplicative BNA is enjoined, the funds that Defendant would resume paying to Plaintiffs are funds that Defendant is not entitled to as a matter of law. *See supra* Part VI.A. The improper reduction of Plaintiffs' Medicare reimbursement for LTCH PPS site neutral cases is a windfall for the Medicare program. There is no recognizable injury to the Defendant if the Court enjoins action that only increases this windfall for the Medicare program.

Furthermore, complying with a preliminary injunction against the BNA will not place any significant burden on Defendant. To comply with such a preliminary injunction, CMS will only need to update its LTCH Pricer program with the correct LTCH PPS site neutral payment rate.[35] Updating the LTCH Pricer program is not a burdensome or extraordinary task. In fact, CMS has previously updated portions of the LTCH site neutral payment rate in the LTCH Pricer

[35] The LTCH Pricer program is a software program developed by CMS that calculates the Medicare payment rate. *See* Medicare Claims Processing Manual (CMS Pub. 100-04), Chapter 3, § 150.23.

program mid-year when legally required to do so. For example, last year CMS issued a transmittal notifying its payment contractors that CMS updated the LTCH Pricer program to implement Section 51005(b) of the Bipartisan Budget Act of 2018, Pub. L. No. 115-123, 132 Stat. 64 (2018). Section 51005(b) required CMS to reduce the IPPS comparable amount component of the site neutral payment rate by 4.6% in FYs 2018 through 2026 to pay for a two-year extension of the transition period to site neutral payment. Thus, CMS updated the LTCH Pricer and issued a transmittal directing the Medicare contractors to "pay claims with the updated . . . LTCH PPS Pricer[] issued with this [change request]" and "reprocess . . . LTCH PPS claims impacted by this [change request] with a discharge date on or after October 1, 2017." *See* CMS Transmittal 4046 (Change Request 10547) at 8-9 (May 10, 2018).

The duplicative BNA deprives Plaintiffs of millions of dollars of Medicare reimbursement each year. This hardship is a threat to Plaintiffs' continued existence. Conversely, Defendant faces no hardship and minimal administrative burden from discontinuing the BNA pending final judgment in this litigation. The balance of equities therefore firmly supports granting Plaintiffs' request that this Court enjoin the duplicative BNA.

D. An Injunction is in the Public Interest

A preliminary injunction against the duplicative BNA would also serve the public interest. This Court has previously found that "in the context of Medicare-reimbursement cases, 'the Secretary's compliance with applicable law constitutes a separate, compelling public interest.'" *Texas Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224, 245 (D.D.C. 2014) (Sullivan, J.) (quoting *In re Medicare Reimbursement Litig.*, 309 F. Supp. 2d 89, 99 (D.D.C. 2004); *see also N. Mariana Islands v. United States*, 686 F. Supp. 2d 7, 21 (D.D.C. 2009) ("The public interest is served when administrative agencies comply with their obligations under the APA.") (citing *New Jersey v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980)).

Here, a preliminary injunction would serve the public interest for several reasons. First, the public interest is served by ensuring that the Defendant complies with the APA, the SSA, and other federal laws at issue in this Medicare reimbursement case. *See In re Medicare Reimbursement Litig.*, 309 F. Supp. 2d at 99. Second, other courts have found that there is a "critical interest in maintaining the integrity of the Medicare program for the benefit of providers, patients and taxpayers generally." *Neurological Assocs.-H. Hooshmand, M.D., P.A. v. Bowen*, 658 F. Supp. 468, 473 (S.D. Fla. 1987). The same rationale applies here. Preventing Defendant from making inaccurate payments to Plaintiffs maintains the integrity of the Medicare program and thus serves the public interest. Third, there is a public interest in ensuring that Plaintiffs' LTCHs will remain open and continue to treat Medicare beneficiaries who are critically ill and/or medically complex, including beneficiaries that might qualify for a site neutral payment. There are less than 400 LTCHs nationwide,[36] so when a LTCH closes, the community may no longer have access to this level of hospital care if there is not another LTCH in the area. Finally, a preliminary injunction serves the public's interest by allowing the Plaintiffs' to continue to provide the services and programs that they have traditionally offered. Due to the cuts in Medicare reimbursement from site neutral payment, that includes the erroneous BNA, the Plaintiffs have already been forced to take a number of drastic actions, including discontinuing important programs and services, limiting the number of site neutral patients they treat, and closing LTCHs altogether. Cronin Aff. ¶ 9; Stober Aff. ¶ 9 ("We have already been forced to reallocate other revenue to subsidize the treatment of Medicare patients, limit hiring, reduce corporate positions, cut services and programs, and close some LTCHs

[36] MedPAC, *March 2019 Report to the Congress: Medicare Payment Policy* 287, 290 (2019), http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf?sfvrsn=0.

altogether."); Fegan Aff. ¶ 9; Algood Aff. ¶ 9 ("The company has also had to reduce the number of Medicare site neutral payments by nearly 50% given the financial condition those patients would place on our hospitals."). An injunction would therefore serve the public interest by allowing Plaintiffs, for the first time, to manage the critically necessary care for Medicare and other patients within the correct site neutral payment amounts.

VII. CONCLUSION

Plaintiffs have established that they are entitled to a preliminary injunction because they are likely to succeed on the merits, they will suffer irreparable harm absent an injunction, the balance of equities tips in their favor, and a preliminary injunction is in the public interest. *Winter*, 555 U.S. at 20. Even assuming *arguendo* that the Plaintiffs did not make a strong showing on any one of these factors, a preliminary injunction is still warranted because under the sliding scale approach "a particularly strong showing in one area can compensate for weakness in another." *Brady Campaign to Prevent Gun Violence*, F. Supp. 2d at 11. Accordingly, Plaintiffs respectfully request that the Court enjoin Defendant's CMS from applying the duplicative BNA to Plaintiffs' LTCH PPS site neutral cases in FY 2019 and in all subsequent years, pending further order by the Court.

Dated: April 5, 2019

Respectfully Submitted,

/s/ *Jason M. Healy*

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 5th day of April, 2019, true and exact copies of Plaintiffs' Application for a Preliminary Injunction and Request for Expedited Hearing, were served by hand-delivery to:

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