IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. ALEX M. AZAR, II, in his official capacity as the Secretary of Health and Human Services, *et al.*, Defendants.	Civil Action No. 1:18-cv-02084-RC

***AMICUS CURIAE* BRIEF OF THE FEDERATION OF AMERICAN HOSPITALS IN SUPPORT OF NEITHER PARTY**

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Local Rule 7(o)(5) of this Court and Rules 26.1 and 29(a)(4)(A) of the Federal Rules of Appellate Procedure, *amicus curiae* Federation of American Hospitals ("FAH") is a nonprofit trade association of health systems. FAH is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. The Federation has no parent company, and no publicly held company holds more than a ten percent interest in the Federation.

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STATEMENT OF IDENTITY AND INTERESTS OF *AMICUS* AND AUTHORITY TO FILE

Amicus Curiae the Federation of American Hospitals ("FAH")[1] has a compelling interest in the remedy this Court will fashion in light of the Court's December 27, 2018 entry of judgment in favor of plaintiffs.[2]

FAH is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Dedicated to a market-based philosophy, the FAH provides representation and advocacy on behalf of its members to Congress, the Executive Branch, the judiciary, media, academia, accrediting organizations, and the public.

FAH's members include teaching and non-teaching, short-stay acute, inpatient rehabilitation, long-term acute care, psychiatric and cancer hospitals in urban and rural America, and provide a wide range of acute, post-acute and ambulatory services.

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[1] The undersigned certifies that the parties have consented to the filing of this brief, no counsel for a party authored this brief in whole or in part, no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief, and no person or entity other than FAH made a monetary contribution to its preparation or submission.

[2] The FAH expresses no opinion on this Court's determination that the Secretary exceeded his authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) in setting the 340B drug reimbursement rates in the calendar year ("CY") 2018 Outpatient Prospective Payment System ("OPPS") Final Rule for purposes of this brief. *See* Mem. Op. at 33. In its December 27, 2018 Memorandum Opinion, however, this Court ordered supplemental briefing from the parties on the appropriate remedy, including the relief's proper scope and implementation. Mem. Op. at 35–36. In discussing the need for supplemental briefing on potential remedies, the Court referenced offsets to OPPS payment rates for non-drug items and services. The FAH's members relied on those referenced OPPS payment rates and have already received reimbursement for services rendered in 2018 under those prospectively set payment rates. In the view of the FAH, the positive 3.2 percent adjustment that was made by CMS to achieve projected budget neutrality in 2018 is beyond the scope of judicial review in the case at bar, and any relief awarded should not impact payments made or expected to be made to non-340B facilities.

FAH's members are deeply affected by any changes to Medicare reimbursement. That is why the FAH routinely submits comments to the Centers for Medicare & Medicaid Services ("CMS") on Medicare payment rulemakings and offers guidance to courts regarding Medicare reimbursement principles. Just as in those cases, the FAH writes to offer guidance, from the non-340B hospitals' perspective, on the harmful impact that wholesale, retrospective changes to prospectively set outpatient payment rates would have on American health care.[3] In fact, our analysis, derived largely from information CMS makes available as part of its annual OPPS rulemaking, shows that approximately 2,450 non-340B hospitals were impacted by the 3.2 percent budget neutrality adjustment adopted by CMS for 2018 based on the estimated impact of the negative payment adjustment for 340B drugs.

ARGUMENT

I. The Positive 3.2 Percent Budget Neutrality Adjustment Adopted and Applied by CMS for 2018 is Beyond the Scope of this Action and any Relief for Hospitals Participating in the 340B Program Need Not Achieve Actual Budget Neutrality

The FAH's members are paid under the hospital Outpatient Prospective Payment System ("OPPS"), which reimburses hospitals directly for outpatient items and services through prospectively determined rates. *See* 42 U.S.C. § 1395*l*(t); *see also Amgen Inc. v. Smith*, 357 F.3d 103, 106 (D.C. Cir. 2004). As was the focus of the parties' briefing and this Court's Memorandum Opinion, the final rule setting the OPPS prospective rates for calendar year

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[3] Investor-owned hospitals are not eligible to participate in the 340B program, even though the vast majority far surpass the statutory threshold for serving low-income patients, and, through generous charity care and related programs, incur uncompensated care costs that meet or exceed the level of non-profit hospitals, measured as a percent of operating cost. Rather, 340B eligibility among hospitals is largely restricted to certain public or non-profit hospitals. 42 U.S.C. § 256b(a)(4)(L).

("CY") 2018 decreased the rate of Medicare reimbursement for separately payable drugs and biologicals acquired by a hospital outpatient department under the 340B program ("340B drugs"). *See generally* Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52,356, 52,493–511, 52,622–25 (Nov. 13, 2017) ("CY 2018 OPPS Final Rule"). Separately, CMS estimated that this negative payment adjustment for 340B drugs would reduce 2018 OPPS expenditures by 1.6 billion dollars and, based on this projection, CMS adopted a positive adjustment of 3.2 percent for all OPPS non-drug items and services in order to achieve prospective budget neutrality in accordance with 42 U.S.C. § 1395*l*(t)(9)(B). *Id.* at 52,624.

In this action, the Plaintiffs only challenge CMS's payment reduction for 340B drugs and only for CY 2018.[4] *See* Compl. (Sep. 5, 2018, ECF No. 1). There is no allegation that CMS acted without statutory authority when it modeled out expected 2018 OPPS expenditures and adopted a positive 3.2 percent adjustment under 42 U.S.C. § 1395*l*(t)(9)(B) designed to achieve prospective budget neutrality based on CMS estimates.[5] Therefore, this Court should not call

[4] Although the action is currently confined to CY 2018 OPPS claims, Plaintiffs have stated their intention to amend their complaint to address CY 2019 OPPS claims in the near future. *See* Pls.' Supp. Br. Remedies, 1 n.1 (ECF No. 32). The arguments presented herein have equal applicability to any CY 2019 challenge, when and if such a challenge properly comes before this Court.

[5] In the CY 2018 OPPS Final Rule, CMS explicitly addressed the applicability of the budget neutrality requirements of § 1395*l*(t)(9)(B), finalizing its proposal that "reduced payments for separately payable drugs and biologicals purchased under the 340B Program would be included in the budget neutrality adjustments, under the requirements in [42 U.S.C. § 1395*l*(t)(9)(B)]." 82 Fed. Reg. at 52,623; *see also* 82 Fed. Reg. at 52,624–25 (responding to comments on budget neutrality and finalizing the 3.2 percent adjustment "to maintain budget neutrality within the OPPS"). Any assertion by the Secretary that the challenged adjustments at bar here could be implemented in a non-budget neutral manner, *see* Oral Arg. Tr. 34: 6–7, *Am. Hosp. Ass'n v. Azar*, No. 18-5004, Docket No. 1770299 (D.C. Cir. Jan. 24, 2019), is both erroneous and patently inconsistent with the Secretary's determination to the contrary in the CY 2018 OPPS Final Rule.

into question the propriety of the 3.2 percent adjustment, which was properly adopted based on CMS's prospective estimates and should determine that the 3.2 adjustment cannot be directly or indirectly recouped by CMS or otherwise retroactively rescinded. Moreover, this Court lacks jurisdiction to review the 3.2 percent adjustment by virtue of 42 U.S.C. § 1395*l*(t)(12)(C), which explicitly bars "administrative or judicial review" of periodic adjustments made under subsection (t)(9)(B).[6] In sum, subsection (t)(9)(B) requires CMS to adopt prospective budget neutrality adjustments based on its estimates, CMS properly did so in adopting the 3.2 percent OPPS adjustment, and this Court need not and cannot retrospectively modify the 3.2 percent adjustment in order to achieve actual budget neutrality for 2018.

II. This Court Is Not Permitted Under the Medicare Act to Fashion a Budget Neutral Remedy

In calling for supplemental briefing, this Court expressed concern that the retroactive OPPS payments sought by Plaintiffs "would presumably require similar offsets elsewhere." Mem. Op. 35. This concern is premised on "the 'havoc that piecemeal review of OPPS payments could bring about' in light of *the budget neutrality requirement*." *Id.* (quoting *Amgen, Inc. v. Smith*, 357 F.3d 103, 112) (emphasis added). In fashioning a remedy here, however, the Court need not achieve budget neutrality, and the Medicare Act does not permit CMS to make any offsets to achieve actual or retrospective budget neutrality.

As briefly touched on above, the Medicare Act requires that CMS adjust payment rates within OPPS in a budget neutral manner to account for the decreased payments for 340B drugs in advance of the commencement of each OPPS fiscal year. *See* 42 U.S.C. § 1395*l*(t)(9)(B). Importantly, however, while Congress very clearly intended that budget neutrality be reached

[6] As the Court notes, subsection (t)(12)(C) erroneously cites to subsection (t)(6) rather than (t)(9) due to a scrivener's error. Mem. Op. at 20 n.13.

within this prospective payment system, Congress only required that the Secretary make adjustments to achieve a prospective estimate of budget neutrality. To conceive of budget neutrality as a retrospective requirement would wreak havoc on Medicare's payment systems.

The text of the Medicare Act provides support for the prospective-only nature of the budget neutrality requirement:

> If the Secretary makes adjustments under subparagraph (A), then the adjustments for a year may not cause the *estimated amount* of expenditures under this part for the year to increase or decrease from the *estimated amount* of expenditures under this part that would have been made if the adjustments had not been made.

42 U.S.C. § 1395*l*(t)(9)(B) (emphases added). Paragraph (9) is entitled, "Periodic review and adjustments components of prospective payment system," and subparagraph (A), which triggers the budget neutrality provision, requires the Secretary to review and revise "the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2)" not less than annually to take into account various factors and information. 42 U.S.C. § 1395*l*(t)(9)(A). These statutory provisions describe the OPPS prospective rulemakings CMS undertakes prior to the start of each calendar year. The budget neutrality provision cited above focuses on "estimated" amounts for the coming year. CMS similarly recognizes the prospective nature of this budget neutrality requirement. *See, e.g.*, the CY 2003 Final Rule, 67 Fed. Reg. 66,718, 66,754 (Nov. 1, 2002) ("With respect to budget neutrality, section 1833(t)(9)(B) of the Act [42 U.S.C.§ 1395*l*(t)(9)(B)] makes clear that any adjustments to the OPPS made by the Secretary may not cause *estimated* expenditures to increase or decrease.") (emphasis added). Thus, while budget neutrality remains a rate-setting requirement guiding adjustments *prospectively*, the law does not permit post-hoc reconciliation or recoupment to achieve budget neutrality *after* actual payments are made to providers. *Cf. Cty. of L.A. v. Shalala*, 192 F.3d 1005, 1016-17 (D.C. Cir. 1999) (finding the Secretary's long-held interpretation of the Medicare

Act's outlier-payment provision that "there is no necessary connection between the amount of *estimated* outlier payments and the *actual* payments made to hospitals for cases that actually meet the outlier criteria" to be "a reasonable interpretation") (emphases added); Physician Fee Schedule ("PFS") Update for CY 2003, 68 Fed. Reg. 9,567, 9,568 (Feb. 28, 2003) (noting that, where "estimates" were used to determine the PFS sustainable growth rates ("SGRs") for fiscal years 1998 and 1999, such estimates may not be "recalculated to reflect later, after-the-fact actual data" absent specific congressional authorization).

Likewise, on remand or in setting OPPS rates for future years, it would be improper for the Secretary to recoup the 3.2% adjustment that was lawfully applied to non-340B OPPS claims (whether by implementing a prospective negative adjustment designed to recoup approximately $1.6 billion in payments or by applying a new negative adjustment to non-340B claims that is designed to render any positive adjustment for 340B claims budget neutral). Put simply, the Secretary did not err in applying a positive adjustment to non-340B claims in order to achieve budget neutrality in CY 2018 based on estimates undergirding the CY 2018 OPPS Final Rule. Thus, any remedy must not explicitly or implicitly recoup non-340B payments, which were properly made under the CY 2018 OPPS Final Rule.

FAH's members, non-340B hospitals, relied on and were properly paid under an OPPS payment rate designed to be budget neutral based on CMS estimates. That the CY 2018 OPPS payment rate may not ultimately result in actual budget neutrality, whether due to this Court's decision, fluctuations in service volumes, or any host of other factors, should not (and does not, under the Medicare Act) jeopardize the payments that were made under the prospectively set payment rates. Moreover, this Court lacks jurisdiction to review the 3.2 percent adjustment by

virtue of 42 U.S.C. § 1395*l*(t)(12)(C), which explicitly bars "administrative or judicial review" of prospective budget neutrality adjustments.

III. The Medicare Act Does Not Contemplate or Authorize the Recoupment of Amounts Properly Paid Under Prospectively Set OPPS Rates

As CMS routinely has opined and various courts have agreed, the idea that payment will be made at a predetermined, specified rate serves as the foundation of the Medicare prospective payment systems, of which OPPS is one. *See, e.g.*, *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1232 (D.C. Cir. 1994); *Anna Jacques Hosp. v. Burwell*, 797 F.3d 1155, 1169 (D.C. Cir. 2015); *Skagit Cty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386 (9th Cir. 1996). The D.C. Circuit has recognized these core principles of predictability and finality, finding that "the Secretary's emphasis on finality protects Medicare providers as well as the Secretary from unexpected shifts in basic reimbursement rates" and permits hospitals to rely on the predetermined rates and resulting payments made thereunder. *Methodist Hosp.*, 38 F.3d at 1232.

Critically, the Medicare Act does not generally permit reconciliation between anticipated aggregate payment amounts and actual aggregate payments under a prospective payment system. Thus, where changes to a prospective payment system produce alleged "overpayments," these purported overpayments cannot be recouped absent specific statutory authorization. By way of example, the provisions of the Medicare Act establishing the inpatient prospective payment system ("IPPS") and the OPPS each contain language authorizing the Secretary to adopt prospective adjustments to the IPPS or OPPS payment amounts to eliminate estimated *future* (but not past) changes in aggregate payments that are due to changes in the coding or classification of inpatient discharges or covered outpatient department services that do not reflect

real changes in case mix or service mix. 42 U.S.C. §§ 1395ww(d)(3)(A)(vi), 1395*l*(t)(3)(C)(iii).[7] Thus, when CMS made changes in documentation and coding under the IPPS for Federal Fiscal Year ("FY") 2008, it adopted payment adjustments under 42 U.S.C. § 1395ww(d)(3)(A)(vi) designed to prospectively eliminate the increase in aggregate payments expected to result from the documentation and coding changes rather than case mix changes. *See* Changes to the Hospital IPPS and FY 2008 Rates, 72 Fed. Reg. 47,130, 47,186 (Aug. 22, 2007). Congress reduced the amount of the payment adjustment by statute, however, and provided narrow authority for CMS to recoup from FYs 2010, 2011, and 2012 payments the estimated amount of the increase in aggregate FYs 2008 and 2009 payments. TMA, Abstinence Education, and QI Programs Extension Act of 2007, Pub. L. No. 110-90, § 7, 121 Stat. 984, 986–87 (2007) ("TMA"); *see also* Changes to the Hospital IPPS and FY 2008 Payment Rates, 72 Fed. Reg. 66,580, 66,886 (Nov. 27, 2007) (finalizing changes to the FY 2008 IPPS adjustments in compliance with § 7 of the TMA). Then, Congress again acted in 2013 to permit additional recoupment adjustments in FY 2014, 2015, 2016, and 2017 to offset increases in aggregate IPPS payments for FYs 2008 through 2013. *Id.* at § 7(b), *amended by* American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 631(b), 126 Stat. 2313 (2013) ("ATRA"). Although the Medicare Act permits CMS to implement prospective adjustments to eliminate anticipated overpayments in future years, 42 U.S.C. § 1395ww(d)(3)(A)(vi), the explicit and limited

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[7] In relevant part, the statutory language provides as follows: "Insofar as the Secretary determines that [certain IPPS or OPPS] adjustments . . . for a previous fiscal year (or estimates that such adjustments for a future fiscal year) did (or are likely to) result in a change in aggregate payments under this subsection during the . . . year that are a result of changes in the coding or classification of [discharges or covered outpatient department services] that do not reflect real changes in [case mix or service mix], the Secretary may adjust [the average standardized amounts or the conversion factor] computed under this [paragraph or subparagraph] for subsequent fiscal years so as to eliminate the effect of such coding or classification changes."

authority set forth in section 7(b) of the TMA and section 631(b) of ATRA was necessary in order to recoup for purported overpayments in prior years. *See, e.g.*, Hospital IPPS and Fiscal Year 2014 Rates, 78 Fed. Reg. 50,496, 50,514 (Aug. 19, 2013) (acknowledging that any FY 2010 through 2012 "overpayments could not be recovered by CMS [prior to the passage of ATRA] as section 7(b)(1)(B) of Public Law 110–90 [TMA] limited recoupments to overpayments made in FY 2008 and FY 2009.").

No specific statutory authorization for recoupment by CMS of the prospectively set CY 2018 OPPS rates exists here. Defendants' suggestion that 42 U.S.C. § 1395hh(e)(1)(A) authorizes the Secretary to apply the 2017 OPPS Final Rule "retroactively to meet the budget neutrality requirement," Defs.' Br. Remedy at 8 (ECF No. 31), is simply misplaced. The statutory scheme here establishes a prospective payment system, meaning that "retroactive application" of a new rule could never be "necessary to comply" with statutory requirements for the OPPS, as would be required to meet the exception to the general prohibition on retroactive Medicare rules in § 1395hh(e)(1)(A).

Moreover, in line with the finality and predictability principles underlying the OPPS, the FAH's members relied on and already have received reimbursement under the prospectively set payment rates for the outpatient non-drug items and services they provided to Medicare beneficiaries in CY 2018. Any error identified in CMS's 340B reimbursement rate-setting in the CY 2018 OPPS Final Rule cannot be imputed to all hospitals nationwide who properly relied on the prospectively set CY 2018 OPPS payment rates. Likewise, the Secretary cannot remedy any purported CY 2018 underpayments for 340B drugs by increasing payments for 340B drugs in a future payment year in a budget neutral manner (*i.e.*, by reducing payments for non-340B items

and services) because this would amount to an unlawful retroactive recoupment of CY 2018 payments that were properly made to all hospitals under the CY 2018 OPPS Final Rule.[8]

CONCLUSION

In fashioning any relief, the Court should not call into question the unchallenged 3.2 percent budget neutrality adjustment properly adopted based on CMS estimates, or otherwise attempt to achieve actual budget neutrality for CY 2018 OPPS expenditures because the Court lacks jurisdiction to review CMS's budget neutrality adjustment. Likewise, this Court should determine that CMS lacks authority to recoup any or all of the 3.2 percent budget neutrality adjustment or to offset any recovery by Plaintiffs with negative OPPS adjustments or otherwise.

[8] Similarly, when and if a challenge to the 340B payment reduction in the CY 2019 OPPS Final Rule properly comes before this court, the Court should refrain from altering the CY 2019 OPPS reimbursement rate that was prospectively established for non-340B hospitals nationwide.

Dated: February 7, 2019

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 29(a)(4), I hereby certify this brief complies with the requirements of Local Rule 7(o)(4) and Fed. R. App. P. 29(a)(5) and 32(g)(1) because it contains 3,130 words, according to the count of Microsoft Word.

Dated: February 7, 2019

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