IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as the Secretary of Health and Human Services, *et al.*,

Defendants.

No. 18-2084 (RC)

BRIEF OF THE FEDERATION OF AMERICAN HOSPITALS AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS

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CORPORATE DISCLOSURE STATEMENT

Amicus Curiae Federation of American Hospitals is a nonprofit trade association of health systems. The Federation 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, INTERESTS, AND AUTHORITY TO FILE[1]

Amicus Curiae the Federation of American Hospitals (Federation) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. Dedicated to a market-based philosophy, the Federation provides representation and advocacy on behalf of its members to Congress, the Executive Branch, the judiciary, media, academia, accrediting organizations, and the public. The Federation's members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals in urban and rural America and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services.

The Federation's members are deeply affected by any changes to Medicare reimbursement rates that the Department of Health and Human Services (HHS) determines for hospital outpatient services according to an intricate statutory system known as the Outpatient Prospective Payment System (OPPS). *See* 42 U.S.C. § 1395*l*(t). That is why the Federation routinely submits comments to the Centers for Medicare & Medicaid Services (CMS) on Medicare payment rulemakings and offers guidance to courts regarding Medicare reimbursement principles in this space.

In 2018, HHS decreased the Medicare reimbursement rate for drugs purchased by hospitals under the 340B program, reasoning that the decrease was justified because 340B hospitals acquire drugs at significantly reduced prices. *See* Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and

[1] No party or 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 the Federation or its counsel made a monetary contribution to this brief's preparation or submission. All parties have consented to the brief's filing.

Quality Reporting Programs, 82 Fed. Reg. 52,356 (Nov. 13, 2017). The agency estimated that this negative payment adjustment for 340B drugs would reduce expenditures for 2018 by $1.6 billion. Because of the statute's budget-neutrality provision, HHS redistributed those savings by making an offsetting 3.2% increase in the reimbursement rates for non-drug outpatient items and services provided by all OPPS hospitals. *Id.* at 52,623. HHS adopted the same adjusted rate and maintained the 3.2% increase in each of the last five years. *See* Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 58,818, 58,975-77 (Nov. 21, 2018); Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 84 Fed. Reg. 61,142, 61,321-27 (Nov. 12, 2019); Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 85 Fed. Reg. 85,866, 86,042-55 (Dec. 29, 2020); Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 86 Fed. Reg. 63,458, 63,461, 63,645-46, 63,648 (Nov. 16, 2021). More than two thousand non-340B hospitals benefited from the 3.2% positive adjustment, including the Federation's member hospitals. *See* Avalere Health, OPPS Medicare Part B Payment Impact Analysis, at 9-10 (Mar. 2021), *available at* https://www.fah.org/wp-content/uploads/2021/04/20210326_OPPS_Analysis_for_FAH.pdf (Avalere Health Analysis).

A few months ago, the Supreme Court held that HHS acted unlawfully by reducing the drug reimbursement rates for 340B hospitals relative to other hospitals in the 2018 and 2019 OPPS. *American Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896 (2022). But the Supreme Court did

not address the proper remedy to which 340B hospitals are now entitled, leaving the question of remedy to this Court.

The Federation writes to explain that, in crafting relief for the 340B hospitals resulting from the invalidation of the OPPS Rules, the Medicare statute forecloses any attempt to offset remedial payments through retroactive recoupments of funds from non-340B hospitals. Nor does the budget-neutrality provision of the OPPS, as the government has previously suggested, allow—let alone require—the retroactive recoupment and reallocation of funds already paid out as reimbursements for items and services provided in past calendar years. The budget-neutrality provision requires only that HHS adopt prospective budget neutrality adjustments based on its estimates for the following calendar year. The agency is fully capable of remedying its past underpayments to 340B hospitals without disturbing the funds already distributed to non-340B hospitals.

The Federation also writes to help inform the Court's consideration of the equities at issue by offering the non-340B hospitals' perspective on the harmful effects that wholesale, retrospective changes to prospectively-set hospital outpatient payment rates would have on American health care. The Federation's members relied on those OPPS payment rates and have already received reimbursement for services rendered in 2018 through 2022 under those prospectively-set payment rates. This reality reinforces that any relief awarded to 340B hospitals in this action should not affect payments made or expected to be made to non-340B hospitals.

ARGUMENT

Throughout this litigation, HHS has wielded "budget neutrality" as a shield to judicial review. HHS insisted all the way to the Supreme Court that a judicial ruling invalidating its past reimbursement rates for outpatient services rendered by certain hospitals would require

retroactive offsets elsewhere in the OPPS—a prospect that the agency deemed so "impractical" that it should suffice to block judicial review entirely. *American Hosp. Ass'n*, 142 S. Ct. 1896, slip op. at 8. The Supreme Court unanimously rejected that view as inconsistent with the statutory text and traditional presumption in favor of judicial review of administrative action, *id.* at 7-8, and went on to invalidate the 2018 and 2019 OPPS 340B drug reimbursement policy, *id.* at 9. Following the Supreme Court's decision, the government cannot now brandish budget neutrality as a justification for retroactively recouping reimbursements already made under the OPPS. It is not. Nothing in the Medicare Act—budget-neutrality provisions or otherwise—allows HHS to claw back lawful payments to non-340B hospitals.

I. THE MEDICARE STATUTE DOES NOT ALLOW HHS TO MAKE ANY OFFSETS TO ACHIEVE ACTUAL OR RETROSPECTIVE BUDGET NEUTRALITY.

As the Supreme Court said just months ago, the text and structure of the Medicare statute "make this a straightforward case." *American Hosp. Ass'n*, 142 S. Ct. 1896, slip op. at 10. The statute does not authorize the agency to recoup five years-worth of payments for hospital outpatient items and services because it failed to comply with its own statutory obligations, and the agency cannot ignore that reality under the guise of an obligation of budget neutrality.

A. The OPPS's statutory text does not allow HHS to retroactively recoup reimbursements in the name of budget neutrality.

The Medicare statute does not allow HHS to recoup or reallocate actual payments under the OPPS such that unanticipated expenditures in one area are offset by retroactive clawbacks elsewhere. That absence of authority makes sense: The relevant subsection is entitled "*Prospective* payment system for hospital outpatient department services" and (unsurprisingly) addresses the factors HHS must consider when determining the OPPS rates for the *following* calendar year. 42 U.S.C. § 1395*l*(t) (emphasis added). HHS revises the OPPS rates each year

via notice-and-comment rulemaking and publishes them before they go into effect. Hospitals then receive the predetermined OPPS rate for a service in every instance in which they provide the service, meaning that "hospitals are not reimbursed for the actual costs incurred in providing care." *American Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1234 (D.C. Cir. 2020), *cert. denied sub nom. Am. Hosp. Ass'n v. Becerra*, 141 S. Ct. 2853 (2021), *reh'g denied*, 142 S. Ct. 920 (2021).

Nothing in the text authorizes HHS to claw back funds from previous years because HHS miscalculated or misapplied some portion of the OPPS formula. And the narrow exception to the Medicare statute's general prohibition on retroactive rulemaking—when "retroactive application is necessary to comply with statutory requirements," 42 U.S.C. § 1395hh(e)(1)(A)(i)—does not, as the government has suggested in earlier phases of this litigation, Defs.' Br. on Remedy at 8, ECF No. 31, provide the requisite specific statutory authorization for recoupment. The OPPS is a *prospective* payment system, meaning that "retroactive application" of a new rule is never "necessary to comply" with statutory requirements of the OPPS. 42 U.S.C. § 1395hh(e)(1)(A)(i). The government cannot locate a "newfound power" to retroactively recoup and reallocate Medicare reimbursements in such broad language of an "'ancillary provision[]' . . . designed to function as a gap filler" that has never been employed in this manner. *West Virginia v. EPA*, 142 S. Ct. 2587, 2610 (2022) (citation omitted).

Nor can any retroactive-recoupment power be divined from the statute's budget-neutrality provision. *See* 42 U.S.C. § 1395*l*(t)(9)(B), (14)(H). When HHS adjusts the groups, relative payment weights, and wage indices in the OPPS for the upcoming year, budget neutrality requires that any changes "may not cause the estimated amount of expenditures . . . to increase or decrease from the estimated amount of expenditures . . . that would have been made if the adjustments had not been made." 42 U.S.C. § 1395*l*(t)(9)(B). In plain English: The

impact of any adjustment, up or down, must be estimated and offset elsewhere so that the total estimated budget remains the same.

The government's past litigation posture presumes there must be actual equivalence between the prospectively-estimated budget neutrality calculations and actual payments furnished in a particular year, or that unanticipated additional payments must be offset by retroactive savings elsewhere. But careful readers will notice that the budget neutrality provision applies just to the "*estimated* amount of expenditures"—not the *actual* amount of expenditures. The budget-neutrality provision addresses only estimated costs for the following calendar year. The estimates are just one of the inputs into the OPPS formula subject to the agency's notice-and-comment rulemaking each year—but after those rules are issued for a particular year, the estimates do not change as a result of unanticipated increases in spending. And while budget neutrality remains a rate-setting requirement guiding rate adjustments going forward, the law does not permit retroactive reconciliation or recoupment to achieve budget neutrality after actual payments are made to providers. That the payment rates for the last five calendar years may not ultimately result in actual budget neutrality, whether due to HHS's misinterpretation of its statutory obligations, fluctuations in service volumes, or any host of other factors, does not jeopardize the actual payments made during those years under the prospectively-set payment rates. Accordingly, once expenditures are actual rather than estimated, the budget-neutrality requirement is inapplicable by its own terms.[2]

[2] Nor does *Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004), support the government's position, as it has previously insisted, *see* Defs.' Opp'n Br. on Remedy at 12-13 n.5, ECF No. 36. *Amgen*, which involved neither budget neutrality nor retroactive recoupments, held only that the court could not review the particular adjustments challenged there. *Amgen*, 357 F.3d at 112-118. Moreover, any credit the court may have lent to the government's argument that judicial review would "interfere with the Secretary's ability to ensure budget neutrality," *id*. at 112, does not

B. Common sense and the OPPS's structure confirm that HHS cannot retroactively recoup reimbursements in the name of budget neutrality.

Transforming budget neutrality into a retroactive requirement—retroactively recalculating payments under the OPPS, recouping funds already paid out, and then redistributing them—would wreak havoc on Medicare's payment system. *Cf. Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1233 (D.C. Cir. 1994) (upholding HHS determination that corrections in wage rates used to determine Medicare reimbursement would not be applied retroactively and noting that "retroactive corrections would cause a significant, if not debilitating, disruption to the Secretary's administration of the already-complex Medicare program"). Indeed, "'common sense as to the manner in which Congress would have been likely to delegate' such power" to HHS makes it very unlikely that Congress actually did so. *West Virginia*, 142 S. Ct. at 2609 (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000)) (brackets omitted).

If Congress intended the agency to implement such a sea change in Medicare reimbursement policy in the name of budget neutrality, it would have said so explicitly. "It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme." *Id.* at 2607 (quoting *Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989)). Congress could have conveyed the power of retroactive recoupment explicitly. Or it could have referred to actual rather than estimated costs in creating the OPPS, as it did in other subsections in the same statute. *See, e.g.*, 42 U.S.C. § 1395*l*(i)(2)(A)(i) (referring to "actual audited costs incurred . . . in providing such

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survive the Supreme Court's decision in *American Hospital Association*, which flatly rejected HHS's argument that judicial review was foreclosed "[d]ue to that budget-neutrality requirement" because it "lack[ed] any textual basis." 142 S. Ct. 1896, slip op. at 8. Any retroactive recoupment power is similarly atextual.

services"); *id*. § 1395*l*(dd)(1) (setting repayments for certain colorectal cancer screening tests as "the lesser of the actual charge for the service" and the amount determined under the OPPS). These other provisions demonstrate that "Congress knows exactly how" to give HHS express authority to offset past Medicare overpayments "when it wishes," yet did not do so here. *Ysleta Del Sur Pueblo v. Texas*, 142 S. Ct. 1929, 1942 (2022).

The budget-neutrality provision says nothing about retroactively recouping repayments in the event of administrative error and so does not convey that power either. Extraordinary grants of regulatory authority are rarely accomplished through "modest words," "vague terms," or "subtle device[s]." *Whitman v. American Trucking Ass'ns*, 531 U.S. 457, 468 (2001). "Nor does Congress typically use oblique or elliptical language to empower an agency to make a 'radical or fundamental change' to a statutory scheme." *West Virginia*, 142 S. Ct. at 2609 (quoting *MCI Telecomms. Corp. v. American Tel. & Tel. Co*., 512 U.S. 218, 229 (1994)).

Moreover, the statute's structure suggests that Congress could have foreseen the possibility that judicial intervention would invalidate some portion of the OPPS—and declined to permit, in such a circumstance, a wholesale retroactive allocation of payments already made. The OPPS did not eliminate the statutory right of a hospital to contest a reimbursement determination with HHS and then in court. 42 U.S.C. § 1395ff(b); *see, e.g.*, *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 7-9 (2000). Here, Congress required HHS to treat groups of hospitals the same absent a study of acquisition costs, *American Hosp. Ass'n*, 142 S. Ct. 1896, slip op. at 12, and "HHS may fairly be held to that duty" without presuming that Congress conveyed the extraordinary recoupment powers the government has suggested it possesses. *See H. Lee Moffitt Cancer Ctr. & Rsch. Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 16 (D.D.C. 2018).

C. The statutory and regulatory history of the OPPS further reinforce that HHS lacks authority to retroactively recoup reimbursements in the name of budget neutrality.

While the Medicare statute directs HHS to make certain adjustments to the OPPS prospective payment rates in a manner that is expected to be budget neutral across all hospitals, *see* 42 U.S.C. § 1395*l*(t)(9), the statute does not require actual equivalence between the prospectively estimated budget-neutrality calculations and the actual payment made for a calendar year. Nor does it allow HHS to retroactively disturb payments made under an appropriately budget-neutral system of prospectively set rates to offset later unanticipated additional payments. It could hardly be otherwise, because requiring budget neutrality as to actual expenditures would force the agency to repeatedly make additional payments or recoup costs to account for each ultimate inaccuracy in the relevant estimates—including, for instance, differences between expected and actual amounts of drugs furnished—something that the agency simply does not do under the prospective payment systems.

OPPS's history confirms that it applies only prospectively and does not authorize retroactive reallocations. Before the enactment of the OPPS, HHS reimbursed hospitals retrospectively based on the reasonable costs incurred related to services actually provided. *See* Office of Inspector General; Medicare Program; Prospective Payment System for Hospital Outpatient Services, 65 Fed. Reg. 18,434, 18,436 (Apr. 7, 2000). Congress overhauled that system by adopting the OPPS and required HHS to set reimbursement amounts for hospital outpatient services prospectively at payment rates intended to approximate the costs incurred by efficient providers to encourage more efficient delivery of care. H.R. Rep. No. 105-149, at 1323 (1997). The idea that payments are made at a predetermined, specified rate is the foundation of all Medicare prospective payment systems, including OPPS. *See, e.g.*, *Methodist Hosp. of*

Sacramento, 38 F.3d at 1232; *Anna Jacques Hosp. v. Burwell*, 797 F.3d 1155, 1169 (D.C. Cir. 2015); *Skagit Cnty. Pub. Hosp. Dist. No. 2 v. Shalala*, 80 F.3d 379, 386 (9th Cir. 1996). The core principles of predictability and finality "protect[] Medicare providers as well as the Secretary from unexpected shifts in basic reimbursement rates," permitting hospitals to rely on the predetermined rates and resulting payments. *Methodist Hosp.*, 38 F.3d at 1232.

Indeed, the government has historically maintained that budget neutrality applies on a prospective basis only. *See* Mem. in Supp. of Def.'s Cross-Mot. for Summ. J. and in Opp. to Plf.'s Mot. for Summ. J. (Gov't MSJ), *H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d 1 (No. 1:16-cv-02337-CKK), 2017 WL 11579190 (arguing that HHS "reasonably interpreted § 1395*l*(t)(18)(B) to require payment adjustments on a prospective basis, as is consistent with the OPPS itself and prospective payment systems in general"); *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1016-20 (D.C. Cir. 1999) (HHS's longstanding interpretation of the Medicare Act's outlier-payment provision as including "no necessary connection between the amount of *estimated* outlier payments and the *actual* payments made to hospitals" was reasonable (emphases added and citation omitted)).

And where changes to a prospective payment system produced past allegedly excessive payments, HHS sought specific statutory authorization to recoup the funds—offering further support that the budget-neutrality provision does not *itself* authorize retroactive recalculations. After HHS determined that coding changes had increased inpatient hospital payments in federal fiscal years 2008 through 2013 by approximately $11 billion, Congress acted to provide narrow authority for HHS to reduce future payments in specified years to recoup $11 billion. *See* TMA, Abstinence Education, and QI Programs Extension Act of 2007, Pub. L. No. 110-90, § 7, 121 Stat. 984, 986-987 (2007), *as amended by* American Taxpayer Relief Act of 2012 (ATRA), Pub.

L. No. 112-240, § 631(b), 126 Stat. 2313, 2353-54 (2013). HHS did not claim any preexisting authority to recoup those funds; instead, the explicit and limited authority set forth in section 7(b) of the TMA and section 631(b) of ATRA was necessary to recoup for purported excessive payments in prior years. *See, e.g.*, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates, 78 Fed. Reg. 50,496, 50,514 (Aug. 19, 2013) (acknowledging that any overpayments in fiscal years 2010 through 2012 "could not be recovered" prior to the passage of ATRA); *see also* Medicare Program; Physician Fee Schedule Update for Calendar Year 2003, 68 Fed. Reg. 9,567, 9,568 (Feb. 28, 2003) (noting that "estimates" used to determine sustainable growth rates for Physician Fee Schedule in fiscal years 1998 and 1999 may not be "recalculated to reflect later, after-the-fact actual data" absent specific congressional authorization). Despite years of litigation, HHS has not identified any instance in which it has exercised systematic recoupment authority absent congressional authorization—perhaps because it never has.

Moreover, HHS has retroactively corrected underpayments in a non-budget neutral fashion under Section 1395*l*(t) voluntarily, without "suggest[ing] any conflict between that retroactive adjustment and budget neutrality." *H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 15. For example, in 2006, HHS made a "retroactive payment adjustment" under § (t)(2)(E) that applied to a group of rural hospitals the agency said it had mistakenly excluded from that year's prospective adjustment. Medicare Program; Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates, 71 Fed. Reg. 67,960, 68,010 (Nov. 24, 2006). The agency did not offset the cost of doing so by retroactively recouping payments it had already made to other providers. *H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 15.

This history confirms that budget neutrality does not apply retroactively. And as HHS has long acknowledged, a prospective-only policy preserves the expectations of all parties and facilitates the economic incentives and predictability that Congress intended. HHS cannot remedy its statutory violation by recouping the 3.2% adjustment that was lawfully applied to non-drug OPPS claims, whether by recovering past payments or by implementing a prospective negative adjustment.

II. ECONOMIC REALITIES CURRENTLY FACED BY HOSPITALS PROVIDE ALL THE MORE REASON TO CONCLUDE THAT HHS LACKS AUTHORITY TO RETROACTIVELY RECOUP OPPS PAYMENTS.

The government retroactively recouping funds from non-340B hospitals is not just illegal. It is also terrible policy. Any attempted recoupment would cause chaos for hospitals and come at the worst possible time for them and their finances.

A. Non-340B hospitals relied on OPPS payment rates in past years and have already received reimbursements at those rates for services rendered in those years, and retroactive recoupment would imperil the critical community services these hospitals provide.

Retroactive recoupment of Medicare reimbursements means that hospitals would be forced to return or forgo vital funding, despite providing essential healthcare services at exceedingly low (or often negative) margins. Indeed, hospitals' Medicare overall operating margin was negative 8.5% in 2020—and negative 12.6% absent federal pandemic relief funds, which have now largely expired. MedPAC, Report to the Congress: Medicare Payment Policy, at 69 (Mar. 2022), *available at* https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_SEC.pdf.

Federation members, all of which are ineligible for 340B discounts as tax-paying hospitals, serve as essential health care institutions for some of the nation's most-vulnerable communities, providing uncompensated and discounted care to patients who have few, if any,

alternatives to address their health care needs. Federation member hospitals provide these underserved patient populations the full range of healthcare services, including emergency services, preventative care, and the treatment of life-threatening and debilitating conditions in rural and urban areas across the United States. More than two thousand non-340B hospitals, including Federation members, saw an increase in Medicare payments as a result of the 3.2% payment adjustment in each of the last five years, providing much-needed additional resources to care for some of the country's most at-risk populations. *See* Avalere Health Analysis at 9-10.

Many Federation member hospitals meet and exceed the applicable low-income patient population thresholds that would make them eligible to participate in the 340B program if tax-paying hospitals were not statutorily excluded. *See* 42 U.S.C. § 256b(a)(4)(L)(i). Indeed, non-340B hospitals spend the same 2.5% of total operating costs on charitable services as 340B hospitals.[3] Federation member hospitals spend an even greater 4.4% share. Uncompensated care services—a broader measure of unreimbursed care recognized by CMS, *see* 42 C.F.R. § 412.106(g)(1)(iii)(C)(5)—account for just 3.5% of total operating costs at 340B hospitals, but account for 3.7% at non-340B hospitals and 5.7% at Federation member hospitals.

The government recognized in *H. Lee Moffitt Cancer Center* that "retroactively recalculating payments under the OPPS" could "adversely impact[] the reliance interests of hospitals operating under the OPPS." Gov't MSJ, *H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d 1 (No. 1:16-cv-02337-CKK). It should do the same here. In line with the finality and predictability principles underlying the OPPS, the Federation's member hospitals relied on,

[3] This cost information was developed from the latest cost reports for hospitals with cost reporting periods ending between 10/1/2020 and 12/31/2021 as contained in the CMS Healthcare Provider Cost Reporting Information System file dated June 30, 2022, *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports.

received reimbursement under, and have long-since used or obligated funds from the prospectively-set payment rates for 2018 through 2022 to deliver services to Medicare patients. The Court should not tolerate hospitals nationwide bearing the cost of HHS's own error in calculating the drug reimbursement rate for 340B hospitals, particularly when non-340B hospitals had no reason to think that the 3.2% positive adjustment could retroactively disappear five years later. Simple fairness dictates that the government not penalize non-340B hospitals for its own mistake. *See Freeman v. Pitts*, 503 U.S. 467, 487 (1992) ("Equitable remedies must be flexible if these underlying principles are to be enforced with fairness . . . .").

B. A trifecta of historic challenges—COVID-19, inflation, and hospital-staffing shortages—renders any attempted retroactive recoupment particularly ill-advised.

Most of the nation's hospitals and health systems operated on razor-thin margins before the COVID-19 pandemic. *See* FTI Consulting, Assessing the Adequacy of Proposed Updates to the Hospital Inpatient Prospective Payment System, at 2 (2022), *available at* https://www.fticonsulting.com/-/media/files/us-files/insights/reports/2022/jun/assessing-adequacy-proposed-updates-hospital-inpatient-payment-system.pdf (FTI Consulting Report). Unprecedented growth in hospital expenses, coupled with potential future COVID-19 surges and record inflation, now place hospitals in an even-more-precarious situation. Retroactively recouping a significant share of half a decade's worth of OPPS payments would be nothing short of disastrous for hospitals already on the brink of financial ruin.

For more than two years, hospitals have been on the front lines of the COVID-19 pandemic, which has significantly strained an already-fragile healthcare workforce with over 80 million cases, over 4.6 million hospitalizations, and nearly 1 million deaths. *Massive Growth in Expenses & Rising Inflation Fuel Continued Financial Challenges for America's Hospitals &*

Health Systems, Am. Hosp. Ass'n, https://www.aha.org/guidesreports/2022-04-22-massive-growth-expenses-and-rising-inflation-fuel-continued-financial (last visited Aug. 12, 2022). The pandemic also coincided with a range of other financial and operational challenges like historic volume and revenue losses and skyrocketing expenses. Record inflation has made increases in expenses "severely detrimental to hospital finances, leading to billions in losses and over 33% of hospitals operating on negative margins." *Id*. "[H]ospital margins are still in the red" more than halfway through 2022. Erik Swanson, *National Hospital Flash Report: July 2022*, Kaufman Hall (Aug. 1, 2022), https://www.kaufmanhall.com/insights/research-report/national-hospital-flash-report-july-2022. Hospital "expenses remain at historic highs, leaving hospitals with cumulatively negative margins" that "remain significantly lower than pre-pandemic levels." *Id*.

Labor costs are a significant driver of these historic expenses. The pandemic further accelerated competition between hospitals and travel and temporary nurse staffing firms that are attracting a greater share of the workforce. FTI Consulting Report at 3-4. "The cost of contract labor relative to total labor expenses increased five-fold in 2022 compared to 2019," largely the result of hospitals needing "to replace departing staff nurses with travel or agency nurses." *Id*. Contract nurses come at a significantly-increased cost, forcing hospitals to shell out triple the median wages of employed nurses in March 2022. *Id*.

The financial health of rural hospitals, including many Federation members, is particularly perilous. Forty-six percent of rural hospitals have a negative operating margin, and over 100 rural hospitals have closed since 2010. *See* The Chartis Group, Crises Collide: The COVID-19 Pandemic And The Stability Of The Rural Health Safety Net, at 2 (Feb. 2021), https://www.chartis.com/sites/default/files/documents/COVID%20and%20the%20Stability%20of%20the%20Rural%20Health%20Safety%20Net.pdf. As it has everywhere else, the COVID-19

pandemic has only exacerbated those financial challenges, forcing some rural hospitals to reduce or suspend outpatient services. *Id.* at 1, 6. The median distance to the most common healthcare services increases by 20 miles when rural hospitals close, resulting in even greater barriers to care for communities. U.S. Gov't Accountability Off., GAO-21-93, Rural Hospital Closures: Affected Residents Had Reduced Access To Health Care Services, at 14-15 (Dec. 2020), https://www.gao.gov/assets/gao-21-93.pdf.

The economic realities facing hospitals provide all the more reason to conclude that HHS lacks the authority to retroactively recoup OPPS reimbursements. *See West Virginia*, 142 S. Ct. at 2608-09. The OPPS does not allow—let alone require—HHS to remedy its mistake by robbing Peter to pay Paul. And any remedy here should not inadvertently suggest that HHS has the ability to retroactively reallocate OPPS payments, which would be an unprecedented development in the history of Medicare reimbursement, given that the statute does not convey that power. HHS has the tools it needs to make Plaintiffs whole—without touching OPPS reimbursements to non-340B hospitals.

CONCLUSION

For the foregoing reasons, any relief granted to the 340B hospitals should not affect payments to non-340B hospitals.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on August 12, 2022, the foregoing was electronically filed through this Court's CM/ECF system, which will send a notice of filing to all counsel, who are registered users.

/s/ Sean Marotta
Sean Marotta