Federation of American Hospitals®

Charles N. Kahn III
President and CEO

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Via electronic submission at *http://www.regulations.gov*

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1793-P, Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 (Vol. 88, No. 131), July 11, 2023.

Dear Administrator Brooks-LaSure:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC, and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, children's, and cancer services. The FAH appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) about the above-referenced proposed rule, published in the Federal Register (88 Fed. Reg. 44,078) on July 11, 2023 (Proposed Rule).

As taxpaying hospitals, FAH member hospitals are ineligible to participate in the 340B drug discount program, and their payments for drugs payable under the Outpatient Prospective Payment System (OPPS) were not reduced under the payment reduction for 340B-acquired drugs that was challenged and found unlawful in *American Hospital Association v. Becerra*. But, with the implementation of the 340B payment reduction in 2018, FAH member hospitals, like all Medicare-participating hospitals, had their prospectively set OPPS rates for non-drug items and services positively adjusted by 3.2 percent based on CMS's prospective estimate of savings under the 340B payment adjustment. Earlier in 2023, CMS reversed this payment reduction prospectively with a negative 3.09 percent adjustment, an amount calculated to prospectively eliminate the positive 3.2 percent adjustment adopted in 2018. As such, payments for non-drug items and services under the OPPS have appreciably declined for all hospitals in 2023, creating

significant financial pressures for hospitals still grappling with the impacts of the COVID-19 pandemic, extraordinary inflation, supply-chain constraints, and workforce shortages.

Against this backdrop, starting in 2025, CMS proposes to recover $7.8 billion (representing approximately 3.19 percent of non-drug OPPS payments made to hospitals between 2018 and 2022) through a negative OPPS recoupment adjustment of 0.5 percent that will last approximately 16 years. ***The estimated $7.8 billion represents lawfully received payments for non-drug items and services furnished in 2018 through 2022 under prospectively set payment rates, and the FAH strongly opposes the recovery of these funds through any mechanism.***

The Medicare statute forecloses any attempt to offset remedial payments through prospective recoupments of funds from OPPS hospitals. Nor do the budget neutrality provisions of the OPPS allow—let alone require—the prospective recoupment of funds already properly paid for non-drug items and services provided in past calendar years. The OPPS budget neutrality provisions require that HHS adopt prospective budget neutrality adjustments based on its *estimates* for the following calendar year. The statute does not permit after-the-fact adjustments in the name of budget neutrality—and, in fact, such adjustments are contrary to the basic structure of the OPPS as a prospective payment system. Nor are such measures necessary—or appropriate—to effectuate a remedy to CMS's unlawful payment reductions affecting 340B-acquired drugs: The agency is fully capable of acquiescing to the Supreme Court's decision and remedying the OPPS underpayments on 340B-acquired drugs without disturbing the five years of lawful payments for non-drug items and services made to all hospitals based on CMS's 2018 prospective estimates.

Hospitals have properly spent and obligated these funds, relying on the certainty provided by the prospective payment system during what was the most trying period for hospitals in the history of the Medicare program. ***The recovery of these payments, whether through a direct recoupment or the proposed rate reduction, is unlawful, in excess of the Secretary's authority under the Medicare statute, and fundamentally contrary to the statutorily prospective nature of OPPS payments.***

<u>Background: The $7.8 Billion in OPPS Payments for Non-Drug Items and Services Were Properly and Lawfully Made to Hospitals</u>

Effective for calendar year 2018, CMS 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.[1] *See* Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52,356 (Nov. 13, 2017). The agency

[1] These discounts are not available to taxpaying hospitals. 42 U.S.C. § 256b(a)(4)(L) (eligibility among hospitals is largely restricted to certain public or non-profit hospitals). This exclusion from the 340B program remains in place despite taxpaying hospitals' strong track records with respect to uncompensated care costs and charity care costs. As the FAH noted in its September 13, 2022 letter, an examination of cost reports in CMS's HCRIS file dated July 30, 2022, shows that non-340B hospitals actually had marginally higher uncompensated care cost rates (3.7 percent) than 340B hospitals (3.5 percent) as a percentage of total operating costs. In addition, charity care cost rates were comparable between 340B and non-340B hospitals (2.5 percent) and markedly higher at FAH members' hospitals (4.4 percent).

estimated that this negative payment adjustment for 340B drugs would reduce OPPS expenditures for covered drugs by $1.6 billion in 2018. In order to maintain aggregate OPPS payments pursuant to statute, CMS used this prospective estimate of savings to craft an offsetting 3.2 percent increase in OPPS rates for non-drug outpatient items and services provided by all OPPS hospitals. *Id.* at 52,623; *see* 42 U.S.C. 1395*l*(t)(9)(B) (requiring that "adjustments for a year may not cause the *estimated* amount of expenditures . . . for the year to increase or decrease from the *estimated* amount of expenditures . . . that would have been made if the adjustments had not been made") (emphasis added). When it became clear that this 3.2 percent adjustment was actually insufficient to avert a decrease in aggregate OPPS payments while the 340B drug payment reduction remained in place, CMS rejected calls to prospectively supplement the 3.2 percent adjustment for 2022, concluding that the agency need not revisit its prior budget neutrality estimations and emphasizing the prospective nature of budget neutrality adjustments. 86 Fed. Reg. 63,458, 63,648 (Nov. 16, 2021). Every Medicare hospital had its OPPS payments for non-drug items and services adjusted between 2018 and 2022 based on CMS's 2018 budget neutrality estimations, including FAH member hospitals.

Following extensive litigation, the Supreme Court held that the 340B drug payment reduction in the 2018 and 2019 OPPS was unlawful. *American Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896 (2022). ***Importantly, the 3.2 percent budget neutrality adjustment was never challenged in this litigation or otherwise and was not set aside or found to be unlawful.*** In fact, throughout the litigation, CMS wielded "budget neutrality" in an attempt to shield the case from judicial review. CMS insisted all the way to the Supreme Court that a judicial ruling invalidating its past reimbursement rates for outpatient drugs 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. *Id.* at 1903. 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 1902-03, and went on to invalidate the 2018 and 2019 OPPS 340B drug reimbursement policy, *id.* at 1906. The Supreme Court declined to opine on the appropriate remedy for the reduced payment amounts to 340B hospitals. On January 10, 2023, the district court concluded that the 340B payment rates in the 2018 to 2022 OPPS rules are unlawful, and it remanded the matter without vacatur "to give the agency the opportunity to remediate its underpayments." *American Hosp. Ass'n v. Becerra*, No. CV 18-2084 (RC), 2023 WL 143337, at *1 (D.D.C. Jan. 10, 2023).

<u>The Agency Should Simply Acquiesce to the Courts' Decisions in Making the Lump Sum Payment for 340B-Acquired Drugs (Part II.B.1.a)</u>

The FAH supports CMS's proposal to make "one-time lump sum payments to affected 340B covered entities calculated as the difference between what they were paid for 340B drugs (ASP minus 22.5 percent or an adjusted WAC or AWP amount) during the relevant time period (from CY 2018 through September 27th of CY 2022) and what they would have been paid had the 340B payment policy not applied." 88 Fed. Reg. at 44,083. ***But we strongly disagree with CMS's assertion that it can lawfully rely on 42 U.S.C. § 1395l(t)(2)(E) and (t)(14)(H) as authority for making the proposed remedial repayments to 340B hospitals.*** 88 Fed. Reg. at 44,083-84. Put simply, these provisions relate to the determination of payment under "a *prospective* payment system," 42 U.S.C. § 1395*l*(t)(1)(A) (emphasis added), and are incapable of

supporting the Secretary's adoption of "an equitable retroactive adjustment" on their own or in conjunction with CMS's limited retroactive rulemaking authority under 42 U.S.C. § 1395hh(e)(1)(A).[2]

Rather, a far more appropriate legal authority exists for the lump-sum remedial repayments: acquiescence to the Supreme Court's and district court's decisions. There is a long history of CMS effectuating adverse judicial rulings through acquiescence to the ruling courts' decisions. *See, e.g.*, *Grant Medical Center v. Hargan*, 875 F.3d 701 (D.C. Cir. 2017); *Johnson v. U.S. R.R. Retirement Bd.*, 969 F.2d 1082, 1092 (D.C. Cir. 1992). In fact, here, the agency has *already* acquiesced to the district court's decision vacating the prospective application of the 340B payment rate in the 2022 OPPS rule, *Am. Hosp. Ass'n v. Becerra,* No. CV 18-2084 (RC), 2022 WL 4534617 (D.D.C. Sept. 28, 2022), without relying on any special authority for instructing the MACs to process or reprocess payments. *See* 88 Fed. Reg. at 44,088 ("[A] large portion of the CY 2022 340B drug claims for dates of service between January 1, 2022, and September 27, 2022, have already been remedied as a result of being processed or reprocessed at the default drug payment rate."). CMS can and should likewise do so with respect to remedying the remaining 340B-acquired drug payments for 2018 through 2022. The Proposed Rule provides no rationale for failing to use this comparatively straightforward authority for providing make-whole relief to 340B hospitals.[3]

The FAH therefore urges CMS to simply acquiesce to the decisions of the Supreme Court and lower court and move forward with providing make-whole relief to 340B hospitals through lump sum payments.

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[2] The Medicare Act broadly prohibits retroactive rulemaking with two limited exceptions: (1) when "retroactive application is necessary to comply with statutory requirements" or (2) where "failure to apply the change retroactively would be contrary to the public interest." 42 U.S.C. § 1395hh(e)(1)(A). The Proposed Rule suggests retroactive rulemaking authority only with respect to the drug payment methodology for 340B-acquired drugs, presenting no argument that payments for non-drug items and services may be changed retroactively or that CMS may retroactively re-estimate its budgetary projections from 2018. Because the OPPS is expressly required to be *prospective* in nature, "retroactive adjustments" to past years' payment rates (particularly in a budget neutral manner) are not "necessary to comply" with statutory requirements of the OPPS. 42 U.S.C. § 1395hh(e)(1)(A)(i). And it is not in the public interest to engage in the retroactive adjustment of prospective payment rates (particularly when doing so would upset the reliance interest of all hospitals with respect to payment for non-drug items and services) when make-whole relief can be implemented without revisiting 2018 through 2022 OPPS rates.

[3] It is also worth noting that acquiescence avoids the pitfalls and legal risks of relying on "adjustment" authorities to support the remedial payments to 340B hospitals. As the Supreme Court recently held in *Biden v. Nebraska*, words like "modify" and "adjust" are inherently limited and incremental in scope. Such statutory authority permits an agency "to change moderately or in minor fashion" but cannot authorize the agency to "transform" or make "'basic and fundamental changes in the scheme' designed by Congress." 143 S. Ct. 2355, 2368–69 (2023) (quoting *MCI Telecomms. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994)). An "adjustment" of this scope is not moderate or minor. Moreover, the proposed recoupment of $7.8 billion would impermissibly make "basic and fundamental changes" (*id.* at 2368) to the prospective payment system Congress contemplated with its admitted retroactivity as discussed further below.

CMS May Not and Should Not Recoup $7.8 Billion in Non-Drug OPPS Payments (Part II.B.2)

The FAH strongly opposes the destabilizing, unlawful, and unwarranted recovery of $7.8 billion in lawful non-drug OPPS payments under the guise of budget neutrality. As noted above, the Supreme Court did not specify a remedy in its ruling. In the course of litigation, the American Hospital Association (AHA) correctly stated that the Secretary may make 340B hospitals whole for past shortfalls without offsetting budget neutrality reductions. The statute does not authorize the agency to recoup five years-worth of payments for hospital outpatient non-drug 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. ***As the FAH has explained in prior OPPS rulemaking comments, the Medicare Act does not permit CMS to make any offsets to achieve actual or retrospective budget neutrality, and, to the extent that CMS finalizes its proposed lump-sum payments to 340B hospitals, those payments may not be adopted in a budget neutral fashion because any offsetting payment reduction would unlawfully recoup past payments that were properly made for non-drug OPPS items and services.***

The Medicare statute does not allow CMS to recoup or reallocate actual payments under the OPPS such that unanticipated expenditures in one area are offset by retroactive claw backs elsewhere. That absence of authority makes sense: The fundamental premise of the OPPS is that the payment system is *prospective*. To that point, the relevant subsection is entitled "*Prospective* payment system for hospital outpatient department services". It begins by requiring that "the amount of payment . . . shall be determined under a *prospective* payment system," and it (unsurprisingly) addresses the factors CMS must consider when determining the OPPS rates for the *following* calendar year. 42 U.S.C. § 1395*l*(t) (emphasis added). By its clear terms, the Medicare Act requires that CMS *prospectively* adjust payment rates within the 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, while Congress very clearly intended that budget neutrality be reached within this *prospective* payment system, Congress permits that the Secretary make adjustments only to achieve a *prospective estimate* of budget neutrality. To conceive of budget neutrality as a retrospective requirement would be inconsistent with the text and structure of the statute and wreak havoc on Medicare's payment systems and the reliance interest of stakeholders throughout the health care system.

The text of the Medicare Act plainly conveys 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).[4] Paragraph (9) is entitled "Periodic review and adjustments components of prospective payment system," and subparagraph (A), which triggers

[4] 42 U.S.C.§ 1395*l*(t)(14)(H) does not add to this requirement; instead, it simply refers back to subsection (t)(9)(B) in providing that expenditures resulting from paragraph (14) are taken into account under paragraph (9) only starting in 2006.

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 that CMS undertakes with respect to each calendar year prior to the start of that calendar year. The budget neutrality provision cited above addresses only *estimated* costs for the *coming* calendar year, and it provides no basis for addressing expenditures in *prior* years or for reconciling adjustments with the *actual* amount of expenditures. The estimates are just one of the inputs into the OPPS formula subject to the agency's notice-and-comment rulemaking each year—and, critically, after a rule is finalized for a particular year, the estimates do not change as a result of unanticipated increases or decreases in spending, and the budget neutrality provision, by its plain terms, has no further application. CMS itself has long-recognized the prospective nature of this budget neutrality requirement. *See, e.g.,* 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). While budget neutrality remains a rate-setting requirement guiding adjustments *prospectively,* the law does not permit the proposed *post-hoc* recoupment to achieve budget neutrality *after* actual payments are made to providers.

Likewise, in setting OPPS rates for future years, the Secretary lacks the authority to indirectly recoup payments that resulted from CMS's lawfully applied and unchallenged 3.2 percent budget neutrality adjustment, which the agency adopted in CY 2018 and maintained without further adjustment through CY 2022, in an alleged attempt to offset the proposed lump-sum relief to 340B hospitals. ***Put simply, the Secretary did not err in applying a positive adjustment to non-340B claims in order to achieve budget neutrality based on the agency's estimates in the CY 2018 OPPS Final Rule. And any new adjustment, under the plain terms of the budget neutrality provision, must reflect estimated savings and costs in the following year, not the costs associated with any other year or the costs of any lump-sum payment. Thus, any remedy should not and may not either directly or indirectly seek to recoup non-drug payments, which were properly made under the OPPS Final Rules in CYs 2018-2022.***

Critically, the Medicare Act ***does not permit after-the-fact reconciliation*** to achieve *actual* budget neutrality in a given payment year under any prospective payment system (except in very narrow circumstances explicitly prescribed by Congress). Thus, where, for *any* reason, a prospective payment system ultimately produces payments beyond those anticipated, such payments may not be recouped absent specific statutory authorization. By way of example, the provisions of the Medicare Act establishing the inpatient prospective payment system (IPPS) and those establishing 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).[5]

[5] 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

Although the Medicare Act permits CMS to implement *prospective* adjustments to eliminate anticipated excess payments in future years (42 U.S.C. § 1395ww(d)(3)(A)(vi)), the statute includes no general authority for CMS to impose adjustments designed to recoup prior-year payments later assessed to have increased aggregate expenditures. This would undermine the fundamental statutory scheme inherent in a prospective payment system. A narrow exception proves this general rule: In 2007, Congress passed the TMA, Abstinence Education, and QI Programs Extension Act of 2007, Pub. L. No. 110-90, § 7, 121 Stat. 984, 986–87 (2007) (TMA), to specifically authorize additional adjustments during specified fiscal years to recoup certain FY 2008 and FY 2009 payments that CMS attributed to changes in coding or classification rather than case mix. And in 2013, Congress amended the TMA to authorize additional adjustments during specified fiscal years to recoup a related $11 billion in purported excess payments between FY 2008 through 2013. American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 631(b), 126 Stat. 2313 (2013) (ATRA). Tellingly, Congressional action was required to specifically authorize such after-the-fact reconciliation. *See, e.g.,* Hospital IPPS and Fiscal Year 2014 Rates, 78 Fed. Reg. 50,496, 50,514 (Aug. 19, 2013) (acknowledging that any FYs 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 comparable specific statutory authorization for recoupment of amounts properly paid at the prospectively set CYs 2018-2022 OPPS rates exists here.

Bolstering this plain understanding of the statute, 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 the 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. ***Any attempt at after-the-fact rebalancing would be contrary to such principles and therefore fundamentally at odds with Congress's intent that rates be established*** **prospectively** ***under the OPPS.*** And the Supreme Court's recent analysis in *Biden v. Nebraska* (*see* n.3, above) provides further support for rejecting CMS's attempt to distort the fundamental nature of prospective budget neutrality adjustments by characterizing recoupment of prior-year budget neutrality adjustment payments as (another) budget neutrality "adjustment."

Moreover, it cannot seriously be disputed that CMS has authority to correct underpayments in a non-budget neutral manner: CMS *itself* has long 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. v. Azar*, 324 F. Supp. 3d 1, 15 (D.D.C. 2018). For example, in 2006, CMS 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

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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."

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. 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 (ECF No. 17), *H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d 1 (D.D.C. No. 1:16-cv-02337-CKK). The same fundamental fairness concern exists here. In line with the finality and predictability principles underlying the OPPS, FAH member hospitals relied on, received reimbursement under, and have long-since used or obligated funds from amounts paid at the prospectively-set payment rates for 2018 through 2022 to deliver services to Medicare patients.[6]

CMS's citation to cases addressing some common-law right to recoup overpayments or monies "wrongfully paid" does not resuscitate CMS's misguided and unlawful recoupment proposal. *See* 88 Fed. Reg. at 44,082 (citing for support *Chaves Cnty. Home Health Serv., Inc.* v. *Sullivan,* 931 F.2d 914, 918 (D.C. Cir. 1991); *United States* v. *Lahey Clinic Hosp., Inc.,* 399 F.3d 1, 16 (1st Cir. 2005); *Mount Sinai Hosp. of Greater Miami, Inc.* v. *Weinberger,* 517 F.2d 329, 345 (5th Cir.), *modified,* 522 F.2d 179 (5th Cir. 1975)). These cases stand only for the proposition that the agency has a right to file a court action based in common law to recoup or recover funds that were unlawful when paid, such as for "medically unnecessary services" (*Mount Sinai*, 517 F.2d at 345), Medicare "overpayments" deriving from allegedly medically unnecessary tests and billing practices violative of Medicare reimbursement policies (*Lahey*, 399 F.3d at *6-7), and Medicare "overpayments" deriving from payments for non-covered services (*Chaves Cnty.,* 931 F.2d at 915-17). No court or administrative tribunal has found that hospital payments for non-drug items and services in CYs 2018-2022 were unlawfully paid or received. The OPPS rate for these services was prospectively set by CMS and hospitals properly claimed and received Medicare payment for these services based on CMS's prospective estimations and resulting rates. In other words, these payments were lawful when paid and will continue to be lawful after CMS provides remedial payments to 340B hospitals.

The FAH also disagrees with CMS's rationale that recoupment is necessary to avert a "windfall" to hospitals paid under the OPPS. CMS states that "failing to budget neutralize the remedy payments would mean that the additional payments for non-drug items and services that were made from CY 2018 through CY 2022 to achieve budget neutrality for the 340B payment policy . . . would be a windfall, especially to non-340B hospitals that were not subject to decreased drug payments from CY 2018 through CY 2022." 88 Fed. Reg. at 44,082. CMS goes on to suggest that it proposes to exercise its authority under subsection (t)(2)(E) to "offset the extra payments . . . made for non-drug items and services from 2018 through 2022 because "those payments have proven to be an unwarranted windfall." *Id.* FAH member hospitals, like

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[6] In the Proposed Rule, CMS seeks to distinguish its long history of authorizing non-budget neutral remedies by suggesting that the impact of those prior adjustments was often minor, whereas adopting a non-budget neutral remedy here would "not be de minimis." 88 Fed. Reg. at 44,080-81. This explanation falls short. "[A]n agency literally has no power to act . . . unless and until Congress confers power upon it." *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986). There is no "de minimis" exception to this basic tenet of administrative law and separation of powers. Rather, CMS's attempts to rationalize its position serves only to underscore that CMS's proposal arbitrarily departs from the agency's own long-standing understanding that the Medicare Act authorizes non-budget neutral remedies. *See FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 250 (2012) (it is arbitrary and capricious for an agency to fail to acknowledge its position is, in fact, changing).

all hospitals paid under the OPPS, properly relied on the prospectively set payment rates applied to non-drug items and services in 2018 through 2022 and already have received proper payment for services furnished in those years under those lawful and prospectively-set OPPS payment rates for non-drug items and services. ***Nothing has changed with respect to the value of the non-drug items and services furnished over those five years, and nothing has changed with respect to the financial position of non-340B hospitals. In short, the payments to non-340B hospitals for non-drug items and services were not a windfall when made and any remedy with respect to 340B-acquired drug payments cannot transform those non-drug payments to other hospitals into a windfall now.***[7]

It is fundamental to the nature of a prospective payment system that CMS's estimates may, despite a sound methodology, diverge from the actual facts in the end. By statue, certain OPPS adjustments are budget neutralized based on the amount by which "the estimated amount of expenditures" under the OPPS will increase or decrease. 42 U.S.C. § 1395*l*(t)(9)(B). There is no process under the OPPS for retrospective reevaluation of these estimates, such that underestimates and overestimates do not create windfalls to hospitals or the Medicare Trust Fund. Rather, any divergence between such prospective estimates and actuality does not on its own make those prospectively set payment rates invalid or call into question any provider's entitlement to payments made under the prospective payment system. In the context of the OPPS, then, any relief awarded to 340B hospitals does not upset the appropriateness of past OPPS payment rates for non-drug items and services and does not create a windfall, particularly with respect to non-340B hospitals.

Moreover, this lawful 3.2 percent payment adjustment for non-drug items and services implemented in 2018 represented a much-needed bump in Medicare payment for primary and emergency care, as well as outpatient procedures and other non-drug services—a welcome increase in a chronically underfunded system during a once-in-a-century pandemic. Hospitals have recently confronted a 3.09 percent payment reduction for non-drug items and services as a part of the reversal of the 340B drug payment program in 2023. 87 Fed. Reg. 71,748, 71,975 (Nov. 23, 2022). Any direct prospective reduction in OPPS payments for non-drug items and services to offset relief provided to 340B hospitals would be not just unlawful—it would also risk further harm to Medicare beneficiaries by placing unnecessary and unfair additional financial strain on hospitals already grappling with the destabilizing effects of the COVID-19 pandemic, record inflation, and acute labor shortages. Moreover, such an approach would be inherently inequitable and arbitrary because, among other things, it would artificially depress OPPS payments for critical non-drug items and services.

Importantly, the proposed 0.5 percent rate reduction over sixteen years would ultimately result in the hospitals included in the rate reduction *losing more than these hospitals collectively received for CYs 2018-2022 from the budget neutrality adjustment*. Two factors lead to this arbitrary and capricious result: a shrinking number of hospitals will participate in the recoupment and Medicare Advantage (MA) penetration will impermissibly magnify the recoupment's

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[7] CMS's suggestion that "failing to budget neutralize the remedy payments" made to 340B hospitals would create a "windfall, especially to non-340B hospitals" (88 Fed. Reg. at 44,082) is thus illogical and unsupported. The financial situation of non-340B hospitals and their entitlement to payment for outpatient services furnished between 2018 and 2022 are wholly unchanged by the proposed remedy payments for 340B-participating hospitals, and those remedy payments cannot transform lawful OPPS payments into a windfall.

financial harms. First, CMS proposes to recoup the aggregate $7.8 billion in past payments from a smaller universe of hospitals than the group that actually received the 3.2 percent adjustment between 2018 and 2022, essentially burdening the hospitals participating in the recoupment with repayment of monies received by other hospitals not subject to recoupment. This is because the $7.8 billion proposed recoupment target includes adjusted non-drug payments made to hospitals that newly enrolled between 2018 and 2022 and to hospitals that have or will close over the course of the 16-year recoupment.

Second, rapidly growing MA penetration will precipitate unanticipated and excessive harm to hospitals subject to the recoupment. As MA penetration grows, the volume of Part B claims will proportionally shrink compared to Part C claims for outpatient services. As a result, the recovery of $7.8 billion could be further prolonged beyond CMS's 16-year projection while the financial harms of the recoupment are magnified by depressed MA payments from MA plans that incorporate the OPPS rate in their provider agreements or pay out-of-network providers for emergency and other outpatient services pursuant to 42 C.F.R. § 422.214(b). Between 2018 and 2023, MA penetration increased from 37 percent to 51 percent nationwide, and MA penetration is set to continue this period of rapid growth. Nancy Ochieng *et al.*, Kaiser Family Foundation, Medicare Advantage in 2023: Enrollment Update and Key Trends (Aug. 9, 2023), *at* https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-enrollment-update-and-key-trends/. These hospital losses with respect to Part C payments are not accounted for in CMS's aggregate recoupment target and the projected rate reductions, yet they will inevitably produce significant and unnecessary harms for participating hospitals while generating savings for the Medicare program well beyond the $7.8 billion target. At the same time, MA organizations will receive an unwarranted windfall because MA plans would in all likelihood bear no responsibility to remedy past payment reductions for 340B-acquired drugs and would also benefit from reduced outpatient rates.

Finally, we briefly address CMS's request for comments on delaying the proposed reduction to the conversion factor from CY 2025 to CY 2026. Such a delay is warranted when hospitals are already confronting a 3.09 percent payment reduction for non-drug OPPS items and services imposed beginning in 2023, and hospitals have not fully recovered from the destabilizing impacts of the COVID pandemic and unprecedented workforce shortages, inflation, and supply chain disruptions. If CMS had authority to impose the recoupment (it does not), it should also do so in a manner that minimizes provider burdens through a prolonged recoupment schedule while avoiding changes to the Outpatient PRICER that would impact the basis for many MA payments.

In sum, FAH members relied on and were properly paid under an OPPS payment rate properly designed to be budget neutral based on CMS estimates. That the CY 2018-2022 OPPS payment rates may not result in *actual* budget neutrality, whether due to the Supreme Court's decision, fluctuations in service volumes, or any host of other factors, should not (and lawfully cannot) directly or indirectly jeopardize the payments that were made under the prospectively set payment rates. ***Therefore, the FAH strongly opposes CMS's proposal to recoup the 3.2 percent adjustment that was lawfully applied to non-drug OPPS claims in CYs 2018-2022 by implementing a prospective 0.5 percent rate reduction.***

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The FAH appreciates the opportunity to submit these comments on these important issues to patients and providers. If you have any questions, please contact me or any member of my staff at (202) 624-1500.

Sincerely,