Federation of American Hospitals

Charles N. Kahn III
President and CEO

September 15, 2025

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

RE: CMS-1834-P; Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency; 90 *Fed. Reg.* 33,476 (July 17, 2025).

Dear Dr. Oz:

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 comment to the Centers for Medicare & Medicaid Services (CMS) regarding the Calendar Year (CY) 2026 Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems proposed rule (Proposed Rule). This letter details FAH's comments on several issues in the Proposed Rule. Among other issues, our comments to CMS:

EXECUTIVE SUMMARY

OPPS Update and 340B Recoupment

CMS proposes to increase OPPS rates by 2.6 percent (a 3.3 percent market basket less a 0.7 percent productivity adjustment) but would further reduce payments by 2.0 percent to accelerate recoupment of $7.8 billion in lawful non-drug OPPS payments made from 2018–2022 as part of its 340B Remedy Rule. The FAH strongly opposes this retrospective recoupment which is unlawful, in excess of the Secretary's authority under the Medicare statute, and fundamentally contrary to the statutorily prospective nature of OPPS payments. The 2 percent reduction threatens hospital stability, and inappropriately shifts funds to Medicare Advantage (MA) organizations. We urge CMS to rescind the recoupment.

Further, the FAH requests CMS adopt a one-time forecast error adjustment to the CY 2026 OPPS update based on the forecast shortfalls in the hospital market basket in FY 2021 through FY 2024 totaling 4.6 percent. The market basket forecasts have significantly understated the actual increase in hospital costs by a combined 4.6 percentage points due to an unprecedented confluence of circumstances during the COVID-19 PHE and resulting inflationary pressures. The FAH requests that, in recognition of this unique and extraordinary situation, CMS apply a positive adjustment of 4.6 percentage points to the OPPS update.

Site-Neutral Payment Proposals

The FAH opposes CMS's proposal to expand site-neutral payment policies for the administration of Part B drugs in excepted, off-campus provider-based departments. CMS has not demonstrated that there has been unnecessary increases in the volume of administration services or conducted any assessment of patient acuity for these hospital-level services. These cuts will undermine access for American seniors—particularly in rural and underserved communities. Further, in addition to being deeply flawed and unlawful, the proposed payment cut for drug administration services is an adjustment that could only be implemented in a budget-neutral manner in accordance with the strict requirements of the OPPS. Therefore, if CMS implements any variation on the proposed payment cut despite the concerns raised in this letter, the FAH strongly urges CMS to do so in a budget neutral manner, as required by statute.

Elimination of the Inpatient-Only (IPO) List

CMS proposes to eliminate the IPO list over a three-year period beginning in CY 2026. The FAH opposes the proposed, arbitrary elimination of the IPO list as it would create inappropriate safety risks for Medicare beneficiaries (including MA beneficiaries), impose administrative burdens on physicians and hospitals, increase beneficiaries' financial burden, and erode the value of Part A coverage and Part C basic benefits. The FAH urges CMS to retain the IPO list as a vital patient-safety tool, supported by annual, evidence-based review. Wholesale elimination would expose beneficiaries to inappropriate outpatient procedures, increase disputes with MA plans, and erode the clarity of Part A and Part C benefits.

Hospital Price Transparency

The FAH continues to support price transparency initiatives that provide patients with clear, accurate, and actionable information. However, the current approach of publishing vast amounts of hospital reimbursement data is not providing patients with useful or actionable pricing information. The FAH believes both hospitals and users of hospital price transparency data would benefit from a period of relative regulatory stability during which the already widespread hospital compliance championed by CMS may be further improved. Rather than again revising recently implemented requirements so soon, CMS should instead focus on implementing the Department of Health and Human Services Office of Inspector General's (OIG) recommendation to create a training and compliance program tailored for small and rural hospitals that are struggling to comply with the already technically complex requirements. In accordance with Executive Order 14192, CMS should be actively seeking ways to reduce hospital burden that was largely introduced by the prior administration. Therefore, the FAH recommends that CMS maintain the hospital price transparency rules in their current form and seek ways to reduce hospital burden.

Market-Based MS-DRG Proposals

The FAH strongly opposes CMS's proposal to require the disclosure of median payer-specific negotiated rate data for MA plans, as well as the incorporation of such data into the MS-DRG weighting methodology. At its core, the proposal pursues an impermissible goal—shifting from a relative resource-

based MS-DRG weighting system to one based on purported "market" rates. CMS lacks any authority to adopt a "market-based" MS-DRG weighting methodology because Congress has explicitly instructed CMS to weight MS-DRGs based on "relative hospital resources used with respect to discharges" for each MS-DRG. The Proposed Rule severely underestimates the operational burdens and costs of compliance and overestimates the value and utility of median payer-specific negotiated rate data. Although the FAH supports continued efforts to improve upon the accuracy and appropriateness of relative weight calculations, we oppose upending the current cost-based methodology through the use of payer-specific negotiated rate data. Therefore, the FAH strongly urges CMS to abandon the proposed market-based MS-DRG data collection and relative weighting calculation methodology as unlawful and inappropriate.

The FAH urges CMS to finalize OPPS policies that sustain hospital access to outpatient and emergency services, avoid unlawful recoupments, protect patient safety, and ensure transparent yet workable reporting.

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The FAH appreciates the opportunity to offer comments on the CY 2026 OPPS/ASC Proposed Rule. Our detailed comments are included in the following pages in Appendix A of our letter. If you have any questions or would like to discuss further, please do not hesitate to contact me or a member of my staff at (202) 624-1500.

Sincerely,

APPENDIX A

FAH DETAILED COMMENTS ON CFY 2026 OPPS/ASC PROPOSED RULE (CMS-1834-P)

II.B. The Market Basket Update Should Be Increased to Account for Forecast Error

CMS proposes an OPPS update for CY 2026 based on a market basket update of 3.2 percent less 0.8 percentage points for total factor productivity or 2.4 percent. By law, CMS is required to update OPPS rates by the same update that applied under the IPPS.[1] As CMS has already finalized an update of 2.6 percent for the FY 2026 IPPS,[2] it is clear that CMS will be adopting a CY 2026 final rule OPPS update of 2.6 percent (3.3 percent market basket less 0.7 percentage points for total factor productivity) exclusive of an addition 2.0 percent reduction that CMS will be applying to recoup past additional payments for 340B acquired drugs—a reduction opposed by FAH for reasons explained in more detail below.

The FAH reiterates our prior comments asking that CMS account for prior year understatements of the market basket that have permanently resulted in updated IPPS and OPPS rates that are below the rate of inflation. As the FAH has previously noted, prior year market baskets from FY 2021 through FY 2023 did not capture profoundly aberrant and historic economic forces that fueled rapid cost increases for goods and services purchased by hospitals. As shown in the below table, the hospital market basket for these three years was understated by a total of 4.3 percentage points relative to the update hospitals received based on a projected market basket.

This update means the increase in hospital IPPS and OPPS rates has been a combined 4.3 percentage points below the rate of inflation resulting in a permanent loss of hospital purchasing power. While forecast error for FY 2024 was less, it remains at -0.3 percentage points understating the FY 2024 market basket for the 4th consecutive year.

Hospital Market Basket	FY 2021	FY 2022	FY 2023	FY 2024[3]
Forecast Used in the Update	2.4	2.7	4.1	3.3
Actual Based on Later Data	3.0	5.7	4.8	3.6
Difference	-0.6	-3.0	-0.7	-0.3

To address the permanent underpayment to hospitals by an update below the rate of inflation, **the FAH requests CMS to do a one-time adjustment to the market basket update of 4.3 percentage points to account for difference between projected market basket and actual market basket between FY 2021 and FY 2024.**

[1] Section 1833(t)(3)(C)(iv) of the Social Security Act.

[2] 90 FR 36902

[3] OACT, 1st quarter 2025 release of the market basket information with historical data through the 4th quarter of 2024 (Market Basket Data | CMS) for the actual update based on later utilization.

In addition, CMS proposed reducing the proposed market basket update with a 0.8 percentage point total factor productivity adjustment that will be 0.7 percentage points based on the final IPPS rule. This total productivity adjustment is inappropriate in that it contemplates improbable and overstated gains in productivity for the hospital sector as noted by the CMS Office of the Actuary (OACT) itself.

In a memorandum dated June 2, 2022, OACT stated: "over the period 1990-2019, the average growth rate of hospital TFP using the two methodologies ranges from 0.2 percent to 0.5 percent, compared to the average growth of private nonfarm business TFP of 0.8 percent." The memorandum also indicates that an assumed future rate of hospital industry productivity growth of 0.4 percent per year remains reasonable compared to an assumed rate of productivity growth in the private nonfarm business sector of 1.0 percent.[4]

The FAH shares OACT's skepticism regarding the offset to the hospital market basket for the 10-year average in economy-wide nonfarm total factor productivity. One reason that hospitals may not be able to realize the same growth in general economy wide productivity is that hospital services are highly labor intensive. As labor represents nearly 70 percent of the index, hospitals have little opportunity to obtain productivity gains from non-labor inputs as may be occurring in other industries that are less labor intensive.

The FAH understands that CMS is required by law to adjust the market basket update for total factor productivity. However, the FAH asks CMS to consider that the adjustment for total factor productivity reduces the update below what even OACT says is reasonable for hospitals to achieve when deciding on our request for a forecast error correction in its application of an update for hospital outpatient services for 2026.

V.B.7 CMS Lacks Legal Authority to Recoup $7.769 Billion Lawfully Paid for Non-Drug Items and Services From 2018 Through 2022 (42 C.F.R. § 419.32(b)(1)(B)(iv)(B)(*12*))

As taxpaying hospitals, FAH member hospitals are ineligible to participate in the 340B drug discount program, and their Medicare payments for drugs payable under the 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 increased by 3.2 percent based on CMS's Sprospective estimate of savings attributable to the 340B payment adjustment. These increased payments were required based on the OPPS' budget neutrality provisions, and they have not been challenged in any litigation. These increased payments were not a windfall at the time, and nothing has subsequently transformed them into a windfall, particularly for non-340B hospitals that received no part of the lump-sum payments remedying the 340B payment adjustment. In the CY 2023 OPPS/ASC final rule with comment period, CMS prospectively eliminated the 340B payment reduction and with a 3.09 percent payment cut, returned OPPS rates for non-drug items and services to the rate that would have been in place if the 340B payment reduction had never been

[4] Paul Spitalnic, Stephen Heffler, Bridget Dickensheets and Mollie Knight, "Hospital Multifactor Productivity: An Update Presentation of Two Methodologies Using Data through 2019." Hospital Multifactor Productivity: An Updated Presentation of Two Methodologies Using Data through 2019 (cms.gov).

implemented.[5] As such, payments for non-drug items and services under the OPPS have appreciably declined for all hospitals starting in 2023.

Against this backdrop, in the 340B Remedy final rule, CMS promulgated 42 C.F.R. § 419.32(b)(1)(B)(iv)(B)(*12*), which would recoup $7.769 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 starting in CY 2026 and lasting for approximately 16 years. The Proposed Rule would now quadruple the payment reduction to 2.0 percent beginning in CY 2026, effectuating the recoupment in approximately six years. The FAH strongly opposes this accelerated recoupment schedule, and the even more accelerated alternative policy option of a 5.0 percent payment cut over three years. ***Moreover, because the $7.769 billion represents lawfully received payments for non-drug items and services furnished in 2018 through 2022 under prospectively set payment rates, the FAH strongly opposes the recovery of these funds through any mechanism and over any time frame.***

As the FAH explained in its comments on the 340B Remedy proposed rule, the Medicare statute forecloses any attempt to offset the 2024 lump-sum payments to 340B hospitals through prospective recoupments of funds from all 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 CMS adopt prospective budget neutrality adjustments based on its *estimates* for the next 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 has already remedied the OPPS underpayments on 340B-acquired drugs through lump-sum payments to 340B hospitals in 2024. The agency is neither required nor authorized to disturb the five years of lawful payments for non-drug items and services made to all hospitals based on CMS's 2018 prospective estimates through a recoupment carried out in future years.

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 due to the COVID-19 public health emergency, labor shortages, supply chain disruptions, and record inflation. ***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.***

A. Background: The $7.769 Billion in OPPS Payments for Non-Drug Items and Services Were Properly and Lawfully Made to Hospitals

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.[6] *See* CY 2018 OPPS/ASC Final Rule, 82 Fed. Reg.

[5] 87 Fed. Reg. at 71,973-76.

[6] 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

52,356 (Nov. 13, 2017). The agency 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. CY 2022 OPPS/ASC Final Rule, 86 Fed. Reg. 63,458, 63,648 (Nov. 16, 2021). Every Medicare-participating 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 CY 2018 and 2019 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 CMS's arguments 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 preamble to the 340B Remedy final rule turns this history on its head, suggesting that the Court recognized a budget neutrality requirement and that the availability of retrospective *judicial* review of the agency's actions (which is always retrospective[7]) permits retrospective review by the agency as well. 88 Fed. Reg. at 77,717, 77,158. The Supreme Court, however, expressly declined to opine on the appropriate remedy for the reduced payment amounts to 340B hospitals, and certainly did not endorse or recognize the permissibility of unwinding lawful non-drug payments as part of any remedy. 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-

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in place despite taxpaying hospitals' strong track records with respect to uncompensated care and charity care costs. As the FAH noted in its September 13, 2022 and September 5, 2023 letters, 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).

[7] 340B hospitals initially brought a pre-implementation challenge to the drug payment policy, but the suit was dismissed because a pre-implementation challenge does not satisfy the presentment requirement of 42 U.S.C. § 405(g). Because any judicial review under the OPPS requires such presentment, such judicial review is always and necessarily retrospective.

2084 (RC), 2023 WL 143337, at *1 (D.D.C. Jan. 10, 2023). The court expressly did not rule on the permissibility of budget neutralizing the remediation of underpayments. *Id.* at *5 n.7.

Pursuant to the November 8, 2023 340B Remedy final rule, 88 Fed. Reg. 77,150, CMS issued 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. ***The FAH believes that, with these lump-sum payments to 340B-participating hospitals, CMS has remedied these 340B payment cuts, and further agency action is neither required nor authorized on this issue.***

The 340B Remedy final rule, however, improperly asserted that the lump-sum payments were made under 42 U.S.C. § 1395*l*(t)(2)(E) and (t)(14)(H) and that they must be made in a budget-neutral manner. 88 Fed. Reg. at 77,158. As discussed more fully in our comments on the 340B Remedy proposed rule, 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).[8] Moreover, these "adjustment" authorities are a poor fit for the remedial payments. As the Supreme Court 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)). More recently, the D.C. Circuit confirmed that the term "adjustment" elsewhere in the Medicare Act likewise "connotes 'increment or limitation.'" *Bridgeport Hosp. v. Becerra*, 108 F.4th 882, 888 (D.C. Cir. 2024). An "adjustment" of this scope is not moderate or minor. Moreover, the recoupment of $7.769 billion would impermissibly make "basic and fundamental changes" (id. at 2368) to the prospective payment system Congress contemplated with its admitted retroactivity.

B. <u>CMS is Not Authorized to And Should Not Recoup $7.769 Billion in Non-Drug OPPS Payments</u>

In providing for the lump-sum payment to remedy CMS's 340B-acquired drug payment policy, the agency also finalized a recoupment of $7.769 billion beginning in 2026. Under 42 C.F.R. § 419.32(b)(1)(B)(12), CMS intended to effectuate this recoupment through a 0.5 percent payment cut that

[8] Title XVIII of the Social Security 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). Although the 340B Remedy proposed rule did not indicate that the agency could or would use retroactive rulemaking authority for the recoupment of $7.769 billion from OPPS hospitals through prospective rate reductions, in the 340B Remedy final rule, CMS asserted that it had retroactive rulemaking authority to effectuate the recoupment. 88 Fed. Reg. at 77,175. 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 retroactively adjust 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.

would remain in place for the approximately 16 years it would take to recover $7.769 billion. CMS now proposes a 2.0 percent payment cut for six years or, alternatively, a 5.0 percent payment cut for three years.

The FAH strongly opposes the destabilizing, unlawful, and unwarranted recovery of $7.769 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 the lump-sum remedial payments to 340B hospitals cannot be budget neutralized through a payment cut in later years or otherwise 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 the Secretary to 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).[9]

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

[9] 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.

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* 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. For example, CMS noted in the CY 2003 Final Rule that, "[w]ith 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." 67 Fed. Reg. 66,718, 66,754 (Nov. 1, 2002) (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 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, CMS cannot 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).[10]

[10] Specifically, 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."

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*, which was applied last year by the D.C. Circuit to Medicare Act adjustment authority (*see* discussion above, page 88) 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 42 U.S.C. § 1395*l*(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. 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.[11]

CMS's citation in the 340B Remedy rule 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 77,154 (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 payment 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 77,153-54. 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.* at 77,154. FAH member hospitals, like 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-***

[11] In the 340B Remedy rule, CMS attempted to distinguish its long history of authorizing non-budget neutral remedies by suggesting that the agency in those cases "round[ed] to $0 payment amounts that would have only a de minimis impact on estimated expenditures." 88 Fed. Reg. at 77,177. This explanation falls short. At no point in these prior agency actions did the agency round the impact to $0; rather, it focused on the importance of finality in OPPS rates and reliance interests. There is no "de minimis" exception to the basic tenet that an "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). Rather, CMS's attempts to rationalize its position serves only to underscore that CMS's recoupment 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).

340B hospitals. In short, the payments to non-340B hospitals for non-drug items and services were not a windfall when made and the lump-sum payments to 340B hospitals in early 2024 did not and cannot transform those non-drug payments to non-340B hospitals into a windfall now.[12]

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, whether due to unforeseen factual developments or successful legal challenges. 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. Rather, any divergence between such prospective estimates and actual experience 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 increase 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). The prospective recoupment OPPS payments for non-drug items and services to offset relief provided to 340B hospitals is not just unlawful—it also risks further harm to Medicare beneficiaries by placing unnecessary and unfair additional financial strain on their community hospitals. 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.

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 recoupment of the 3.2 percent adjustment that was lawfully applied to non-drug OPPS claims in CYs 2018-2022 by implementing any prospective rate reduction.***

C. The Recoupment Adjustment Will Operate to Recoup Amounts in Excess of the 3.2 Percent Adjustment Paid by Each Hospital

Importantly, the recoupment adjustment will ultimately result in the hospitals included in the rate reduction *losing more than these hospitals collectively received for CYs 2018-2022 from the budget*

[12] CMS's conclusion 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 77,153-54) 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.

neutrality adjustment. Two factors lead to this arbitrary and capricious result: a shrinking number of hospitals will participate in the recoupment and the growth in Medicare Advantage (MA) penetration will impermissibly magnify the recoupment's financial harms.

First, CMS proposes to recoup the aggregate $7.769 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 $7.769 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 three-, five-, or 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 $7.769 billion could be further prolonged beyond CMS's six-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 out-of-network provider payments for emergency and other outpatient services are made pursuant to 42 C.F.R. § 422.214(b). Between 2018 and 2025, MA penetration increased from 37 percent to 54 percent nationwide, and MA penetration is set to continue this period of rapid growth. Nancy Ochieng *et al.*, Kaiser Family Foundation, Medicare Advantage in 2025: Enrollment Update and Key Trends (July 28, 2025), *at* https://www.kff.org/medicare/medicare-advantage-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. At the same time, because the prospective recoupment adjustment is incorporated into the Medicare Advantage capitation rates,[13] the payment cut will generate savings for the Medicare Part B trust fund well beyond the $7.769 billion target. Notably, these capitation rates were not impacted by the 340B drug payment policy or the budget neutrality adjustment between 2018 and 2022, so the Part B trust fund savings that result from incorporating the recoupment adjustment into the Medicare Advantage capitation rate operate as an additional recoupment that is improperly ignored by the 340B Remedy final rule and the Proposed Rule. At a minimum, the Part B trust fund savings that result from the incorporation of the recoupment adjustment into capitation payment need to be accounted for when assessing whether the $7.769 billion target.

D. The Proposed Increase to the Rate Cut Would Provide a Windfall to Medicare Advantage Organizations

For PY 2026, CMS incorporated the 0.5 percent prospective recoupment under 42 C.F.R. § 419.32(b)(1)(B)(iv)(B)(*12*) into the capitated prospective payment to Medicare Advantage organizations.[14] The current proposal would not adjust these capitated Medicare Advantage payments, but as CMS notes elsewhere in the Proposed Rule, MA plans frequently negotiate payments based on Medicare rates. 90 Fed. Reg. at 33,806. Thus, if the proposed 2.0 percent payment cut is implemented, MA

[13] *E.g.*, 2026 Announcement, pp.44-46 (Apr. 7, 2025), *at* https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/announcements-and-documents/2026.

[14] 2026 Announcement, pp.44-46 (Apr. 7, 2025), *at* https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/announcements-and-documents/2026.

organizations' capitated payment will not incorporate the quadrupling of the payment cut in CY 2026 (or, under the alternative proposal, the order-of-magnitude increase to the payment cut), but at least some or perhaps most MA organizations will attempt to incorporate these significantly greater cuts in their outpatient payments to contracted hospitals. The resulting discrepancy in rates paid to MA organizations and rates paid by MA organizations would create an unwarranted and inappropriate windfall for MA organizations, and would actively harm providers while providing no benefit to Medicare beneficiaries or the Part B trust fund.

V.C & XII.F Notice of Intent to Conduct Medicare OPPS Drugs Acquisition Cost Survey

CMS is proposing to collect drug acquisition costs to provide information from hospitals that could be used to inform payment rates for specified covered outpatient drugs (SCODs) and drugs and biologicals CMS historically treats as SCODs. The FAH believes that a survey of drug acquisition costs could provide accurate information, provided that the Secretary appropriately distinguishes between the average acquisition costs for those hospitals that acquire drugs with significant discounts through the 340B drug discount program, and the average acquisition costs for those that do not. The FAH, however, emphasizes that the change in OPPS drug payments based on the survey data, is subject to budget neutrality requirements under the OPPS. Thus, to the extent that any payments for OPPS drugs are reduced for a year, CMS must offset such payment reductions by increasing payments for non-drug OPPS items and services. Furthermore, as drug utilization and payment rates under the resulting payment policy shift over time, CMS must continue to update its budget neutrality analysis to appropriately offset anticipated changes in drug spending with appropriate increases in non-drug OPPS payments.

Survey Scope. CMS proposes to collect hospital acquisition cost data for all SCODs and other drugs and biologicals CMS historically treats as SCODs. This approach, however, would create a considerable burden for hospitals, and the FAH believes that CMS could use one of two sampling approaches to reduce survey burden while ensuring accurate results. First, CMS could use a sampling and extrapolation approach to determine the average acquisition costs of drugs as a percentage of the average sales price (ASP) reported. This sampling and extrapolation approach would necessitate categorizing drugs into set categories such as high-volume, mid-volume, low-volume, and orphan drugs, and then randomly selecting a statistically valid sample of 340B-acquired and non-340B acquired drugs within each such category to survey. The drug prices as a percentage of ASP from this sample could then be extrapolated to the entire category of drugs. In short, CMS would survey a representative sample of drugs and use the survey data and appropriate statistical analysis to determine the hospital acquisition cost for each drug. This approach is wholly consistent with 42 U.S.C. § 1395l(t)(14)(D)(ii), which requires the Secretary to "conduct periodic subsequent surveys to determine the hospital acquisition cost for each" drug (emphasis added). A survey can determine drug acquisition costs either by (1) directly surveying the drug acquisition costs for each drug (the approach proposed by CMS) or (2) by surveying the drug acquisition costs for a representative sample of drugs in a manner that allows CMS to then determine the average acquisition cost of each drug to be determined by the agency. Congress could have mandated the former approach by requiring "surveys of the hospital acquisition cost for each" drug (i.e., direct surveys of drug acquisition costs). But instead, Congress left the door open for appropriate and sound sampling and extrapolation of survey data by only requiring that the survey enable the agency to determine the hospital acquisition cost for each drug. CMS

should consider using this statutory flexibility to reduce the survey's burden, which will in turn help to support a higher response rate.[15]

Alternatively, CMS could confine the survey to those drugs that account for the vast majority of OPPS spending. Under this approach, CMS would use the resulting data to set payments only for the surveyed drugs based on the average acquisition cost for 340B hospitals and for non-340B hospitals pursuant to 42 U.S.C. § 1395l(t)(14)(A)(ii). Because hospital acquisition cost data for the non-surveyed drugs would not be available to CMS, CMS would be required to continue to set payment for these non-surveyed drugs for all hospitals using its current average sales price methodology pursuant to 42 U.S.C. § 1395l(t)(14)(A)(iii)(II). Previously, the GAO determined that just 53 drugs (identified by HCPCS code) accounted for 86 percent of Medicare spending on SCODs. The list of drugs that account for the vast majority of Medicare spending on SCODs has certainly evolved in the intervening years, but this historic data confirms that CMS could use a narrower, focused survey to develop an impactful acquisition-cost-based payment policy for select, high-impact drugs. Moreover, a narrower survey would be of value in informing the most appropriate and effective survey methods for future years.

Net Acquisition Cost and Units Reported. As proposed, the survey would ask hospitals to report the total units purchased and total net acquisition cost, net of all rebates and discounts, of each purchased drug by National Drug Code (NDC). Respondent OPPS-participating hospitals would thus report data for all drugs acquired during the specified timeframe, regardless of how the drug was ultimately utilized (i.e., responses would include all acquired drugs, whether used in the inpatient or outpatient setting or for Medicare or non-Medicare patients). This approach is generally consistent with how drugs are acquired by hospitals and acquisition data is maintained.

The FAH, however, recommends that CMS further refine its instructions on the calculation of the total units purchased and total net acquisition cost to account for certain situations that are not informative of the actual acquisition cost. For example, the FAH believes that the reporting of total units purchased should be net of units returned to the manufacturer and that such returns should also be removed from the total net acquisition costs. At present, the proposed instructions do not address returned units, and the FAH recommends clarifying that returned units are removed from the total units purchased and from the total net acquisition cost when finalizing the survey. It would be particularly inappropriate to retain returned units in the total unit count but then apply the manufacturer's refund for those units to reduce the net acquisition cost for those drugs. Rather, the data for returned units should be removed from both data points.

Survey Period, Frequency, and Updates. The FAH agrees that the proposal to collect data on purchases during a one-year timeframe of July 1, 2024, through June 30, 2025 represents an optimal time frame. The acquisition costs of drugs frequently change, and the average acquisition cost calculated over a shorter timeframe (e.g., a calendar quarter) may be skewed by temporary supply-chain issues or other factors that would cause the average acquisition cost to be under- or over-stated. In contrast, a one-year acquisition timeframe would appropriately capture the range of acquisition costs for each surveyed drug in that year. Moreover, the FAH believes that responding to the survey with acquisition data for a one-year

[15] Notably, the GAO emphasized the significant burden of the drug survey and indicated that its decision to accept data "in any format" reduced the burden of responding to the survey for hospitals, which "was critical to achieving good response rates." GAO, Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS, p.12 (GAO-06-372) (April 2006), *at* https://www.gao.gov/assets/gao-06-372.pdf.

timeframe is no more burdensome than responding with acquisition data for a shorter timeframe. Therefore, the FAH believes that the proposed timeframe is the most appropriate.

The FAH also supports minimizing survey burden by conducting a survey no more than once every four years, as long as drug payments are kept current with quarterly adjustments based on changes to the ASP. Importantly, a revised survey is not necessary to adjust the payment amount under 42 U.S.C. § 1395l(t)(14)(A)(iii)(I). By statute, the average acquisition costs for the drug and hospital group must be determined "taking into account the hospital acquisition cost survey data," and therefore the agency can use other data to keep payment amounts current. Thus, if the survey indicates that the average acquisition cost for a particular drug for non-340B hospitals is equal to 3% more than the ASP,[16] the average acquisition cost should automatically update with CMS's quarterly updates to its ASP data so that it does not fall below or increase above the survey-determined amount of 3% more than the ASP.

Data Validation and Confidentiality. The FAH believes that some data transparency is necessary to ensure the integrity of the payment system and appropriateness of payment. However, if data is identifiable to individual hospitals, this may suppress responses in light of the sensitivity of drug pricing data. Therefore, to promote a broad response while still ensuring that third parties can replicate CMS's acquisition cost estimates by drug and class of hospital, the FAH recommends that all four data fields (total units and net acquisition costs for 340B and non-340B drugs) be made available at the hospital level with pseudonymized provider numbers, but that all hospital identifiers (e.g., state or location data, NPIs, etc.) be excluded from the data sets that can be accessed by the public or those with data use agreements.

V.B.9. OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals: Payment for Skin Substitutes

Beginning January 1, 2026, CMS proposes to pay for skin substitutes as separately payable supplies under the OPPS when used during a covered application procedure. CMS is proposing analogous changes to its payments in the 2026 PFS proposed rule that will result in consistent payment across sites of service for skin substitutes.

Specifically, CMS proposes to pay for skin substitutes by establishing three groups of products based on FDA approval types: (1) human cell/tissue-based, (2) PMAs and (3) 510(k)s and ASP data when available by product. Previously, for hospitals, CMS used claims and cost report data for mean unit costs (MUC) and ASP +6% data for products not having claims data.

Due to CMS's concerns about incentives for office practices to choose more expensive products than medically necessary, CMS proposes a single payment rate for all three skin substitute product classifications. As a companion policy, CMS proposes a new OPPS Status Indicator "S1" for products paid under this policy.

While the FAH recognizes that CMS's intent is to address some of the potential abusive pricing practices and the use of skin substitute products with limited clinical evidence, ***CMS's proposed payment reductions are too drastic and arbitrary, and could stymie long-term innovation in wound care technologies and their application in non-traditional clinical applications.*** In addition, the FAH is

[16] For clarity, in this example where acquisition cost is 3% higher than ASP, the total payment level for the drug would still need to include the additional 6% add-on for drug preparation, storage, etc. similar to the current level of ASP plus 6%.

concerned that these drastic one-size fits all payment reductions could have unintended consequences on applications where these skin substitute products are essential in the treatment of Medicare beneficiaries, such as in burn care units within hospitals, and other advanced wound care settings. Without a prudent and cautious approach, the FAH is concerned that significant market disruption could result from these payment reductions and could inadvertently lead to reduced beneficiary access to these products and potentially negative beneficiary outcomes such as an increase in infections, and in the most serious cases, even amputations. ***The FAH urges CMS to focus on alternative, more targeted approaches that provide appropriate payment for skin substitutes for certain clinical indications, such as in burn care units, where this type of wound care is critical for better patient outcomes.***

IX. The IPO List Should be Retained as a Critical Patient Safety Tool and to Ensure that Procedures Are Appropriately Paid and Provided Under Medicare Part A (42 C.F.R. §§ 419.22(n), 419.23, 412.3(d)(2))

The FAH strongly opposes CMS's proposal to eliminate the Inpatient Only (IPO) list, which designates those procedures that are not payable under the OPPS because they can only be appropriately provided on an inpatient basis. The assignment of procedures to the IPO list takes into account key clinical considerations that preclude the procedure from being provided to Medicare beneficiaries on an outpatient basis: (1) the invasive nature of the procedure, (2) the need for at least 24 hours of postoperative recovery time, and (3) the underlying physical condition of the patient who would require the surgery.[17] CMS annually reviews the IPO list to identify any services that should be removed from or added to the list based on the most recent data and medical evidence available using criteria specified annually in the OPPS rule. Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting, but Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting.[18] Ultimately, the IPO list serves as an important programmatic safeguard, ensuring that Medicare beneficiaries undergoing any of the 1,731 procedures on the IPO list receive inpatient care and monitoring, and its proposed elimination without any supporting clinical analysis arbitrarily removes an important patient safety mechanism.

Instead, the FAH supports retaining the IPO list—which consists of procedures that are currently performed appropriately and safely only in the inpatient setting—as well as CMS's current process for removing procedures based on clinical criteria. The five criteria established by CMS to evaluate procedures for potential removal address (1) the extent to which outpatient departments are equipped to provide the procedure to the Medicare population, (2) whether the simplest procedure described by the code may be furnished in most outpatient departments, (3) whether the procedure is related to codes that have already been removed from the IPO list, (4) whether the procedure is furnished in numerous hospitals on an outpatient basis, and (5) whether the procedure can be appropriately and safely furnished in an ASC. If CMS determines that one or more of these criteria is met for a given procedure under consideration for removal from the IPO list, CMS may remove it. By annually applying these clinical and patient safety-oriented criteria on a case-by-case basis, CMS can ensure that the IPO list only covers those procedures that continue to be inappropriate for the Medicare population in the outpatient setting. Under the Proposed Rule, however, these clinical considerations would not come into play and Part A coverage would turn largely on

[17] 65 Fed. Reg. 18,434, 18455 (April 7, 2000).

[18] 65 Fed. Reg. at 18443.

the physician's expectations concerning the length of stay under 42 C.F.R. § 412.3(d)(1).[19] The risk of an unsafe procedure being performed outpatient are more acute for Medicare beneficiaries that are covered under Medicare Part C. MA organizations are required to provide inpatient coverage for "services and procedures that the Secretary designates as requiring inpatient care under 42 CFR 419.22(n)." 42 C.F.R. § 422.101(b)(2). The proposed elimination of the IPO list would eliminate the clarity of this coverage, particularly for stays expected to span less than two midnights. In this way elimination of the IPO list may jeopardize MA coverage despite the treating physician's professional judgment that the care should be furnished on an inpatient basis, fueling expensive MA-provider disputes under the other inpatient admission criteria (*i.e.*, the two-midnight benchmark and the case-by-case exception). ***The FAH opposes the proposed, arbitrary elimination of the IPO list as it would create inappropriate safety risks for Medicare beneficiaries (including MA beneficiaries), impose administrative burdens on physicians and hospitals, increase beneficiaries' financial burden, and erode the value of Part A coverage and Part C basic benefits.***

The Proposed Rule cites a range of evolving considerations—such as advances in medical technology, increased reliance on physician judgment, and lessons learned during the COVID-19 Public Health Emergency—as justification for eliminating the IPO list, but none of these factors warrant the proposed fundamental shift in policy. The IPO list remains a critical safeguard in ensuring that complex procedures are performed in settings equipped to manage potential complications, protect patient safety, and support equitable access to care for Medicare beneficiaries. Advances in outpatient care are undeniable, but they do not eliminate the need for clear, consistent standards—especially when clinical appropriateness, administrative clarity, and financial protections for beneficiaries are at stake. As medical practice continues to evolve, CMS should continue the annual process of refining the IPO list to reflect current capabilities—rather than removing a longstanding framework that continues to offer value to patients, providers, and the broader healthcare system.

The IPO List Reduces Administrative Burdens Without Eroding Professional Judgment. As a general matter, the FAH agrees that the appropriate site of service for a particular procedure should typically be determined by surgeons and their patients. But it does not follow from this general observation that physician judgment is undermined by defining those procedures that cannot be appropriately provided to Medicare beneficiaries on an outpatient basis and should not be payable under the OPPS. By way of example, CMS's long-standing recognition that the leg amputation described by CPT code 27592 (amputation, thigh, through femur, any level; open, circular (guillotine)) should only be provided to Medicare beneficiaries on an inpatient basis and paid under the IPPS simply reflects the invasive nature of the procedure and its indisputable and inherent risks. By categorically restricting coverage to the inpatient setting for these amputations based on the clinical evidence, CMS appropriately advances patient safety without meaningfully limiting any physician's clinical judgment. Moreover, in doing so, CMS fulfills its statutory obligation to designate services as "hospital outpatient services" under 42 U.S.C. § 1395*l*(t)(1)(B)(i).

Meanwhile, the proposed elimination of the IPO list along with the continued operation of the two-midnight rule would inappropriately result in level-of-care determinations based largely on the patient's

[19] Physicians may still exercise their judgment that inpatient care is appropriate in other cases under 42 C.F.R. § 412.3(d)(3), but this case-by-case exceptions is not as widely used as the IPO list or the two-midnight benchmark, which are comparatively simpler to apply.

expected length of stay and would increase the paperwork and administrative burdens where a patient is admitted for a short stay to undergo a procedure that should only be performed on an inpatient basis. When finalizing the two-midnight rule in 2013, CMS stated its "belie[f] that inpatient-only procedures are appropriate for exclusion from the two-midnight benchmark" and assured beneficiaries and providers that "inpatient-only procedures currently performed as inpatient 1-day procedures will continue to be provided as inpatient 1-day procedures" under the final rule.[20] Thus, the two-midnight rule explicitly endorsed categorical inpatient treatment for procedures on the IPO list, preserving CMS's determination that inpatient admissions are appropriate for these procedures in all cases. This approach ensures that procedures designated as inpatient-only can be provided on an inpatient basis *regardless of the expected length of stay*, unless and until CMS determines outpatient coverage is appropriate after considering the five clinical criteria for removal from the IPO list. Notably, some current inpatient-only procedures map to MS-DRGs with geometric mean and/or average lengths of stay less than two midnights, such that it is anticipated that a significant number of these procedures would not cross a second midnight in the Medicare population.

Despite argument to the contrary, the Proposed Rule would effectively eliminate Part A coverage for these invasive 1-day procedures except in circumstances where the physician exercises his or her clinical judgment to order an inpatient admission "based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event" and the medical record supports these factors.[21] Establishing that an inpatient 1-day procedure qualifies for inpatient treatment on a case-by-case basis creates burdens for physicians and hospitals and risks the inappropriate migration of inpatient 1-day procedures to the outpatient setting simply out of reluctance to use the case-by-case exception. In addition, the factors used for these case-by-case determinations were developed against the backdrop of the IPO list and thus focus on patient-specific considerations without generally accounting for factors that govern inclusion on the IPO list (e.g., the invasive nature of the procedure and the general need for postoperative care). In short, the elimination of the IPO list alongside the two-midnight rule suggests that an inpatient admission for a 1-day procedure that was on the IPO list before its elimination would only be permissible based on case-by-case, patient-specific considerations. As discussed further below, these problems will be more acute for the growing population of Medicare Advantage beneficiaries who will not benefit from the current clarity that facilitates the prompt and appropriate authorization of inpatient admissions when a procedure on the IPO list is authorized.

This significant change increases the administrative and documentation burden associated with an inpatient admission for an invasive surgical procedure where medical advancements have reduced the average length of stay but significant risks remain, particularly in the Medicare population (*e.g.*, carotid stenting or transcatheter aortic valve replacement (TAVR)). The Proposed Rule does not address the provider burdens or patient risks inherent in eliminating clear inpatient coverage under Medicare Part A and C for 1-day procedures currently on the IPO list. Rather than continuing a long-standing measure that promotes patient safety by making inpatient coverage for select procedures manifestly clear through a definitive IPO list, CMS contends that other safety measures—which operate through the creation of risk for providers—are sufficient and appropriate. The FAH disagrees. The IPO list properly and importantly *facilitates* safe care by setting clear expectations about the setting of care (and assuring coverage for inpatient care) in a relatively narrow range of cases, which is something that enforcement- and liability-

[20] 78 Fed. Reg. 50,496, 50,947 (Aug. 19, 2013).

[21] 42 C.F.R. § 412.3(d)(3).

oriented tactics cannot and do not do. Rather than relying on adverse consequences for unsafe care, the FAH urges CMS to continue to facilitate patient safety by itself adhering to patient safety criteria when defining "hospital outpatient services" under 42 U.S.C. § 1395*l*(t)(1)(B)(i).

The elimination of the IPO list would also risk eroding Part A coverage for skilled nursing facility (SNF) care following an inpatient procedure, increasing the risk to Medicare beneficiaries that experience post-procedure complications. At present, every Medicare beneficiary undergoing a procedure on the IPO list is admitted as an inpatient, in part to ensure that the patient receives adequate post-procedure monitoring for complications. If complications arise, the patient's inpatient stay might extend past three days, qualifying the beneficiary for SNF Part A coverage to ensure adequate and appropriate post-acute skilled nursing care. Without the IPO list, however, there's a risk that the physician will delay inpatient admission until after complications arise because, before that point, discharge prior to the second midnight might be possible. Although the time the patient spends in observation care is considered for purposes of the two-midnight rule, it is not considered for purpose of the three-day qualifying hospital stay. Because the elimination of the IPO list would be expected to result in some inpatient admissions being newly delayed by one or more midnights, some Medicare beneficiaries will not qualify for Part A SNF coverage due to time spent in observation. Not only does this erode the value of Part A SNF coverage, but it also places beneficiaries at risk for inadequate post-acute care and readmission.

In short, the necessity of an inpatient admission for a procedure on the IPO list should be beyond clinical question, but the Proposed Rule would require case-by-case scrutiny of these inpatient admissions in cases where the patient can be discharged before the second midnight and risks delaying inpatient admission to ensure the two-midnight benchmark is passed. This approach inappropriately focuses clinical judgment on the length of stay and case-by-case exceptions despite the categorical appropriateness of inpatient admissions for procedures included on the IPO list. Worse yet, resulting admission delays would jeopardize coverage for post-acute skilled nursing care.

Elimination of the IPO List Erodes the Part A Benefit and Increases the Financial Burden on Beneficiaries. The elimination of the IPO list will also create financial burdens for Medicare beneficiaries because Medicare Part B coverage is associated with more significant cost-sharing obligations as compared to Part A coverage. Although the Part B coinsurance amount for a service is capped at the applicable Part A hospital inpatient deductible amount for that year, this cap does not adequately limit the beneficiary's cost-sharing obligation for outpatient services. A beneficiary that had previously paid the entirety of his or her inpatient deductible amount for that year would still be faced with a coinsurance obligation for the outpatient procedure when s/he would have incurred no further cost-sharing obligations if the procedure had been performed on an inpatient basis. Likewise, payment of the maximum outpatient coinsurance amount for a procedure would not satisfy a beneficiary's inpatient deductible obligation for a subsequent admission in the same year.

In addition, the outpatient cost-sharing limit applies on a service-by-service basis, so beneficiaries may incur coinsurance obligations up to the cap for each service. The Proposed Rule notes that most of the procedures on the IPO list would likely be assigned to a comprehensive APC (C-APC) upon removal, limiting beneficiaries to a single, capped coinsurance obligation for the C-APC. 90 Fed. Reg. at 33,668. But, even if each procedure is assigned to a C-APC, beneficiaries may still receive items and services that are separately payable when furnished with a C-APC (*e.g.*, a procedure assigned to a new technology APC) and thus may incur coinsurance obligations for multiple items and services. Furthermore, a Medicare

beneficiary will incur outpatient coinsurance obligations associated with certain outpatient services furnished in the days prior to the outpatient procedure, when those services would have been included on the Part A bill under the three-day payment window policy and would have resulted in no further cost-sharing obligations if the procedure had been performed on an inpatient basis. Thus, the coinsurance cap and the use of C-APCs does not adequately limit Medicare beneficiaries' cost-sharing obligations for outpatient services, and the proposed elimination of the IPO list would expand Medicare beneficiaries' financial exposure and erode the value of their Part A coverage. These expanded cost-sharing obligations also operate to the financial detriment to Medicaid programs, which are responsible for the Medicare coinsurance obligations of dually eligible beneficiaries.

CMS Lacks Sufficient Data to Assign Procedures on the IPO List to APCs. Although the Proposed Rule includes proposed APC assignments for 269 musculoskeletal-related services and 16 non-musculoskeletal services, it fails to provide sufficient data or rationale for the proposed assignments. In past years, CMS has based APC assignments for procedures removed from the IPO list on the estimated costs derived from available claims data and the 50th percentile IPPS payment for the procedure without major complications or comorbidities to determine the appropriate APC assignment.[22] But the assignments proposed in Table 69 are supported by limited analysis and rationale. The Proposed Rule acknowledges that several HCPCS codes proposed to be removed from the IPO List are currently assigned to the Level 6 Musculoskeletal Procedures APCs, but have significant CY 2024 claims volume, with several codes having more than a thousand single claims from which to calculate their geometric mean costs. As a result, CMS proposes to establish a 7 level Musculoskeletal Procedures APC series for CY 2026, which is warranted. Still, the limited analysis and rationale do not provide sufficient explanation of the methodology for proposing APC assignments for these procedures that would be eliminated from the IPO lists, such that stakeholders can meaningfully comment on the proposed assignments.

Implications of Elimination of IPO List for Alternative Payment Models (APMs). The Proposed Rule wholly fails to address how the elimination of the IPO list would impact episode-based and total cost of care models, including the mandatory Transforming Episode Accountability Model (TEAM) that begins on January 1, 2026. The growing focus on and expansion of various APMs for Medicare benefits necessitates a clear and transparent plan for addressing the impact of removing procedures from the IPO list on these APMs. In commenting on the Proposed Rule, stakeholders cannot readily engage with CMS on the potential ramifications of removing entire categories of procedures from the IPO list as part of the phased elimination of the list because CMS has not provided any indication as to the extent to which any of the procedures would be expected to migrate to the outpatient setting. It may be that clinical considerations would preclude most of the procedures proposed for removal in CY 2026 from being performed in the outpatient setting on Medicare beneficiaries, which would limit any impact on APMs. But the Proposed Rule suggests that an unspecified number of these procedures could be performed in an outpatient setting at an unspecified frequency. To the extent that any outpatient migration is reasonably expected, it is critical that CMS project the magnitude of the effect and propose necessary adjustments to episode-based and total

[22] For example, in the 2020 OPPS Proposed Rule, CMS evaluated the estimated costs for CPT code 27130 (total hip arthroplasty) based on the available claims data and the 50th percentile for MS-DRG 470 against the geometric mean cost for the Level 5 Musculoskeletal Procedures APC series to explain the proposed assignment of the procedure to APC 5115. 84 Fed. Reg. 39,398, 39,460 (Aug. 9, 2019).

cost of care models if, for example, it is expected that the shift will skew certain procedures toward beneficiaries in poorer general health and with higher risks for complications.

Adverse Impact for Medicare Part C Beneficiaries. Finally, the elimination of the IPO list risks adverse impacts for Medicare beneficiaries enrolled in Medicare Advantage (MA) plans, but the Proposed Rule fails to address the collateral harm to these beneficiaries or the associated increased burden and cost of coverage disputes. Although the IPO list was adopted as "a valuable tool for ensuring that the OPPS only pays for services that can safely be performed in the hospital outpatient setting,"[23] it also plays an important role in the Part C context, ensuring that MA organizations provide appropriate inpatient coverage for the invasive and risky procedures that warrant inclusion on the list. MA organizations are required to provide inpatient coverage for medically necessary services on the IPO list under 42 C.F.R. § 422.101(b)(2) and cannot require that the care be furnished on an outpatient basis. And where MA organizations deny inpatient coverage for a procedure that should only be provided on an inpatient basis, the IPO list promotes the efficient resolution of the resulting coverage dispute.

Without the IPO list, it is likely that Medicare beneficiaries that elect Part C coverage will experience increased denials of inpatient coverage for invasive procedures that require intensive postoperative monitoring and care, even though MA organizations are required to provide coverage consistent with inpatient criteria (*i.e.*, the two-midnight benchmark and the case-by-case exception under 42 C.F.R. § 412.3(d)(1) and (3)). As we have shared in previous comment letters on the MA Program, there has been and continues to be a significant trend among MA organizations of denying coverage and authorizations for inpatient admissions ordered by physicians and reclassifying them as outpatient observations stays. Following CMS's clarification of MA organizations' inpatient coverage obligation and modernization of 42 C.F.R. § 422.101, we understand that many MA organizations have improved their authorization and coverage practices for inpatient procedures on the IPO list (although problems remain with respect to admissions under the two-midnight benchmark and case-by-case exception). Elimination of the IPO list risks reversing these coverage gains, jeopardizing the health of Medicare beneficiaries, and saddling hospitals with the additional administrative burden of appealing denials and reclassifications for procedures that are not appropriately provided in the outpatient setting.

Burden of Pricing Procedures Never Performed Outpatient: CMS's proposal to completely eliminate the IPO list will require the agency to establish OPPS prices for all HCPCS codes. It is not necessary to establish OPPS prices for services that have little to no likelihood of being performed on an outpatient basis, and undertaking a purely academic pricing exercise is not a prudent use of CMS resources. For instance, CPT code 33945 is for "Transplantation of heart." There is no circumstance where a heart transplant would be performed outpatient in the current medical environment. CMS's policy to eliminate the IPO list and price all services under the OPPS would require the agency unnecessarily price a heart transplant as an outpatient service. There will be hundreds of other services currently on the IPO list where OPPS pricing is indisputably unnecessary because the state of medical technology and current standards of care do not allow the procedure to safely be performed on an outpatient basis. Rather than using limited agency resources to assign every procedure on the current IPO list to an APC regardless of whether the procedure can be appropriately and safely furnished in an outpatient setting, CMS should only undertake this pricing work for procedures where performance on an outpatient basis might be more likely for specific patients with existing technology. CMS's current policy allows such procedures to be brought to their

[23] 78 Fed. Reg. 75055 (Dec. 10, 2013).

attention and removed from the IPO list and for CMS to carefully consider how to price such procedures on an outpatient basis.

Alternative Proposal. Although the FAH supports retaining the IPO list in its current form, if CMS finalizes the phased elimination of the IPO list, the FAH strongly urges CMS to take an alternative approach that mitigates at least some of the concerns above. Under this alternative approach, CMS would remove the IPO list as a bar to outpatient coverage but continue to use it as a list of procedures that automatically meet the criteria for inpatient admission until the Secretary determines the service or procedure is more commonly performed in the outpatient setting than in the inpatient setting. This approach would preserve the current clarity of coverage that facilitates prompt inpatient admissions and preserves appropriate coverage for post-hospital SNF care. Moreover, for beneficiaries covered under Part C, it would continue to ensure appropriate inpatient coverage as a basic benefit and avoid the administrative burden of coverage disputes under the two-midnight rule and case-by-case exception.

To effectuate this alternative proposal, CMS would revise 42 C.F.R. § 412.3 to specify that "An inpatient admission for a surgical procedure specified as inpatient only under § 419.22(n) of this chapter as it existed on January 1, 2021 is generally appropriate for payment under Medicare Part A regardless of the expected duration of care until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting than the inpatient setting."

X.D. Inpatient Procedures that Do Not Meet the Criteria for Removal from the IPO List Should Be Indefinitely Exempted from Medical Review

If CMS finalizes the phased elimination of the IPO list despite the concerns set forth above, the FAH supports the proposed indefinite exemption from certain medical review activities for procedures on the IPO list as of January 1, 2021, until *two years after* the Secretary determines that the service or procedure is more commonly performed in the outpatient setting. 90 Fed. Reg. at 33,696. This Secretarial determination would be based on claims data that demonstrates that the service or procedure is being performed more than 50 percent of the time in the outpatient setting in a single calendar year.

In this context of the proposed phased elimination of the IPO list, any medical review of the removed procedures would create administrative burdens and costs for providers without any associated benefit to the Medicare Program or beneficiaries. ***Unless and until a procedure removed as part of the proposed elimination of the IPO list is determined by CMS to be safe and appropriate for Medicare beneficiaries in the outpatient setting, the exception from medical review should continue for that procedure. Furthermore, if and when a procedure is determined by CMS to be safe and clinically appropriate for outpatient delivery, providers should be given two years to update their billing systems and gain experience with respect to the newly removed procedures, consistent with CMS's past practice with respect to procedures removed from the IPO list based on clinical considerations.*** In the interim, an inpatient admission for a procedure that has been removed from the IPO list should not be subject to patient status reviews and the admission should be categorically presumed to be appropriate based on CMS's prior determination that the procedure is only clinically appropriate when furnished on an inpatient basis.

X.A. The Administration of Part B Drugs in Excepted Off-Campus Provider Based Departments is Not Unnecessarily Increasing in Volume and the Proposed Rate Cut for These Services is Unlawful and Improper

The Proposed Rule would cut the payment rate for the 61 different drug administration services that are currently assigned to Ambulatory Payment Classification (APC) codes 5691, 5692, 5693, and 5694 when provided at an excepted, off-campus provider-based department (PBD) (*i.e.*, a PBD that bills with the modifier "PO") to just 40 percent of the outpatient rate.[24]

CMS has asserted that it has the authority to implement this significant payment adjustment in a non-budget neutral manner under 42 U.S.C. § 1395*l*(t)(2)(F), which requires CMS to "develop a method for controlling unnecessary increases in the volume of covered [outpatient department (OPD)] services." The FAH strongly opposes this proposed payment reduction (as well as the continuation of the current payment reduction for clinic visit services in excepted, off-campus PBDs) because it is not a method for controlling unnecessary increases in volume, rather, it addresses a purported volume increase that Congress has already addressed under section 603 of the Bipartisan Budget Act of 2015 ("Section 603"), and it fails to provide any deference to physician's judgment as to the clinical necessity of the hospital outpatient setting. For these reasons, the FAH strongly urges CMS not to finalize the payment reduction for drug administration services and to eliminate the payment reduction for clinic visit services. Furthermore, the FAH maintains that these existing and proposed 60 percent payment cuts constitute "adjustments" that are subject to the budget neutrality requirements set forth in 42 U.S.C. § 1395*l*(t)(9)(B), and we urge CMS to return the OPPS to the budget neutral payment system required by Congress.[25]

In *American Hospital Association v. Azar*, the United States District Court for the District of Columbia held that the site-neutral payment adjustment for clinic visits is a "price-setting tool" that is "manifestly inconsistent with the statutory scheme" of the OPPS. 410 F. Supp. 3d 142 (D.D.C. 2019). After reviewing the structure of the OPPS, the court concluded:

> [I]f CMS wishes to reduce Outpatient Prospective Payment System payments for E&M services, it must make budget-neutral adjustments to either that service's relative payment weight or to other adjustments under paragraph (t)(9)(A). Alternatively, CMS may update the conversion factor to apply across-the-board cuts under paragraph (t)(9)(C). But nothing in the adjustment or payment scheme permits service-specific, non-budget-neutral cuts. (Id.)

Id. The court thereafter properly dismissed the contention that subsection (t)(2)(F) permits CMS to "supersede Congress' carefully crafted relative payment system by severing the connection between a service's payment rate and its relative resource use." Id. at 158. Moreover, even if the payment reduction fell within CMS's (t)(2)(F) authority, it cannot be adopted in a non-budget neutral manner because "Congress did not intend CMS to use an untethered 'method' to directly alter expenditures independent of other processes" under the OPPS. Id. at 159. Ultimately, Congress "retains for itself the authority" to make these kinds of complicated payment decisions, and CMS cannot ignore and circumvent the multi-factored,

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[24] The current physician fee schedule (PFS) relativity adjuster is set at 40 percent of the amount that would have been paid under the OPPS. 90 Fed. Reg. at 33687.

[25] These concerns are detailed further on pages 1 through 9 of the FAH's September 24, 2018 letter (https://downloads.regulations.gov/CMS-2018-0078-2612/attachment_1.pdf) commenting on the improper use of this same statutory authority to support a payment reduction for clinic visits services (HCPCS code G0463) furnished in an excepted, off-campus PBD. This letter is incorporated herein by reference

complicated annual process required by statute by unilaterally setting service-specific rates without regard to their relative position or budget neutrality. Id. at 160.

On appeal, the United States Court of Appeals for the District of Columbia applied *Chevron* deference and reversed, concluding that "Congress did not 'unambiguously forbid' the agency" from implementing the non-budget neutral payment adjustment and that "the agency reasonably read subparagraph (2)(F) to allow a service-specific, non-budget-neutral reimbursement cut" in these circumstances. 964 F.3d 1230, 1241 (D.C. Cir. 2020). Critically, the D.C. Circuit *did not exercise independent judgment* in determining the meaning of subsection (t)(2) and (t)(9) and *did not purport to identify the best reading* of the statute.

Following the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. ___, 144 S.Ct. 2244 (2024), however, *Chevron* is overturned and courts must exercise their independent judgment in deciding whether an agency has acted within its statutory authority without deferring to an agency's interpretation of the law. Following *Loper Bright*, an agency can no longer rely on statutory ambiguity and reasonableness to defend its action. The Proposed Rule only indirectly references this seismic change in the law, asserting that its own statutory interpretation "was, and still is, the best one." 90 Fed. Reg. at 33,685. In doing so, the Proposed Rule cites the D.C. Circuit decision without noting the courts explicit reliance on the *Chevron* framework and wholly omits discussion of the district court decision—the only decision that analyzes the best reading of the statute without use of *Chevron*'s deferential framework. As can be seen from the district court's evaluation of subsection (t)(2) and (t)(9), the "best reading" of the OPPS statute does not permit CMS to impose a non-budget neutral, site-neutral payment adjustment for clinic visits or drug administration services at excepted, off-campus provider-based departments. CMS should therefore decline to adopt the proposed new payment cut and reverse the existing payment cut or, at a minimum, budget neutralize its application consistent with statute.

A. <u>The proposed adjustment is not a permissible "method for controlling unnecessary increases in the volume of covered OPD services."</u>

CMS's proposal to reduce the payment rate for 61 different drug administration services billed with the "PO" modifier is not a "method" as it is not targeted to control a growth in volume and does not distinguish between necessary and unnecessary volume increases. In fact, the data reveals that there is no discernible growth in the proportion of ambulatory services furnished in excepted off-campus PBDs over the past five years. Furthermore, although the Proposed Rule defines OPPS utilization as unnecessary "when it could be provided safely in the physician office, but it is not because of financial incentives," 90 Fed. Reg. at 33,686, the Proposed Rule would cut payment rates for drug administration services that physicians do not typically furnish in their offices. The proposal, therefore, does not satisfy the statutory requirements of 42 U.S.C. § 1395*l*(t)(2)(F), which requires CMS to "develop a method for controlling unnecessary increases in the volume of covered OPD services."

The Proposed Rule is heavily focused on periods of past growth, largely avoiding discussion of recent utilization trends. CMS's own review largely focuses on utilization changes across a 13-year span (between 2011 and 2023) that encompasses growth trends that are not relevant to current utilization changes. For example, CMS states that there has been a 70 percent increase in the volume of chemotherapy claims billed with HCPCS code 96413 (chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug) for services furnished in excepted PBDs between 2011 and 2023. Our review of claims data, however, indicates that claims for this service in excepted, off-campus PBDs are

declining. As shown in Table 1, in 2020, approximately 550,000 units of this code were reported for chemotherapy administrations in excepted PBDs, and this number fell to 546,000 units in 2024.[26] And there was not a single year in this five-year period where excepted PBD claims for this HCPCS code have exceeded 2020 utilization.

TABLE 1: Ambulatory Utilization[27] of HCPCS Code 96413, CY 2020-2024

Year	Hospital Excepted, Off-Campus Outpatient Department		Physician Office		Total Ambulatory
	Units	*% of Total*	*Units*	*% of Total*	*Units*
2020	549,162	13.5%	1,854,640	45.4%	4,082,589
2021	528,349	13.6%	1,749,160	45.1%	3,880,825
2022	504,673	13.5%	1,662,440	44.5%	3,735,039
2023	494,094	13.2%	1,669,160	44.7%	3,737,911
2024[28]	545,696	13.3%	1,866,065	45.5%	4,102,116

This decline in volume of HCPCS code 96413 in excepted PBDs is not explained by increased Medicare Advantage penetration, because when utilization in other outpatient settings is considered, it is clear that Medicare beneficiaries' need for this particular chemotherapy service is stable or growing. As shown in Table 1, our examination of physician billing across this timeframe indicates that approximately 1.85 million units of this service were furnished in the physician office setting in 2020, and that physician office utilization grew to 1.87 million units in 2024. Thus, over the same five-year period, we see stable to growing physician office utilization (+0.6 percent) and stable to declining utilization of the same service in excepted PBDs (-0.6 percent). In the end, the distribution of this service among ambulatory settings has remained stable over the past five years. Despite the emphasis on this HCPCS code in the Proposed Rule, recent utilization data on HCPCS code 96413 directly undercuts CMS's assertion that there is "unnecessary growth" in utilization justifying the proposed payment cut.

In other cases, the data shows significant growth in utilization in the physician office setting alongside much more modest growth in excepted PBDs. For example, CPT code 96405 (chemotherapy administration; intralesional, up to and including 7 lesions) utilization increased by approximately 156 percent in the physician office setting, but only increased by approximately 34 percent in excepted PBDs.

[26] Due to data limitations, the 2024 utilization data is based on quarterly claims data, annualized for the entire calendar year.

[27] Total ambulatory utilization is based on a 100% sample for hospital ambulatory settings and, for non-hospital settings (*e.g.*, ASC and physician office), a 5 percent sample was used and extrapolated to the universe of claims.

[28] For 2024, quarterly data was used and annualized to the entire year.

TABLE 2: Ambulatory Utilization[29] of HCPCS Code 96405, CY 2020-2024

Year	Hospital Excepted, Off-Campus Outpatient Department		Physician Office		Total Ambulatory
	Units	*% of Total*	*Units*	*% of Total*	*Units*
2020	512	3.6%	11,780	82.6%	14,268
2021	620	3.3%	15,860	84.4%	18,783
2022	595	2.4%	21,420	86.5%	24,767
2023	540	1.9%	26,080	90.4%	28,865
2024[30]	688	2.0%	30,129	89.2%	33,772

Looking beyond chemotherapy codes, the data shows variable relative contractions and growth in drug administration services furnished in excepted PBDs and physician offices. This data simply does not support a finding of unnecessary growth in drug administration services furnished in excepted PBDs. In addition, the drug claims billed along with these drug administration codes reflect significant medical advancements and changes in treatment protocols, with new drugs being approved by the FDA and used in hospitals and physician offices for the first time during this five-year period. The Proposed Rule implicitly acknowledges these changes in treatment regimens, noting "increases in the volume of drug administration services provided in OPDs utilized per beneficiary" since 2022. 90 Fed. Reg. at 33,686. But rather than acknowledging the medical bases for these changes (including new drugs and new drug regimens), the Proposed Rule simply and improperly concludes, without any clinical analysis of the drugs administered, that the "increases in the volume of services provided per beneficiary . . . represent[s] unnecessary increases in the volume of covered outpatient department drug administration services." *Id.* at 33,687.

It is also worth noting that the proposed payment reduction would apply to some services that are not currently furnished in excepted, off-campus PBDs. Between 2020 and 2023, there were no Medicare claims for excepted PBDs for the following HCPCS codes: 37195, 90473, 95144, 95170, 96371, 96422, 96423, 96440, and G0012. Even if a payment cut can constitute a "method for controlling unnecessary increases in the volume of covered OPD services" (it cannot), the payment cuts cannot apply to services with negligible utilization. Furthermore, some of the HCPCS codes had negligible to no utilization in the physician office setting, including HCPCS codes 96446, 96542, and C8957. In the proposed rule, CMS states that the provision of a service "in the higher cost OPD when it could be provided safely in the physician office, but it is not because of financial incentives, that represents unnecessary utilization of the OPD setting." 90 Fed. Reg. at 33,686. Where physicians, exercising their professional judgment, largely decline to furnish a service in the physician office setting, however, the assumption that the service can be safely performed in that setting and that hospital outpatient department utilization is unnecessary is unsupportable.

[29] Total ambulatory utilization is based on a 100% sample for hospital ambulatory settings and, for non-hospital settings (*e.g.*, ASC and physician office), a 5 percent sample was used and extrapolated to the universe of claims.

[30] For 2024, quarterly data was used and annualized to the entire year.

In an attempt to nonetheless justify the proposed payment cut, CMS relies on data that is significantly skewed by a period of growth in off-campus PBD utilization that Congress already addressed with Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. No. 114-74), with subsequent refinements under section 16001 of the 21st Century Cures Act (Pub. L. 114-255). Briefly, Section 603 statutorily reduced payments for all outpatient department services furnished in new, off-campus PBDs starting in 2017, retaining full OPPS payments for existing outpatient departments. With the subsequent enactment of section 16001 of the 21st Century Cures Act, starting in 2018, Congress provided full OPPS payments for certain new, off-campus PBDs where the provider had a binding written agreement for the construction of the PBD before November 2, 2015.[31] In doing so, Congress increased the universe of excepted PBDs, and the Congressional Budget Office (CBO) expressly contemplated that the growth in outpatient department services due to these mid-build PBDs would span a number of years. The additional Medicare spending was only anticipated to be $50 million for FY 2018, but was projected to grow by $10 million each year until 2022 when these additional mid-build PBDs would result in an additional $90 million in estimated outlays.[32] In light of this statutory history, Congress addressed the future growth in off-campus outpatient department services with a site-neutral payment policy, but exempted existing off-campus PBDs as well as mid-build PBDs that would not open their doors and reach capacity until months or years later.[33]

Against this backdrop, data spanning the roll-out of Section 603 and the mid-build exception in 2017 through at least 2019 would naturally report growth arising from providers' acquisition or construction of off-campus PBDs. Because Congress has enacted a clear statutory response to these growth factors, CMS's assessment of "unnecessary growth" should not include this period of growth. Rather, the data analysis should appropriately focus on later growth, which is also relevant to assessing whether there is currently unnecessary growth that may properly be the target of a section (t)(2)(F) method. The Proposed Rule, however, focuses on a 2023 MedPAC report, which uses data from three years before the adoption of Section 603 and four years before passage of the mid-build exception to set baseline utilization.[34] The Proposed Rule also cites to data on the increase in hospital or health system ownership of cancer care practices in the twelve years leading up to passage of Section 603.[35] And likewise, CMS's own internal

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[31] Those PBDs that had been opened shortly after passage of Section 603 could also be treated as excepted in 2017, but only if a voluntary attestation under 42 C.F.R. § 413.65(b)(3) had been submitted prior to November 2, 2015.

[32] CBO, Direct Spending and Revenue Effects for H.R. 34, The 21st Century Cures Act p.3 (Nov. 28, 2016), *at* https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr34.pdf.

[33] Even after the last mid-build PBDs were operational, there was volatility around the audit process that may have skewed utilization data for excepted PBDs. In January 2021, hospitals were informed of the outcome of their mid-build audits through the issuance of final determination letters. In light of concerns with the reliability of these determinations, CMS properly rescinded the adverse audit determinations, permitting previously failing providers to obtain updated audit determination letters. This process was not complete until March of 2022. CMS, Audit Results of Mid-Build Exception Requests for Off-Campus Outpatient Departments (March 9, 2022), During this time frame, some providers may have opted to use the "PN" modifier for their mid-build PBDs in the absence of a favorable audit determination.

[34] 90 Fed. Reg. at 33,686-88 (citing https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf).

[35] 90 Fed. Reg. at 33,686 (citing https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0830).

analysis largely uses 2011 utilization as a baseline hospital outpatient department utilization level.[36] Notably, because the use of the PO modifier to identify off-campus PBD services was not mandatory until January 1, 2016, the use of baseline utilization from earlier years in all these data sources and analyses ensures that none are targeted to the proposal regarding excepted off-campus PBDs.

Overall, the Proposed Rule does not present evidence of unnecessary growth in the volume of drug administration services being furnished in excepted off-campus PBDs or that the proposed adjustment is properly targeted to control any such unnecessary volume increases.

In addition to addressing a purported but unsubstantiated volume growth problem following full implementation of Section 603 and the mid-build exception, the proposed payment cut for drug administration services in excepted, off-campus PBDs is not designed to control unnecessary volume increases, and therefore cannot be implemented under 42 U.S.C. § 1395l(t)(2)(F). CMS has not identified a rate by which volume should necessarily increase for drug administration services in off-campus PBDs and, therefore, has no reasonable benchmark against which to measure volume trends with the payment cut in place. ***In the absence of such a benchmark or any effort to distinguish between necessary and unnecessary volume increases, the proposed policy operates as a plain, payment reduction rather than a method to control volume under subsection (t)(2)(F).*** Moreover, the FAH believes that the exclusion of year-to-year monitoring of volume from the proposed policy confirms that the proposal is not designed to operate as a volume-control measure.

Assessing the potential effects of the proposed payment cut reveals a further misalignment between the proposed policy and the requirements of subsection (t)(2)(F) using CMS's own logic. CMS has previously acknowledged the risk that payment cuts could unintentionally increase volume. For example, in the CY 2008 final rule, CMS declined to adopt a sustainable growth rate (SGR)-like methodology for the OPPS, explaining:

> implementing such a system could have the potentially undesirable effect of escalating service volume as payment rates stagnate and hospital costs rise, thus actually resulting in a growth in volume rather than providing an incentive to control volume. Therefore, this approach to addressing the volume growth under the OPPS could inadvertently result in the exact opposite of our desired outcome. 72 Fed. Reg. 66,579, 66,613.

The FAH notes that subsection (t)(2)(F) only authorizes a method for controlling unnecessary increases in volume, so following CMS's own logic, a policy that increases volume through price reductions would not be a permissible volume-control method.

B. <u>CMS's proposed adjustment makes no allowance for the physician's professional judgment concerning the most appropriate site of service for the patient, ignores the significant costs borne by hospital outpatient departments, and jeopardizes patient access to needed services</u>

[36] The Proposed Rule occasionally references data covering later time periods, but not to assess hospital outpatient utilization levels. Rather, the Proposed Rule identifies the number of beneficiaries enrolled in fee-for-service Medicare between 2018 and 2024, and implicitly references the growing complexity of drug administration protocols in recent years, noting that the per-beneficiary volume of drug administration services in hospital outpatient departments has increased since 2022.

The FAH also maintains that the proposed payment cut is flawed as a matter of policy. Much of the Proposed Rule's discussion of the proposed payment reduction for chemotherapy and other drug administration services furnished in excepted, off-campus PBDs turns on the purported equivalence between outpatient services furnished in physicians' offices and those furnished in hospital outpatient departments. Along these lines, the proposed policy would treat an outpatient department and a physician's office as virtually interchangeable, applying the payment cut regardless of patient acuity and the physician's professional judgment. This approach fails to acknowledge the real difference in the resources and level of care offered by hospital outpatient departments and the extraordinary variability in the acuity and needs of patients undergoing chemotherapy or other drug administrations represented by these codes.

There are certain services which simply cannot be furnished in a physician's office, as demonstrated by the fact that there is no non-facility payment rate under the PFS for those services, and there are instances where a physician, in his or her judgment, would determine that a hospital outpatient department, not a physician's office, is the appropriate setting for a particular patient. This decision may be based on the patient's needs, the presence of comorbidities, or a desire for the resources available in an outpatient department.[37] With respect to drug administration services more specifically, a physician may refer a patient to the hospital for a particular infusion or other drug administration because of the acquisition cost of the drugs, the equipment needed to safely store and mix the drugs, and the inherent danger and complexity that the handling and mixing of chemotherapy drugs poses to the patient and staff. Hospitals are subject to specific conditions of participation for pharmaceutical services under 42 C.F.R. § 482.25, and by referring a patient to the hospital, a physician can be assured that his or her patient will only receive drugs compounded, packaged, and dispensed under the supervision of a pharmacist. As a result, hospital outpatient departments typically care for higher-acuity patients and can provide more complex care and drug regimens as compared to a physician's office.

The selection of the appropriate site of service for a particular patient's needs should be left to the discretion of the treating physician, and CMS's decision to cut reimbursement to all drug administration services furnished in excepted off-campus outpatient departments fails to give proper deference to physicians' judgments. Even more, the proposal's uniform treatment of all drug administration services furnished in excepted off-campus outpatient department underscores the fact that the proposal is not targeted at services that are actually "unnecessary," a logical prerequisite to invoking paragraph (t)(2)(F)'s authority.

Moreover, though the proposed payment cut is aimed at outpatient departments, it is physicians who largely make the decisions that drive the volume of outpatient services. As CMS acknowledged in its OPPS proposed rule for CY 1999, "to the extent that hospital outpatient volume is physician driven, an outpatient [sustainable growth rate (SGR)] could arguably be viewed as unnecessarily and unfairly penalizing facilities." 63 Fed. Reg. 47,552, 47,586. This disconnect is particularly clear in the context of drug administration services, which are the subject of this proposal, because physicians actually order each drug administered and outpatient departments are limited in their ability to control the volume of drug administrations furnished.

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[37] A hospital-based outpatient department must be clinically integrated with the hospital, and when the outpatient department's patients require further care, they must have "full access" to the hospital's services. 42 C.F.R. § 413.65(d)(2).

The proposed payment cut for drug administration services furnished in excepted off-campus outpatient PBDs threatens real harm to providers, some of which may be forced to choose between maintaining the off-campus PBD at a loss, reducing their scope of services, or shutting their doors entirely. The impact would be felt most by rural providers[38], which already operate at narrow margins and play a critical role in ensuring access to care in underserved communities, where there may be no reasonably available alternative providers or clinics. Importantly, off-campus PBDs in rural areas are critical to expanding Medicare beneficiary's access to chemotherapy and other services. If drug administration services are confined to on-campus hospital departments in a health professional shortage area, a patient may be left to commute for 30 minutes or more multiple times a week to complete a chemotherapy regimen and receive the antiemetics and other drugs necessary to control debilitating side effects. CMS's proposal contains no safeguards to ensure necessary services would continue to be offered by off-campus PBDs in the communities where they are most needed. The proposal is simply too blunt a tool for the problem CMS claims to have identified, and the FAH urges CMS to leave in place the careful distinction between reimbursement rates for excepted and non-excepted services selected by Congress and set out in Section 603.

Finally, the FAH objects to the use of the PFS relativity adjuster as a volume-control measure because the PFS relativity adjuster does not account in any way for the very real differences between the costs and value of services furnished in a hospital outpatient setting as compared to a physician office setting. CMS designated the Medicare PFS as the applicable payment system for nonexcepted, off-campus PBDs, and the PFS relativity adjuster is intended to adjust the OPPS rate to a Medicare PFS rate. In contrast, reimbursement under the OPPS is based on the relative resources expended in the hospital outpatient setting when furnishing various services or packages of services to Medicare beneficiaries. Congress has rightly designated the OPPS—not the PFS—as the applicable payment system for covered OPD services furnished in an excepted, off-campus PBD, and the PFS relativity adjuster is not an appropriate or useful tool for addressing any issues with the volume of covered OPD services. In the case of drug administration services, for example, hospitals incur the costs of complying with specific conditions of participation for the associated pharmaceutical services under 42 C.F.R. § 482.25, enabling the hospital to safely handle, compound, and administer complicated and dangerous drug regimens. These costs are not captured by the PFS relativity adjuster.

C. CMS's proposed payment cut for excepted, off-campus PBDs is at odds with Congress' express determination in Section 603 that excepted, off-campus PBDs are entitled to full OPPS reimbursement.

Section 603, as tempered by the mid-build exception, represents Congress' thoughtful consideration of MedPAC's recommendation to eliminate the difference in payment between hospital outpatient departments and physician's offices in certain circumstances, and CMS's proposal undermines the balance struck by Congress. Though the legislative history of Section 603 is scant, the statute clearly reflects an understanding that under certain circumstances, the services provided in outpatient departments typically involve higher acuity patients and more complex episodes of care as compared to services provided in a

[38] MedPAC's most March 2025 report shows that rural hospitals had -3.2% Medicare margins in 2023, and hospitals in micropolitan areas had -9.8% Medicare margins. https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch3_MedPAC_Report_To_Congress_SEC.pdf

physician's office, such that the higher reimbursement rate under the OPPS is appropriate. The statute, as amended by the 21st Century Cures Act, also recognizes that hospitals had lawfully made significant investments in existing PBDs and mid-build PBDs based on existing law. To this end, Congress expressly excepted PBDs located on the hospital campus or within 250 yards of a remote location as well as PBDs that provided covered OPD services on or before November 2, 2015, or met the mid-build requirements.

CMS's proposal, however, would essentially reimburse services described by any of the 61 drug administration HCPCS codes and billed with the "PO" modifier as if they were billed by a non-excepted PBD. The proposal would thus improperly erode the express choices that Congress made in passing Section 603. Congress clearly could have chosen to cut reimbursement rates for excepted services, but opted not to do so, and an effort to reverse this decision through rulemaking is in direct conflict with the statute and in excess of CMS's statutory authority.

D. Regardless of whether this proposal is a "method to control volume" within the meaning of 42 U.S.C., section 1395l(t)(2)(F), it is an "adjustment" that is subject to the statute's budget neutrality requirement.

The FAH believes that, in addition to being deeply flawed and unlawful, the proposed payment cut for drug administration services and billed with the "PO" modifier is an adjustment under section 42 U.S.C. § 1395*l*(t)(2) that could only be implemented in a budget neutral manner in accordance with the strict requirements of subsection (t)(9)(B). ***Therefore, if CMS implements any variation on the proposed payment cut despite the foregoing concerns, the FAH strongly urges CMS to do so in a budget neutral manner, as required by statute.***

As CMS has previously observed, the "OPPS is a budget neutral payment system." 82 Fed. Reg. 59,216, 59,484. Accordingly, CMS "has maintained budget neutrality through offsetting estimated payment decreases/increases within the OPPS, such as by increasing/decreasing the conversion factor by an equal offsetting amount." *Id*.; see also 67 Fed. Reg. 66718, 66754 ("With respect to budget neutrality, [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."); *e.g.*, 71 Fed. Reg. 49506, 49533 (42 U.S.C. § 1395*l*(t)(9)(B) "requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a manner that assures that aggregate payments under the OPPS for [the coming calendar year] are neither greater than nor less than the aggregate payments that would have been made without the changes."); 72 Fed. Reg. 42628, 42647 (same); 72 Fed. Reg. 66580, 66610 (same); 73 Fed. Reg. 41416, 41452 (same).

The requirement of budget neutrality derives largely from 42 U.S.C. § 1395*l*(t)(9)(B), which requires that "adjustments" under § 1395l(t)(9)(A) "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." The referenced adjustments described in § 1395*l*(t)(9)(A) expressly include "other adjustments described in paragraph (2)" (i.e., § 1395*l*(t)(2)). Notably, the referenced adjustments are not restricted to adjustments under § 1395*l*(t)(2)(D) and (E); instead, any "adjustment" under subsection (t)(2) constitutes an adjustment under subsection (t)(9)(A). Thus, if CMS develops "a method for controlling unnecessary increases in the volume" of covered outpatient department services and that particular method constitutes an "adjustment," then the provisions of subsection (t)(9)(B) are plainly applicable to that method.

In the Proposed Rule, however, CMS takes the position that the applicability of the budget neutrality provision is determined by whether the statutory provision under which a policy is implemented uses the word "adjustment" instead of whether the policy under review actually constitutes an adjustment. Had Congress intended to limit the budget neutrality provision based on the underlying legal authority for a policy rather than the nature of the policy itself, it would have done so by referencing "other adjustments described in paragraph (2)(D) or (E)." Instead, however, the statute broadly references any "other adjustments described in paragraph (2)," thereby including a method to control volume described in paragraph (2)(F) insofar as the particular method at issue constitutes an adjustment.

Based on the statutory language, it is the FAH's position that, although there are some volume-control methods that are not "adjustments," a particular volume-control "method" may qualify as an "adjustment" and therefore be subject to budget neutrality requirements. ***A payment cut like the one CMS proposes here is unequivocally an adjustment as it reduces (adjusts) the OPPS payment rate for covered outpatient department services described by the 61 drug administration HCPCS codes and billed with the "PO" modifier.*** Indeed, CMS itself identifies the payment change as an adjustment because the payment rate was determined by multiplying the PFS relativity adjuster by the full OPPS payment for a drug administration to produce an adjusted payment amount.

The language of § 1395*l*(t)(9)(C) does not alter the foregoing analysis. Subsection (t)(9)(C) authorizes CMS to "appropriately adjust the update to the conversion factor" if it "determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased beyond amounts established through those methodologies." This language does not speak to whether a method authorized solely under subsection (t)(2)(F) must be budget neutral; rather, it establishes separate authority for adjusting the update to the conversion factor if the volume of services increases beyond the amounts established under subsection (t)(2)(F). If, as CMS asserts, subsection (t)(2)(F) itself authorizes implementation of a non-budget neutral adjustment, Congress would have had no need to adopt subsection (t)(9)(C) because it would be redundant with subsection (t)(2)(F).

Lastly, CMS's contention that a budget neutral adjustment under subsection (t)(2)(F) "would not appropriately reduce the overall unnecessary volume of covered OPD services," 90 Fed. Reg. at 33,690, is not the relevant point. Subsection (t)(2)(F) does not authorize CMS to "reduce the overall unnecessary volume of covered OPD services." Instead, it authorizes CMS to develop a "method" for "*controlling unnecessary increases in the volume of covered OPD services*". It is section 1833(t)(9)(C) that authorizes a change to payment but only when volume of services paid increases beyond those established by the Secretary using the method established under 1833(t)(2)(F). ***Because CMS's proposal exceeds the scope of its statutory authority and risks significant harms, the FAH strongly urges CMS to not finalize the proposed rate cut for chemotherapy and other drug administration services and billed with the "PO" modifier.*** Moreover, following the Supreme Court's decision in *Loper Bright*, CMS should reverse its current payment reduction for clinic visits in excepted off-campus departments, or, at a minimum, implement it in a budget neutral manner.

X.B. OPPS Payments Should Not Be Reduced Under Site-Neutral Payment Policies or Otherwise

The Proposed Rule includes a request for information seeking "feedback on the development of a more systematic process for identifying ambulatory services at high risk of shifting to the hospital setting based on financial incentives rather than medical necessity and adjusting payments accordingly." 90 Fed. Reg. at 33,693. As detailed in our comments on site-neutral payment for clinic services and drug

administration services (Part X.A, above), the FAH strongly opposes CMS's use of site-neutral payment strategies. These strategies are not a method for controlling unnecessary increases in outpatient department volume; rather, they operate as a blunt payment reduction, without regard for the physician's judgment, the patient's clinical condition, and barriers to accessing care in other ambulatory settings. Congress requires that OPPS rates be set based on relative outpatient hospital resource use, and CMS cannot supersede this carefully crafted payment system to set rates for any outpatient department services based on an ASC- or PFS-based payment methodology. Moreover, even if CMS had such authority, the OPPS' budget neutrality requirements would apply, barring CMS from using site-neutral payment strategies to reduce overall OPPS payments.

X.C. Virtual Direct Supervision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR), Pulmonary Rehabilitation (PR) Services and Diagnostic Services Furnished to Hospital Outpatients

During the COVID-19 PHE, CMS allowed direct supervision of CR, ICR, PR and diagnostic services to be furnished remotely via two-way, audio/visual communication technology (but not audio-only), but only when provided by physicians. These flexibilities were extended by law through December 31, 2024, by regulation after the COVID-19 PHE ended. In addition, beginning in 2024, these flexibilities were extended to allow supervision by nurse practitioners, physician assistants and certified nurse assistants eligible to supervise these services in addition to physicians.

In the 2025 PFS rule, CMS revised the definition of direct supervision to extend the availability of virtual direct supervision of CR, ICR, PR and diagnostic services under the PFS through December 31, 2025. Similarly, CMS extended the availability of virtual direct supervision (excluding audio-only) for these same services under the OPPS through December 31, 2025. CMS now proposes to extend virtual supervision (excluding audio-only) of CR, ICR, PR and diagnostic services under the PFS permanently in the 2026 PFS proposed rule (except for services with a 10 or 90-day global period.) Likewise, in the 2026 OPPS proposed rule, CMS now proposes to extend virtual supervision (excluding audio-only) under the OPPS permanently for these same services.

The FAH appreciates and supports these CMS proposals as they would permit greater access to these services, especially amid continuing workforce shortages. In the experience of our member hospitals, physicians and other professionals have been able to provide clinically appropriate supervision for impacted services such as diagnostic tests and incident-to services through synchronous audio-visual telehealth. Further, requiring the physician or other supervising professional to be physically present in the same building has negligible patient-safety benefits. The reality is that a physician office, clinic, or hospital outpatient department typically has many other practitioners on site who can assist if a physical presence is required. Moreover, in an emergency, the most appropriate course of action is to transfer the patient to an emergency department, not wait for the supervising physician or other practitioner to arrive. A virtually available supervisor may even facilitate a faster transfer of the patient to the emergency department when necessary. Moreover, under the proposed permanent policy, there should not be a requirement for a service level modifier to identify when direct supervision is provided via appropriate telehealth technology. Physicians and other supervising practitioners benefit from the flexibility to supervise in person, via telehealth, or through a combination of modalities depending on clinical need and circumstances. In some cases, services may even be supervised in part through an in-person presence and in part through a telehealth modality. Requiring practitioners to track whether and to what extent they supervised through

telehealth would significantly increase administrative burdens associated with these flexibilities, undermining their ability to improve physician care delivery. Because there is no obvious benefit to collecting data on how supervision is facilitated, the burdens associated with a modifier requirement cannot be justified.

XIII.D. Clinical Criteria are Critical to Appropriately Maintaining the ASC Covered Surgical Procedures List

The FAH opposes the proposed amendments to 42 C.F.R. § 416.166, which would eliminate CMS's consideration of safety risks when adding procedures to the ASC covered surgical procedures list (ASC-CPL) and would instead establish nonbinding physician considerations for patient safety. By statute, CMS is required to specify surgical procedures "which also can be performed safely on an ambulatory basis in an ambulatory surgical center." 42 U.S.C. 1395*l*(i)(1). Furthermore, in carrying out this obligation, CMS must "consult[] with appropriate medical organizations." *Id.* From the time that CMS first implemented Part B coverage for ASC services in 1982, 47 Fed. Reg. 34,0082 (Aug. 5, 1982) until now (with the exception of CY 2021), CMS has fulfilled this statutory obligation by considering the specific patient safety factors set forth in 42 C.F.R. § 416.65(b) (1982 to 2007) and 42 C.F.R. § 416.166(b) and (c) (2008 to 2020 and 2022 to present) when adding services to the ASC-CPL. The FAH urges CMS to retain this historical approach. Congress has expressly required CMS to limit the ASC-CPL to those procedures which can be performed safely in an ASC, and CMS cannot ignore this obligation or delegate it to private physicians with nonbinding physician considerations or otherwise.

The current standards and exclusion criteria for the ASC-CPL appropriately prioritize patient safety while still allowing the ASC-CPL to evolve with advancements in surgical care, and they should therefore remain in place. Although ASCs can safely perform a growing array of surgical procedures without having the capacity to provide inpatient care in the case of complications and without having satisfied other hospital conditions of participation (or being licensed and accredited as hospitals), ASCs should not be treated as the equivalent of hospital outpatient departments. ASCs are not regulated as hospitals, and since November 29, 2019, ASCs have not been required to have written hospital transfer agreements or hospital physician admitting privileges.[39] Thus, procedures that pose significant patient safety risks (*e.g.*, procedures that generally result in extensive blood loss, that require major or prolonged invasion of body cavities, directly involve major blood vessels, are generally emergent or life-threatening in nature, or commonly require systemic thrombolytic therapy) should continue to be excluded from Medicare coverage in ASCs to ensure that Medicare beneficiaries receive these services in a setting that allows for rapid intervention and elevation of the level of care in the case of life-threatening complications.

The FAH strongly opposes removal of these exclusion criteria, which have been successfully applied for nearly two decades and have not impeded the expansion of the ASC-CPL to cover a growing list of complicated surgical procedures where permitted by advancements in surgical care. The five exclusion criteria at issue each target surgical procedures that inherently pose significant safety risks because ASCs do not have hospital resources on site to rapidly provide the higher level of care necessary in the case of complications. By way of example, § 416.166(c)(5) excludes surgical procedures that commonly require systemic thrombolytic therapy. These procedures pose significant patient risks that require rapid intervention in a hospital setting in the event of complications, including embolization and stroke. Despite

[39] 84 Fed. Reg. 51,732, 51,738 (Sep. 30, 2019).

significant advancements in surgical care since this exclusion criterion was first finalized in 2007, the risks of systemic thrombolytic therapy continue to be significant, and the categorical exclusion of procedures requiring such therapy from the ASC-CPL continues to be appropriate. Likewise, the other exclusion criteria at issue—which cover surgical procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, directly involve major blood vessels, or are generally emergent or life-threatening in nature—should remain in place.

The Proposed Rule suggests that the concerns warranting adoption of these exclusion criteria have largely been addressed with the passage of time. It is true that significant advancements in medical practice, surgical techniques, and medical technology have permitted a growing list of procedures to be safely performed in an ASC setting, but this is largely because advancements have permitted a growing array of procedures to be performed in a manner that no longer triggers an exclusion criterion. For example, some procedures that previously required major or prolonged invasion of body cavities can now be performed laparoscopically and are no longer excluded under 42 C.F.R. § 416.166(c)(2). Thus, recent advancements in surgical care have minimized the extent to which procedures trigger an exclusion criterion, and these advancements do not call into question the enduring salience of the exclusion criteria in identifying procedures that continue to pose significant and inappropriate safety risks in an ASC setting. In fact, the Proposed Rule does not include any evidence indicating that the patient safety risks associated with procedures that generally result in extensive blood loss, require major or prolonged invasion of body cavities, are generally emergent or life-threatening in nature, or commonly require systemic thrombolytic therapy have been meaningfully reduced by advancements in medical care or provide any other rationale for eliminating these critical exclusion criteria. Rather, it merely defers to "prior interested parties' feedback and public comments" broadly indicating that "many ASCs are currently able to safely provide services with these characteristics." 90 Fed. Reg. at 33,717.

Because the current exclusion criteria at 42 C.F.R. § 416.166(c), in conjunction with the general standards in 42 C.F.R. § 416.166(b), have allowed the ASC-CPL to evolve and expand with surgical advancements while ensuring that procedures that continue to pose significant patient safety risks are restricted to the hospital setting, the FAH strongly urges CMS to retain the existing criteria and standards for the ASC-CPL. In addition, the FAH opposes the addition of the 276 procedures proposed to be added to the ASC-CPL in light of these standards and exclusion criteria. In particular, many of the procedures in Table 80 present significant patient safety concerns, arise in emergency situations, and would necessitate the rapid deployment of hospital resources in the event of complications. The Proposed Rule does not provide any rationale or evidence indicating that each of the 276 procedures would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC or that standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following any of these procedures. By way of example, the list includes repair of a blood vessel with vein graft in the neck (CPT 35231), intrauterine fetal transfusions (CPT 36460), ligation of a major artery in the neck (CPT 37615), and appendectomy (CPT 44950). Each of these procedures (and the remaining procedures in Table 80) pose significant patient safety risks. Medicare coverage for these procedures should therefore remain confined to the hospital environment where a patient can receive prompt inpatient care in the event of complications.

XIV. Cross-Program Proposals for the Hospital Outpatient Quality Reporting (OQR) Program

Adoption of a new electronic clinical quality measure (eCQM) and removal of two existing measures

CMS is proposing the adoption of a new electronic clinical quality measure (eCQM), Emergency Care Access & Timeliness, with the corresponding removal of two existing measures: *Median Time from ED Arrival to ED Departure for Discharged ED Patients* and *Left Without Being Seen*. The FAH supports the replacement of the current measures with the proposed eCQM, recognizing the value of transitioning toward measures that better capture emergency care performance in a more meaningful and standardized way.

However, it is essential that hospitals have adequate time to map the necessary data elements within their electronic health record (EHR) systems and to thoroughly evaluate the validity of the resulting data. Mapping data in vendor systems to align with new specifications can be just as resource intensive as manual abstraction, especially given that the measure specifications were only recently released. Hospitals are only beginning to assess feasibility and to build the clinical workflows necessary to support accurate reporting. The FAH strongly recommends that CMS extend the voluntary reporting period from one year to two years. The additional year will allow hospitals, particularly small and rural facilities that often use different EHR systems across inpatient and emergency department settings, to ensure that their submissions are complete, reliable, and accurate. Providing sufficient lead time will strengthen the measure's implementation and ensure its long-term credibility in the program.

Modify the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults (Hospital Level – Outpatient) Measure from Mandatory Reporting to Continues Voluntary Reporting

The FAH appreciates CMS's proposal to continue voluntary reporting indefinitely. Hospitals have consistently noted the difficulty of collecting data for this measure, given technical and operational challenges. By maintaining voluntary rather than mandatory reporting, CMS appropriately acknowledges provider burden while still allowing facilities to report data as they are able. This approach avoids punitive consequences for non-compliance and will ultimately yield a more accurate and balanced picture of imaging quality in the hospital outpatient setting.

FAH supports these refinements to the OQR program as positive steps toward improving the relevance and feasibility of quality reporting, while also recognizing the need for adequate implementation time and ongoing burden reduction.

XVIII. Overall Hospital Quality Star Rating Modification To Emphasize the Safety of Care Measure Group

The FAH strongly urges CMS not to finalize the proposed changes to the Overall Hospital Quality Star Rating Program for CY 2026. The revisions carry considerable risk for smaller and rural hospitals, reinforce structural flaws in the program's design, and fail to address longstanding concerns raised by hospitals, clinicians, and patient advocates.

The proposed two-stage methodology would cap hospitals in the lowest quartile of Safety of Care measures at four stars in 2026 and then automatically downgrade them by one star beginning in 2027. This blunt approach would disproportionately affect rural, small, and safety-net hospitals, which already face substantial challenges related to resource limitations, geographic barriers, and caring for higher-acuity patients. The Star Ratings framework does not adequately adjust for differences in case mix or social determinants of health, resulting in unfair comparisons and punitive outcomes for hospitals that serve vulnerable communities.

The transitional cap and subsequent downgrade mechanism would also undermine the ability of hospitals to attract patients, maintain staffing levels, and sustain financial viability. Ratings are highly visible and influential, and downgrades based on relative quartiles rather than absolute performance measures could damage reputations and discourage patients from seeking care locally. For institutions already operating on thin margins, particularly in rural or underserved areas, the consequences of such reputational harm could be devastating.

Moreover, the increased weighting of Safety of Care measures, absent robust risk adjustment and error controls, introduces unnecessary complexity and volatility into the system. This will reduce confidence in the Star Ratings among both providers and consumers. Patients may be misled into believing their local hospital provides substandard care when, in reality, the rating reflects factors outside the hospital's control. Such misrepresentation risks reducing access to essential services and exacerbating healthcare disparities in already distressed communities.

FAH recommends that CMS withdraw this proposal and instead engage stakeholders in a transparent, collaborative process to reform the Star Rating Program. We strongly encourage the development of risk-adjusted measures that fairly account for patient complexity and social context, and the use of absolute performance thresholds that reflect meaningful quality differences rather than relative quartiles. Pilot testing any major changes before national implementation will help ensure that ratings are accurate, equitable, and credible to consumers.

XIX. Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges Under the Hospital Price Transparency (HPT) Initiative

The FAH continues to support price transparency initiatives that provide patients with clear, accurate, and actionable information. However, the current approach of publishing vast amounts of hospital reimbursement data is not providing patients with useful and actionable pricing information. Since President Trump issued his June 24, 2019, Executive Order on "Improving Price and Quality Transparency in American Health Care," hospitals' obligations to make public a list of standard charges have undergone a complete transformation. In the space of a few short years, hospitals have gone from making gross charge (*i.e.*, chargemaster) data public to engineering and posting vast complex data on payer-specific negotiated rates, gross charges, and discounted cash pricing, and then standardizing and further expanding publicly posted data to include data elements beyond standard charges.

The frequency and extent of changes in the rules for making public standard charges since 2019, however, have imposed significant costs and burdens on hospitals – particularly those hospitals that prioritized compliance from the outset and then had to revamp their processes as changes were adopted. For example, the most recent changes to the Hospital Price Transparency rule (*e.g.*, inclusion of the estimated allowed amount) only took effect on January 1st of this year, and hospitals have not yet undergone a full update cycle under the new requirements. However, CMS issued additional guidance in May of this year which, while helping to clarify CMS's expectations for meeting the hospital price transparency requirements, also required hospitals to make immediate updates to their MRFs.[40] Smaller and less resourced hospitals are most vulnerable to CMS enforcement actions as a result of these frequent and costly

[40] May 22 2025 Guidance ~ Estimated Amount Field Question · CMSgov/hospital-price-transparency · Discussion #169 · GitHub

changes, as evidenced by CMS's issuance of civil monetary penalty notices in 2025, in which the penalized hospital bed count ranged from less than 30 to 140 with a median of 35.5 beds.[41]

As we stated in our recent response to CMS's hospital price transparency request for information (RFI), against this backdrop, the FAH believes both hospitals and users of hospital price transparency data would benefit from a period of relative regulatory stability during which the already widespread hospital compliance achieved by CMS may be further improved. Rather than revising recently implemented requirements so soon, CMS could instead focus on implementing the OIG's recommendation to create a training and compliance program tailored for small and rural hospitals that are struggling to comply with the already technically complex requirements.[42] In accordance with Executive Order 14192, CMS should be actively seeking ways to reduce hospital burden that was largely introduced by the prior administration. ***Therefore, the FAH recommends that CMS maintain the hospital price transparency rules in their current form and seek ways to reduce hospital burden.***

In addition, the machine-readable file (MRF) data is, at best, an historic representation of likely payment amounts across a population of patients for a single payer's plan.[43] These data cannot be carried over to individual cases because the prospective price for a specific patient's service will always require consideration of the unique factors for the case. Fortunately, there are tools that exist to provide individualized estimates to patients as part of both the hospital and insurer shoppable service requirements. In addition, once the *No Surprises Act* is fully in effect, all patients will receive good faith estimates or advanced explanation of benefits prospectively. While these are by definition "estimates," they are much more likely to produce usable and reliable cost expectations than the MRFs because they are based on an individual's specific situation. Moreover, such estimates are considered part of the patient's medical record and are subject to a patient-provider dispute resolution process when the total billed charges are substantially in excess of the total expected charges in the good faith estimate.[44] Thus, emphasis on the MRFs for consumers of health care services is misplaced.

Further, we note that the Transparency in Coverage regulations, 45 C.F.R. §§ 147.210–147.212, hold the potential to provide the most comprehensive and actionable data for patients, employers, and other users of health care price transparency data because they require pricing information for all provider types, including hospitals. This rule, however, has not been amended since originally promulgated and CMS has not made public any data about enforcement activity and industry compliance. ***Therefore, the FAH recommends that CMS take advantage of this ripe opportunity to promote meaningful price transparency by enforcing the Transparency in Coverage regulations, as CMS has enforced the Hospital Price Transparency regulations.***

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[41] Enforcement Actions | CMS

[42] https://oig.hhs.gov/reports/all/2024/not-all-selected-hospitals-complied-with-the-hospital-price-transparency-rule/

[43] These data in aggregate do not present an accurate picture of the health care financing market, as not all types of rates are represented in hospital price transparency MRFs, for example, capitated payments and value-based purchasing arrangements are not negotiated on an item or service basis and so are not represented.

[44] https://www.cms.gov/files/document/gfe-and-ppdr-requirements-slides.pdf

We appreciate that CMS continues to refine and clarify its guidance for hospitals in the course of the agency's education, monitoring, and enforcement activities of 45 CFR Part 180, but we believe that revisions to the requirements at this time would erode the recent progress that has been made. Specific elements of the proposed changes to 45 CFR180.50 raise significant concerns, particularly with respect to the January 1, 2026, effective date for calculating, formatting, and validating new data elements, the proposed requirement to replace the recently implemented "expected allowed amount" data element with a 10th, median, and 90th allowed amounts using exclusively EDI 835 remittance advice information, and the proposed revision to the attestation.

Replacing the Estimated Allowed Amount with the 10th, Median, and 90th Percentile Allowed Amounts. In this proposed rule, CMS proposes to require hospitals to encode, beginning January 1, 2026, the "median allowed amount," as well as the 10th and 90th percentile allowed amounts, rather than the recently implemented "estimated allowed amount," if a payer-specific negotiated charge can only be expressed as an algorithm or percentage. Under these proposals, the 10th, median, and 90th allowed amounts would be defined as the 10th percentile, median, and 90th percentile (respectively) of the total allowed amounts the hospital has historically received from a third-party payer for an item or service for a time period no longer than the 12 months prior to posting the MRF.

The FAH has two primary concerns related to this proposal. First, the proposed effective date of January 1, 2026, for implementing the proposed changes is operationally infeasible. The proposed implementation date does not provide hospitals with enough time to receive and review a revised CMS template format, collect the newly required information (as proposed, all EDI 835 remittance advice data), calculate new data elements (as proposed, the 10th, median, and 90th percentile allowed amounts), and review these vast amounts of data for accuracy and completeness. Once an updated CMS template, data dictionary, and validator tool are made available, hospitals will need at least 12 months to calculate, encode, validate, and display these data. More time will be required if a hospital, as a result of the new requirements, must hire new staff or a vendor that has expertise in performing the proposed calculations for the 10th, median, and 90th percentile allowed amounts.

Second, as noted above, CMS has recently required hospitals to revise their systems to accommodate the calculation and encoding of an "estimated allowed amount" which is defined as the average dollar amount that the hospital has historically received from a third-party payer for an item or service. In making this new proposal to replace the "estimated allowed amount" with the "median allowed amount," CMS reasons that although the "estimated allowed amount" provides "useful context…these average dollar amounts do not necessarily represent the actual dollar amount an individual would pay for an item or service." Thus, CMS proposes to replace the "estimated allowed amount" with a "median allowed amount." This rationale is misplaced, as neither the "estimated allowed amount" nor the "median allowed amount" represent the "actual dollar amount an individual would pay" nor is one data point any better than the other for bringing meaningfulness to standard charges that can only be represented by a percentage or algorithm. This is because, regardless of dollar amount presented, both are based on past experience and do not predict the future costs for an individual patient. The "estimated allowed amount" is more prospectively meaningful as it allows hospitals to take into consideration all information available to it and, as CMS noted, would represent the hospital's expected reimbursement amount for the item or service in the future, on average.[45] By contrast, the 10th, median, and 90th percentile allowed amounts rely on a single payer-

[45] CY2026 OPPS proposed rule (90 FR 33791).

generated data source and represent what a hospital was actually paid in the past for providing the specified item or service to three specific patients at three specific points in time. Regardless, changing the requirements now would serve only to markedly increase hospital burden without any clear benefit to the public.

The FAH therefore recommends that CMS assess the impact of the recently implemented requirements and guidance related to the "estimated allowed amount" before further revising the MRF requirements. ***The FAH also recommends that CMS retain the "estimated allowed amount" which gives hospitals flexibility to consider all data sources available to them.*** If CMS finalizes its proposals, ***the FAH recommends that CMS provide hospitals with adequate time to implement new MRF requirements by extending the implementation effective date to January 1, 2027.*** Alternatively, at a minimum, CMS could retain the January 1, 2026, effective date but delay enforcement until January 1, 2027. Additionally, if CMS finalizes its proposals, ***the FAH recommends that, to avoid public confusion, CMS acknowledge, as it did with respect to the estimated allowed amount, that the 10th, median, and 90th percentile allowed amounts do not represent 'guaranteed prices' because they are historical, nor would they necessarily represent the amount an individual would expect pay for the item or service.***[46]

Calculation of Allowed Amounts Using Exclusively EDI 835 Remittance Advice Data with a 12-Month Lookback. CMS proposes that, in calculating the 10th, median, and 90th percentile allowed amounts, hospitals must exclusively use EDI 835 ERA transaction data. CMS seeks comment on this proposal and whether there are instances where a hospital would not have access to EDI 835 ERA transaction data. CMS also seeks comment on whether there are alternative data sources it should consider for calculating the allowed amounts and count of allowed amounts.

CMS proposes that hospitals use a 12-month lookback period for calculating the 10th, median, and 90th percentile allowed amounts. Currently, CMS does not specify a lookback period for hospitals when calculating the "estimated allowed amount." This flexibility was intended to reflect the variations in frequency and timing with which hospitals negotiate contracts with payers. However, CMS now believes that if hospitals use substantially different lookback periods, particularly across multiple years, it could distort the allowed amounts, for example, because of pricing changes over time such as inflation, efficiencies, or the introduction of new products or services. Additionally, CMS believes that if hospitals use varied lookback periods it would reduce comparability across MRFs.

CMS also proposes that hospitals encode the count of allowed amounts used to calculate the 10th, median, and 90th percentile allowed amounts. If the hospital has a "0" count of allowed amounts from the most recent 12-month time period from which to derive the allowed amounts, the hospital would encode "0" as the value for the count and encode information to explain the hospital's insufficient claim remittance history in the "additional notes" data element. If the reason for a "0" count is due to a new or revised payer contract, the hospital should encode "new or recently revised payer contract." CMS seeks comment on an alternative approach it considered that would require hospitals to provide the range, or categories, of the count of allowed amounts, rather than a precise count, for example, less than 10, 10-49, 50-99, 100-149, 150-199, 200-499, and 500 and over.

[46] CY 2024 OPPS final rule (88 FR 82100).

The FAH has several concerns related to exclusive use of EDI 835 ERA transaction data to calculate a payer-specific negotiated charge (when it can only be expressed as a percentage or algorithm) and the 12-month lookback period. First, while we believe most hospitals receive remittance advice data in electronic form, as CMS is aware in its capacity as a payer, not all providers do.[47] CMS should take into account that small or rural hospitals may receive remittance advice data on paper.

Second, even if CMS were to permit hospitals to use both electronic and paper remittance advice data for calculation of the 10th, median, and 90th percentile allowed amounts, a one-year lookback may not be enough to accumulate an adequate or meaningful count for a payer's plan with which the hospital has recently negotiated or renegotiated a contract. We are specifically concerned about the inclusion of small data sets in this calculation, for example, for services that the hospital provides infrequently. CMS recognizes challenges related to small data sets when it publishes fee-for-service provider utilization and payment data on its website.[48] As stated in CMS's methodology "To protect the privacy of Medicare beneficiaries, any aggregated records which are derived from 10 or fewer discharges are excluded from the Inpatient dataset." ***Continuing to permit hospitals to calculate and display an "estimated allowed amount" using all the data available to the hospital – including data beyond a 12-month lookback period - mitigates this problem.***

Third, it is unclear how a uniform 12-month lookback period applied to all payers and plans would result in "comparability" across MRFs when the contracts of different hospitals are negotiated at different times and/or contain different conditions of payment. Additionally, identifying a single 12-month period for all EDI 835 remittance advice information would result in a hospital using varying amounts of data availability across all its hospital contracts. In other words, over the 12-month period, there may be a full 12 months of data for one payer's plan but less than 12 months' worth of data for a different payer's plan. At minimum, CMS should clarify how hospitals should apply the 12-month lookback.

For these reasons, ***the FAH recommends that CMS not finalize its proposed changes, and instead retain its current requirements which would continue to permit hospitals' flexibility to use the best data available to it across a timeline that provides for calculation of the best estimated historical average dollar amount.*** If CMS finalizes its policy as proposed, ***the FAH recommends that CMS allow hospitals to leave the 10th, median, and 90th percentile allowed amounts blank when the EDI 835 ERA data count is "less than 10"*** to align with CMS's guidance and best practices for making claims data public.

Proposed Modification of the MRF Affirmation Statement. CMS also proposes to replace the currently required "good faith effort" and affirmation statement in the MRF with a new and expanded attestation, and to encode the name of the hospital chief executive officer, president or senior official designated to oversee the encoding of true, accurate and complete data. Specifically, beginning January 1, 2026, each hospital would be required to attest in its MRF to the following:

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[47] CMS's guidance (Remittance Advice Resources and FAQs) acknowledges that some providers receive remittance advice on paper.

[48] https://data.cms.gov/sites/default/files/2024-06/MUP_INP_RY24_20240523_Methodology_508.pdf (May 2024).

"The hospital has included all applicable standard charge information in accordance with the requirements of § 180.50, and the information encoded is true, accurate, and complete as of the date in the file. The hospital has included all payer-specific negotiated charges in dollars that can be expressed as a dollar amount. For payer-specific negotiated charges that cannot be expressed as a dollar amount in the machine-readable file or not knowable in advance, the hospital attests that the payer-specific negotiated charge is based on a contractual algorithm, percentage or formula that precludes the provision of a dollar amount and has provided all necessary information available to the hospital for the public to be able to derive the dollar amount, including, but not limited to, the specific fee schedule or components referenced in such percentage, algorithm or formula."

We support CMS's goal of ensuring that data in the MRF is accurate and complete. FAH member hospitals invest considerable time and resources to review and validate the data they make available to the public. It is important to recognize that building files that meet the specifications of the HPT rule, which requires compiling and sharing vast amounts of sometimes highly technical data, is challenging; such detailed work can take months to accomplish and, despite a hospital's best efforts, the resulting data, due to the highly complex nature of the data, may still inadvertently contain errors or data glitches. It is also important to remember that the MRF data can become outdated quickly as contracts are frequently updated throughout the year. In fact, some types of charges can change daily based on changes to acquisition costs. All of these factors and others may impact the accuracy and completeness of the HPT MRF files.

The FAH has several specific concerns with the proposed attestation language. First and foremost, by removing the phrase "to the best of its knowledge and belief," the proposed language no longer leaves room for human error and presents a strict liability standard. Allowance for human error is necessary when handling (in some cases, manually) millions of datapoints. Second, the phrase "has provided **all** necessary information available to the hospital for the public to be able to derive the dollar amount" [emphasis added] is overbroad. Some contractual algorithms take into account so many individualized dependencies, they do not lend themselves to being displayed in a single cell in an MRF. If such specificity in an algorithm were possible, there would be no need for an "estimated allowed amount" or, as proposed, the 10th, median, and 90th percentile allowed amounts. Moreover, CMS itself has acknowledged that the MRF data is not intended for direct patient use, and we agree. We believe that it is unrealistic to assume that every member of the public has the expertise necessary to fully understand and accurately use the contractual algorithms displayed. Thus, it is unreasonable to hold hospitals accountable to such a strict liability standard. Finally, payers are responsible for the accuracy and completeness of EDI 835 ERA data, not hospitals. It is therefore unreasonable to hold hospitals accountable for validating the accuracy and completeness of data developed by a third party.

The FAH therefore recommends that CMS retain the affirmation statement in its current form. If CMS decides to finalize a new attestation statement, we recommend, at a minimum, that CMS re-instate the phrase "to the best of its knowledge and belief."

The FAH also has concerns with the proposal that hospitals encode the name of the hospital chief executive officer, president or senior official designated to oversee the encoding of true, accurate and complete data. In the proposed rule, CMS explains its belief that this requirement would establish that the data was reviewed and verified by the hospital's leadership. We question this rationale because the person (or, more realistically, the personnel) responsible for validating the vast amount of data in the MRF is unlikely to be a hospital chief executive officer, president, or senior official. It would be unrealistic to hold

a hospital chief executive officer, president, or senior official responsible for personally validating millions of datapoints. Additionally, CMS explains its belief that this information could also be used by CMS to expedite the agency's ability to quickly identify an individual at the hospital to obtain, where necessary, further clarity regarding the MRF data. However, we question this rationale as CMS already requires hospitals to include such contact information in the .txt files (45 CFR 180.50(d)(6)(i)(D)) for purposes of clarifying MRF data.[49] Finally, the proposed requirement appears to duplicate the existing monitoring authorities CMS established at 45 CFR 180.70(a)(2)(iv) which requires submission of certification by an authorized hospital official as to the accuracy and completeness of the standard charge information in the MRF.

The FAH therefore opposes the proposal to encode the name of the hospital chief executive officer, president or senior official designated to oversee the encoding of true, accurate and complete data as part of the proposed attestation statement.

Proposal to Require Encoding of NPIs in the MRF. In this proposed rule, CMS proposes to revise §180.50(b)(2)(i)(A) to require hospitals, beginning January 1, 2026, to report a unique identifier, specifically their Type 2 (organizational) national provider identifier (NPI), in their MRFs. CMS believes that having hospitals add their NPI(s) to the MRF would improve the comparability of hospital MRF and other health care data, including health plan transparency data from the Transparency in Coverage MRFs. CMS also outlines a number of alternative approaches it considered, including that should a hospital have multiple NPIs, the hospital would be required to report only one of them.

In general, we support the proposal to require including an organizational NPI in the MRF. In particular, ***the FAH supports CMS's proposed alternative approach to require reporting of a single organizational NPI for each hospital's MRF.*** We recommend that CMS limit this requirement to a single Type 2 NPI that has a primary taxonomy code starting with '28' which is the hospital NPI. Including hospital unit NPIs (those starting with '27') will increase burden and potentially create confusion for users of the file.

XX. The Market-Based MS-DRG Data Collection and Relative Weighting Calculation Methodology Are Unlawful and Inappropriate (42 C.F.R. § 413.20(d)(3))

The FAH strongly opposes CMS's proposal to require the disclosure of median payer-specific negotiated rate data for MA plans, as well as the incorporation of such data into the MS-DRG weighting methodology. At its core, the proposal pursues an impermissible goal—shifting from a relative resource-based MS-DRG weighting system to one based on purported "market" rates. CMS lacks any authority to adopt a "market-based" MS-DRG weighting methodology because Congress has explicitly instructed CMS to weight MS-DRGs based on "relative hospital resources used with respect to discharges" for each MS-DRG in 42 U.S.C. § 1395ww(d)(4)(B). Moreover, although CMS has the authority to collect certain information through annual cost reports, this authority only reaches that data that is necessary to determine appropriate payment amounts and does not permit the collection of market data that is wholly irrelevant to

[49] The required .txt data field GitHub instructions state that the hospital must "Indicate the name of a point of contact (POC) that is capable of answering technical questions about your hospital's MRF and the data contained in it" CMS HPT TXT Generator | Hospital Price Transparency

Medicare payment. Finally, the Proposed Rule severely underestimates the operational burdens and costs of compliance and overestimates the value and utility of median payer-specific negotiated rate data. Although the FAH supports continued efforts to improve upon the accuracy and appropriateness of relative weight calculations, we oppose upending the current cost-based methodology through the use of payer-specific negotiated rate data. ***Therefore, the FAH strongly urges CMS to abandon the proposed market-based MS-DRG data collection and relative weighting calculation methodology as unlawful and inappropriate.***

A. CMS Lacks Authority to Require the Disclosure of Median Payer-Specific Negotiated Rate Data or to Make Changes to the MS-DRG Weight Methodology Based on Such Data

The Proposed Rule erroneously suggests that CMS has authority to require providers to submit median payer-specific negotiated rate data under 42 U.S.C. §§ 1395*l*(e) and 1395g(a) and to then reweight MS-DRGs based on this third-party payer rate data. As a preliminary matter, Congress has specifically mandated that CMS use resource-based MS-DRG relative weights rather than any market-based approach. Because the data that CMS proposes to collect does not directly or indirectly capture hospital resource use, they cannot be used to update the relative weights of MS-DRGs. Separately, the cost reporting statutes cited only permit the collection of data for purposes of determining the amount of payment. Because CMS has no authority to alter MS-DRG weights based on payer-specific negotiated rates or otherwise base payment on these rates, CMS also does not have authority to require the submission of this data from providers.

1. The Requirement that MS-DRG Weights be Based on Relative Resource Utilization

Under 42 U.S.C. § 1395ww(d)(4)(B), CMS is required to assign an "appropriate weighting factor" to each MS-DRG, and that weighting factor must reflect "the relative hospital resources" used with respect to discharges classified in that MS-DRG compared to discharges classified within other MS-DRGs. Thereafter, CMS is required to adjust the MS-DRG weighting factors annually to reflect "factors which may change the relative use of hospital resources," including changes in treatment patterns and technology.[50] As such, Congress mandated that CMS establish and update MS-DRG weights based on "relative hospital resources used."[51] Because CMS is required to use a resource-based weighting system, it is precluded from adopting a "market-based" system or otherwise incorporating data on payer-specific negotiated rates into the MS-DRG weighting methodology.

Consistent with this statutory mandate, CMS has spent decades creating and refining an MS-DRG weighting system in which "[e]ach DRG weight represents the average resources required to care for cases

[50] 42 U.S.C. § 1395ww(d)(4)(C)(i). The emphasis on resource-based weighting for MS-DRGs is also evident from the new technology add-on payment statute, which requires that, after the new technology add-on payment period expires, discharges involving the new service or technology be "classified within a new or existing [MS-DRG] with a weighting factor under paragraph (4)(B) that is derived from cost data collected with respect to discharges occurring during such period." 42 U.S.C. § 1395ww(d)(5)(K)(ii)(IV). This provision again confers no latitude for CMS to adopt a market-based weighting system or to otherwise incorporate median payer-specific negotiated weight data into the MS-DRG weighting methodology.

[51] *Id*. § 1395ww(d)(4)(B).

in that particular DRG, relative to the average resources used to treat cases in all DRGs."[52] As the Proposed Rule notes, CMS currently uses a cost-based methodology to determine the relative hospital resources used for each discharge and adjusts MS-DRG relative weights based on these relative costs. This process involves reducing hospital charges to costs using hospital cost-to-charge ratios. The cost-based methodology for MS-DRG weighting has been in place for nearly two decades, beginning with fiscal year (FY) 2007. Prior to the FY 2007 IPPS Final Rule, CMS used a charge-based system for estimating relative hospital resources utilization by MS-DRG. Under this charge-based system, DRG weights were calibrated using standardized relative charges. This system was developed based on the observed correlation between charge-based and cost-based weights. In FY 2007, however, CMS transitioned to a cost-based MS-DRG weighting system in order to address distortions under the previous charge-based system and better capture relative hospital resource utilization.[53] Separately, CMS has refined its process for reducing charges to costs over the years as issues have arisen. The most notable example of this is CMS's much needed 2003 change in the methodology for outlier payments, which addressed the adjustment of cost-to-charge ratios by a subset of providers to maximize outlier payments.[54] The FAH has frequently commented over the decades on ways in which cost-based methodologies can be refined and improved, and we strongly urge CMS to continue along this well-worn path, rather than radically shifting toward an untested and unpredictable new system that is not based on costs.

Unlike the current cost-based system for weighting MS-DRGs, which appropriately seeks to quantify the relative hospital resources used in each discharge, the proposed market-based weighting system would be wholly untethered from the relative hospital resources used. Like the FY 2021 Inpatient Perspective Payment System final rule, which finalized a substantially similar policy, the Proposed Rule does not provide any basis for concluding that median payer-specific negotiated rates could represent the relative hospital resources used in discharges. Rather, the Proposed Rule identifies studies concerning differences in Medicare FFS payment amounts and payer-specific negotiated rates and posits that payer-specific negotiated rates "may reflect the relative hospital resources used within an MS-DRG differently than [the] current cost-based methodology."[55] This is not, however, the conclusion of any of the cited studies. Nor could it be—none of the cited studies even purport to address the relative hospital resources involved in various discharges or otherwise crosswalk any measure of actual hospital resource utilization to payer-specific negotiated rates.

By way of example, the Proposed Rule relies substantially on the FY 2021 IPPS/LTCH PPS final rule, which itself relied substantially on the evaluation of 2013 claims data by Jared Lane K. Maeda and Lyle Nelson to suggest that payer-specific negotiated rates, continuing to assert that it "may reflect the relative hospital resources used," but ***the study made no conclusions regarding relative resource utilization***.[56] In fact, the study does not even use the word "resource" or discuss hospital costs involved in

[52] Proposed Rule, 85 Fed. Reg. at 32,470. Similar statements have appeared annually in IPPS rulemaking since at least the FY 1997 IPPS Proposed Rule. e.g., 61 Fed. Reg. 27,444, 27,445 (May 31, 1996).

[53] 71 Fed. Reg. at 47,882.

[54] 68 Fed. Reg. 34,494, 34497 - 34504 (June 9, 2003).

[55] 90 Fed. Reg. at 33,806.

[56] 90 Fed. Reg. 33,806; Maeda JLK & Nelson L, How Do the Hospital Prices Paid by Medicare Advantage Plans and Commercial Plans Compare With Medicare Fee-for-Service Prices?, *The Journal of Health Care Organization, Provision and Financing*, 2018;55(1-8).

the delivery of care. Moreover, the study did not analyze or assess payer-specific negotiated rates at all, focusing exclusively on claims payments rather than rates.[57] In addition, the limitations of the study call into question whether the observed differences in payment reflect other factors, such as relative patient acuity. The authors expressly noted that they "would not be able to capture" differences in acuity between a Medicare Advantage (MA) patient within a particular DRG and a Medicare fee-for-service patient assigned to the same DRG.[58] This study also did not endeavor to account for the impact of managed care on the observed payment data. For example, a payer's prior authorization requirement for inpatient admissions may result in certain short stays being treated as observation stays such that inpatient discharges skew to higher acuities and higher payment. The impact of these payer behaviors on the data was not evaluated in this study or even acknowledged by the authors. In short, this study and the other cited studies do not include any suggestion—let alone evidence—that either payer-specific negotiated rate or payment data is probative of relative hospital resource utilization.

The Proposed Rule only cites two new studies in proposing its readoption of the previously repealed market-based MS-DRG policy, but neither of these studies suggest any relationship between hospital resource utilization and payer-specific negotiated rates. As acknowledged in the Proposed Rule, Meiselback et al. examined "the ratio of commercial-to-MA prices negotiated by the same insurer," and Randall and Duffy compared payer-specific negotiated rates for health insurance exchange plans, MA organizations (MAOs), and commercial group insurance plans.[59] Thus, not only does this research "not directly address the relationship between payer-specific charges negotiated between hospitals and MAOs and Medicare IPPS payment rates," neither does it do so indirectly, and, like the other cited studies, does not address or suggest any relationship between negotiated rates and hospital resource utilization.

In the end CMS assumes, without evidence or study, that negotiated rates "capture the relative resource use to provide services to patients."[60] Rather, the studies and information provided in the Proposed Rule indicate that relative MA rates largely mirror relative Medicare fee-for-services rates. If and when there are MS-DRGs for which the correlation between MA and Medicare fee-for-service rates is weaker, the assumption that this deviation is the product of differences in relative hospital resource utilization finds no support in the literature and ignores the wide range of factors that would be expected to actually drive hospital-provider negotiations (*e.g.*, supply and demand, including provider location and specialization along with MA network needs). MAOs do not contract to reimburse providers on a reasonable cost basis or otherwise seek to reflect hospital resource utilization in their rates. Moreover, hospitals and MAOs evaluate the entirety of a rate structure when entering into a managed care agreement, without regard for whether the

[57] Median payer-specific negotiated rates may deviate from actual payment amounts. The payment methodologies in managed care agreements may result in variable payment amounts for stays classified to a particular DRG based on factors such as the length of stay or the applicability of a stoploss provision. Because Maeda and Nelson focused on payment amounts, their results may reflect acuity differences and their study is generally inapplicable to CMS's MS-DRG reweighting proposal.

[58] *Id*. at p.3.

[59] 90 Fed. Reg. at 33,806; Meiselbach MK, Wang Y, Xu Jianhui, Bai G, Anderson GF, Hospital Prices for Commercial Plans Are Twice Those For Medicare Advantage Plans When Negotiated By The Same Insurer, Health Aff., 2023;42(8):1110-1118; Randall S, Duffy EL, Insurers Negotiate Lower Hospital Prices for HIX Than for Commercial Groups, The American Journal of Managed Care, 2022;28(9): e347-e350.

[60] 90 Fed. Reg. at 33,807.

rates on an MS-DRG by MS-DRG basis will appropriately reflect relative hospital resource utilization. Despite acknowledging that MA rates reflect various "market constraints and conditions," the Proposed Rule does not attempt to evaluate or quantify the non-resource-based factors that inform MA rate negotiations. Moreover, the non-interference clause statutorily prohibits CMS from ensuring any correlation between MA rates and resource utilization (or even ensuring that MA rates are re-negotiated with any frequency).[61] At base, the unfounded and untested assumption of a correlation between MA rates and resource utilization cannot support the incorporation of market-based data into the MS-DRG weighting methodology, let alone the abandonment of the current cost-based system for determining MS-DRG relative weights.

The Proposed Rule acknowledges that, in the near term, "minimal impacts to the relative weights" would be expected under the proposed policy because MA rates are largely correlated to Medicare fee-for-services rates. But, this assertion does not account for the impact of ceasing to update MS-DRG relative weights based on relative hospital costs. By statute, CMS must update MS-DRG weights "at least annually . . . to reflect changes in treatment patterns, technology . . . , and other factors which may change the relative use of hospital resources" for particular MS-DRGs.[62] Changing to an MA rate-based weighting system in FY 2029, however, would largely freeze relative weights as they were updated in FY 2028 because MA rates are largely based on fee-for-service rates and are not independently updated to reflect the statutory MS-DRG update factors. Thus, the aggregate "minimal impacts" expected by CMS obscure the potentially significant impacts for individual MS-DRGs heavily impacted by changes in treatment patterns, technology, and other factors that change the relative use of hospital resources, and these impacts will grow over time without annual cost-based updates. Along similar lines, annual updates based on MA rates cannot satisfy CMS's statutory obligation to adjust weights based on "factors which may change the relative use of hospital resources."

Overall, even 5 years after CMS first proposed and adopted this policy, there is no reason to suspect that median payer-specific negotiated MA rates for discharges in an MS-DRG would represent relative hospital resource utilization, and the Proposed Rule fails to articulate any basis for determining that any such correlation exists. In contrast, the current cost-based system for weighting MS-DRGs measures hospitals' relative resource utilization, as is required by statute.

2. CMS Cannot Require the Submission of Data that is Immaterial to Payment

Because the weighting factor methodology required under 42 U.S.C. § 1395ww(d)(4)(B) and (C) requires the use of hospital resource utilization data rather than payer-specific negotiated rate data, it follows that neither 42 U.S.C. § 1395g(a) nor § 1395*l*(e) authorizes CMS to gather data concerning median payer-specific negotiated rates through hospital cost reports. The Proposed Rule suggests that CMS is authorized to require submission of this data under 42 U.S.C. §§ 1395g(a) and 1395*l*(e), but these statutes are expressly confined to the submission of data necessary to determine payment. Under the former statute, a provider must "furnish[] such information as the Secretary may request *in order to determine the amounts due such provider* under this part for the period with respect to which the amounts are being paid or any

[61] 42 U.S.C. § 1395w-24(a)(6)(B)(iii) ("the Secretary may not . . . require a particular price structure for payment" under an MAO contract with a provider).

[62] 42 U.S.C. § 1395ww(d)(4)(C).

prior period" in order to receive payment.[63] Likewise, the latter statute bars payment to a provider unless the provider has "furnished such information *as may be necessary in order to determine the amounts due such provider* . . . under this part for the period with respect to which the amounts are being paid or for any prior period."[64]

The Proposed Rule cites to no other statutory authority for the collection of data on median payer-specific negotiated rates, and the cited statutes are inapplicable to the proposed data collection because median payer-specific negotiated rates simply cannot be used as the basis for IPPS payments. As discussed above, Congress requires that CMS weight MS-DRGs based on relative hospital resource utilization, barring the use of the market data CMS proposes to collect.[65] Because CMS cannot use median payer-specific negotiated rate data to assign relative weights to MS-DRGs and CMS has not and cannot propose any other use of the data in determining provider payments, the proposed data collection proposed is unconnected with payment and cannot be adopted under the cost reporting statutes, 42 U.S.C. § 1395g(a) and § 1395*l*(e). Therefore, CMS cannot and should not finalize proposed 42 C.F.R. § 413.20(d)(3).

In sum, CMS does not have the authority to implement its proposal to collect hospitals' median payer-specific negotiated rate data for MA organizations (or otherwise), and it does not have the authority to develop an MS-DRG weighting methodology using such data or otherwise shift from a resource-based weighting methodology to a market-based weighting methodology.

B. The Proposed "Market-Based MS-DRG Relative Weight" Data Collection and Methodology Would Introduce Data Distortions

The absence of statutory authority supporting the proposed data collection and methodology change alone necessitates abandonment of CMS's proposal. ***Even putting the question of authority aside, however, the proposal is simply inappropriate because the shift to relying on median payer-specific negotiated rates to weight MS-DRGs would (1) provide no insight into MS-DRGs that ought to be reclassified and (2) produce skewed or distorted payment rates.***

The Proposed Rule provides a cursory explanation of the goals behind the proposed "market-based MS-DRG relative weight" data collection and methodology, none of which suffices to justify the proposal. First, the Proposed Rule notes that since the FY 2022 repeal of the FY 2021 policy, their view is "generally consistent" that "by reducing our reliance on the hospital chargemaster, we can adjust Medicare payment

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[63] 42 U.S.C. § 1395g(a) (emphasis added).

[64] 42 U.S.C. § 1395*l*(e) (emphasis added).

[65] Previously, CMS had suggested that median payer-specific negotiated rates could be used for determining outlier payments or new technology add-on payments, 85 Fed. Reg. at 32,797, but again, these options are statutorily barred. With respect to outlier payments, the statute explicitly provides that outlier payments are available "where *charges adjusted to cost*" exceed the outlier threshold. 42 U.S.C. § 1395ww(d)(5)(A)(ii) (emphasis added). Similarly, Congress requires that the payment for new technology add-on payments be made "in an amount that adequately reflects *the estimated average cost* of such service or technology." *Id*. § 1395ww(d)(5)(K)(ii)(III) (emphasis added). Moreover, CMS is required to collect data "with respect to the costs" of the new technology or medical service and, after the new technology add-on payment period expires, must use "cost data collected with respect to discharges during such period" to assign an appropriate weighting factor to the new or existing MS-DRG in accordance with 42 U.S.C. § 1395ww(d)(4)(B). *Id*. at § 1935ww(d)(5)(K)(ii)(II), (IV).

rates so that they reflect the relative market value for inpatient items and services."[66] Now, just as it was then, this observation wrongly suggests that such an adjustment is permissible and desirable, when in fact CMS is statutorily precluded from adopting a market-based methodology for inpatient payments. Instead, the goal of any methodology for updating the relative weights of MS-DRGs must be to accurately capture the relative utilization of hospital resources. Moreover, criticisms of the Medicare program's reliance on the hospital chargemaster are inadequate both because they fail to support the transition to a market-based MS-DRG weighting system and because they assume without evidence or analysis that inflated charges distort MS-DRG relative weights. As explained above, CMS uses a cost-based methodology rather than a charge-based methodology. CMS cites no evidence that relative MS-DRG weights calculated using its current cost-based methodology fail to appropriately reflect hospital utilization or are distorted by chargemaster issues. In fact, the chargemaster markup study cited does not address CMS's cost-based methodology for MS-DRG weighting at all, let alone the impact of chargemaster markups on Medicare's calculation of costs or relative MS-DRG weights.[67]

Against this backdrop, the proposed data collection and change to the MS-DRG weighting methodology would also be problematic in terms of data quality and usability issues, some of which are described briefly below.

Impeding Changes to MS-DRG Classifications. Under the present system, CMS uses claims data to detect situations where treatment patterns or technology evolves such that changes to the MS-DRG classification system are appropriate. For example, claims in an MS-DRG might conform to a bimodal curve and data analysis may disclose that the MS-DRG has come to encompass two distinct types of cases with differing resource consumptions that necessitates the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS-DRG. Median payer-specific negotiated rate data, however, would not provide data concerning variation among cases assigned to a particular MS-DRG, and thus could not assist CMS with classification changes necessitated by changes in treatment patterns, technology, or other factors. The Proposed Rule indicates CMS intends to continue estimating and providing MS-DRG relative weights calculated using its current cost-based methodology "for informational purposes," at least "for some period of time."[68] This temporary informational exercise, however, is inadequate to ensure appropriate MS-DRG classification updates over time.

Confounding Variables. The median payer-specific negotiated rate data that CMS proposes to collect would reflect a number of factors, including the patient population served, local market conditions, the impact of prior authorization and utilization management activities, and other factors that drive MA rate negotiations but are unrelated to relative hospital resource utilization. As a result, the rate data would be skewed by factors that do not reflect market rates, let alone relative hospital resource utilization. By way of example, heavy MA penetration in a market may depress median payer-specific negotiated rates, so data from hospitals in that market would be skewed to reflect MA penetration. This is just one example of the

[66] 90 Fed. Reg. At 33,805.

[67] 90 Fed. Reg. at 33,805; Linde S, Egede LE, Do Chargemaster Prices Matter?: An Examination of Acute Care Hospital Profitability, *Med Care*, 2022 Aug 1;60(8):623-630.

[68] 90 Fed. Reg. at 33,810.

many anticipated and unanticipated ways in which median MA negotiated rates reflect factors that are not indicative of market rates or hospital resource consumption.

Excluded and Under/Overweighted Provider Data. In addition, the proposed MS-DRG weighting policy would not capture adequate data to provide a national picture of relative MA rates (even if such data were relevant to MS-DRG weighting). The process would use no data from subsection (d) providers that exclusively contract with MAOs on a capitated basis and/or have no MA network participation agreements, wholly excluding their data from the weighting process. Moreover, in some cases, payment elements that are excluded from the payer-specific negotiated rates for MAOs may skew the data. For example, the payer-specific negotiated rate reported on the machine-readable file for purposes of 45 C.F.R. § 180.50 would exclude components of the total payment amount that are based on risk-sharing or value-based payment methodologies (*e.g.*, a quarterly or annual quality incentive payment or value-based add-on payment). If these payment strategies were uniformly applied across MAOs and providers, the exclusion of these payment elements would not skew the relative weights of MS-DRGs based on this data, but there is no reason to assume such uniformity. Rather, these kinds of payment tools that blend a case-rate methodology with partial capitation, quality incentive payments, or value-based add-on payments are likely to be more widely used by providers that have significant volume and strong outcome measures for the MS-DRG at issue. As a result, the relative weights of MS-DRGs would be skewed, with the relative payment rate for MS-DRGs that are largely furnished by a relatively small subset of hospitals (*e.g.*, those that qualify as centers of excellence) being particularly at risk for underweighting based on excluded components of MAO payments.

In addition, CMS proposes to use Medicare data on fee-for-service case counts to develop a single weighted average standardized median MAO payer-specific negotiated rate by MS-DRG across hospitals. This blending of fee-for-service data with the MA rate data would skew the data based on payer mix because hospitals that largely serve Medicare fee-for-service beneficiaries (*i.e.*, with higher Medicare fee-for-service case counts as compared to MA case counts) will be overrepresented in the data, while those operating in markets with extraordinarily high MA market penetration (*i.e.*, with lower Medicare fee-for-service case counts as compared to MA case counts) will be underrepresented. CMS's most recent MA market penetration data shows that MA penetration at the state and county level ranges from less than 1 percent to over 88 percent.[69] It stands to reason that providers in counties with MA market penetration in excess of the national average would approach MA rate negotiations differently than providers in counties with lower MA penetration, yet the proposed market-based MS-DRG methodology would skew the data to emphasize MA rates for those providers with higher Medicare fee-for-service case counts and less at stake in MA rate negotiations.

Along similar lines, many managed care agreements (including those that adopt DRG-based rates) contain a stoploss provision, under which the payment methodology shifts to a percentage of charges after a particular threshold (*e.g.*, total charges or number of days) is met. Some procedures may be more likely than others to exceed the threshold for stoploss payment, and for certain MS-DRGs, stoploss may be triggered in the majority of cases. In addition, because payers vary in their prior authorization requirements, for some payers, admissions with certain MS-DRGs will skew toward higher acuity patients that are more

[69] CMS, MA State/County Penetration – August 2025, *at* https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contract-and-enrollment-data/ma-state/county-penetration/ma-state/county-penetration-2025-08. Penetration in Puerto Rico and the Virgin Islands even approaches 100% in some areas.

likely to trigger stoploss. In these cases, the MA negotiated rate for the MS-DRG would not exclude this stoploss or outlier data and thus would underweight MS-DRGs with heavier stoploss or outlier payment impacts.

Crosswalking. Under the proposed policy, hospitals would start with their MA rates by MS-DRG as reported on the hospital's most recent machine-readable file published pursuant to 45 C.F.R. § 180.50, excluding any rates that represent capitated payment.[70] Where a case rate is assigned by the MAO to a bundle of items and services not represented by an MS-DRG code, the hospital would be responsible for crosswalking the MAO's code to an MS-DRG, possibly using the CMS GROUPER and associated definitions manual. In these cases, however, more than one MA rate might crosswalk to a particular MS-DRG, depending on how the MAO bundles items and services or classifies cases, and the Proposed Rule provides no guidance for such situations. In addition, the Proposed Rule does not address situations where an MAO bases payment for some inpatient cases under a non-case-rate methodology, such as a per-diem methodology. Because CMS cannot require MAOs to use an MS-DRG-based rate in its provider contracts,[71] some MAO rates will not cleanly crosswalk to an MS-DRG, further narrowing the data available under the proposed policy. And, in the long-term, MAOs and providers may increasingly rely on non-MS-DRG-based rates precisely because the MS-DRG weighting would become less useful as a measure of relative hospital resource utilization for services, compounding these issues.

C. The Proposed Worksheet S-12 is Burdensome and Unclear

Although proposed Worksheet S-12 would use some data that is available from hospitals' machine-readable file prepared under 45 C.F.R. Part 180, it would also require significant and potentially burdensome additional data collections and calculations. It is not clear from the proposed instructions how hospitals should (1) crosswalk the MAO's payment methodology to an MS-DRG for payers that do not use the MS-DRG as a basis of payment and (2) calculate the cases for the weighted median.

With respect to the crosswalking issue, as explained above, hospitals will not readily be able to crosswalk an MAO's rate for an item or service (or bundle of items and services) to a particular MS-DRG when the MAO does not use an MS-DRG-based rate. The proposed instructions, for example, provide no information about how a provider would determine an MS-DRG rate for an MAO that pays for an inpatient stay based on a per-diem rate. Because the length of stay for cases that map to a particular MS-DRG will vary between patients, and the proposed instructions provide no information about how a hospital would go about converting that per-diem rate into an MS-DRG case rate when completing Worksheet S-12. Moreover, an MAO's payment methodology might bundle different cases together such that some cases within an MS-DRG are paid at one rate and others that map to that same MS-DRG are paid at a different rate or such that a single rate is applied to a range of discharges that map to multiple MS-DRGs. The proposed instructions assume that it would be a simple matter of crosswalking one rate to a single guidance and provide no guidance on how the MAO's rate should be determined for a particular MS-DRG when this is not a case. To the extent that a hospital would be required to identify each patient discharge to which a particular rate applied, then determine the MS-DRG that would have applied to that case, and then calculate

[70] 90 Fed. Reg. at 33,808.

[71] 42 USC § 1395w-24(a)(6)(B)(iii) ("the Secretary may not . . . require a particular price structure for payment" under an MAO contract with a provider).

or determine an MS-DRG rate for that payer based on that claims history, CMS severely understates the hospital burden in completing Worksheet S-12 and this burden and approach is wholly unsupported.

Finally, the calculation of the weighted median for each MS-DRG requires "sum[ming] the number of inpatient discharges for each MAO for each MS-DRG." As noted above, this process would be complicated at best when an MAO does not use a basis of payment that can be cleanly expressed as a single MS-DRG case rate. But, even if every one of the hospital's contracted MAOs used an MS-DRG case rate, the count of inpatient discharges may not be clear. A hospital might get a different result depending on whether inpatient discharges are counted as (1) all inpatient discharges for the MAO's members, (2) those inpatient discharges where the MAO made payment (whether inpatient or otherwise), or (3) those inpatient discharges were the MAO paid for the care at the inpatient rate. CMS has been taking important steps to address MAOs' programmatic abuses, including the failure to provide inpatient coverage based on the inpatient coverage criteria set forth at 42 C.F.R. § 412.3 (and incorporated by reference in 42 C.F.R. § 422.101(b)(2)). But FAH members continue to report inappropriate denials that disregard the admitting physician's clinical judgment, including the physician's clinical expectation that the patient will require hospital care that crosses two midnights. As a result, inpatient discharge counts for an MAO will vary depending on whether they include or exclude inpatient care that was denied in full or in part by the MAO. Under the instructions, as proposed, hospitals may take varying approaches, producing inconsistent data. And the act of compiling inpatient discharge data for each MAO and each MS-DRG from paid claims, unpaid claims, or otherwise, creates significant additional burdens for each hospital.

In closing, CMS is statutorily precluded from using MA rate data to update MS-DRG weights, which must be weighted based on relative hospital resource utilization, and the use of MA rates in this way would produce MS-DRG classifications and weights that fail to accurately capture changes in resource utilization. Therefore, in the absence of statutory authority to use MA rates in weighting MS-DRGs, CMS lacks authority to require hospitals to report MA negotiated rates on their cost reports. Even if CMS could adopt such a policy, the proposed methodology would further skew data in ways that further divorce the resulting MS-DRG weights from actual differences in relative hospital resource utilization.